DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Infant Formula Nutrient Requirements

Docket No. FDA-2026-N-10832

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

This proposed rule would, if finalized, update the nutrient specifications for vitamin D, iodine, vitamin A, and manganese in infant formula to reflect the best available scientific evidence on infant nutritional requirements and safe intake levels. Vitamin D is a fat-soluble vitamin essential for calcium absorption, skeletal mineralization, and the prevention of rickets. Clinical symptoms of vitamin D deficiency include hypocalcemia (i.e., low blood calcium levels), hypophosphatemia (i.e., low blood phosphorus levels), tetany, and rickets. We quantify benefits to formula-fed infants from avoided healthcare costs associated with vitamin D deficiency-induced late-onset hypocalcemia. This approach captures the most severe and acute clinical manifestation of vitamin D deficiency and therefore represents a lower bound on the rule's total societal benefits. Additional benefits include reduced risk of inadequate iodine intake, excessive vitamin A exposure, and excessive manganese exposure in formula-fed infants; these benefits are described qualitatively. We quantify costs to infant formula manufacturers from relabeling, reformulation, and administrative costs associated with Before First Processing (BFP) notification submissions. Additional costs would include FDA review costs associated with those submissions. We estimate that the annualized benefits over 10 years would range from $18.8 million to $171.7 million, with a primary estimate of $80.9 million, at a 7 percent discount rate and from $20.9 million to $191.0 million, with a primary estimate of $90.0 million, at a 3 percent discount rate. The annualized costs range from $8.4 million to $31.7 million, with a primary estimate of $17.6 million, at a 7 percent discount rate and from $8.3 million to $31.6 million, with a primary estimate of $17.6 million, at a 3 percent discount rate.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 direct us to assess all benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are economically significant under section 3(f)(1) of Executive Order 12866 if they have an annual effect on the economy of $100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is a significant regulatory action under section 3(f)(1) of Executive Order 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant regulatory actions "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 regulatory action.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we cannot determine with certainty the magnitude of reformulation costs that small infant formula manufacturers would incur under this proposed rule, we find that the proposed rule may have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (Section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $193 million, using the most current (2025) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

This proposed rule would, if finalized, update the nutrient specifications for infant formula to reflect the best available scientific evidence on certain infant nutritional requirements and safe intake levels. If finalized, the proposed changes to the nutrient specifications would generate benefits primarily through (1) reducing the risk of vitamin D deficiency in formula-fed infants and (2) reducing the risk of inadequate iodine intake, excessive vitamin A exposure, and excessive manganese exposure across the formula-fed infant population. The primary quantified benefit is avoided healthcare costs from vitamin D deficiency-induced late-onset hypocalcemia, with a primary annualized estimate of $80.93 million at a 7 percent discount rate and $90.04 million at a 3 percent discount rate. If finalized as proposed, benefits of this rule would begin accruing in 2032, following the proposed three-year compliance period. Additional benefits from iodine, vitamin A,

and manganese specification changes are described qualitatively. The primary present value of quantified benefits is $568.43 million at a 7 percent discount rate and $768.08 million at a 3 percent discount rate.

Costs are one-time and borne by domestic and foreign infant formula manufacturers in the compliance year. The primary annualized cost estimate is $17.64 million at a 7 percent discount rate and $17.57 million at a 3 percent discount rate. The primary present value of costs is $123.86 million at a 7 percent discount rate and $149.86 million at a 3 percent discount rate.

This proposed rule is not expected to generate transfers. Table 1 below presents the ROCIS summary of benefits, costs, and distributional effects of the proposed rule. All monetary values in Table 1 are expressed in 2025 dollars.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Proposed Rule (millions of 2025 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($millions/year)	$80.93	$18.79	$171.65	2025	7%	2027-2036	
		$90.04	$20.90	$190.98	2025	3%	2027-2036	
	Annualized Quantified							
	Qualitative							
Costs	Annualized Monetized ($millions/year)	$17.64	$8.35	$31.70	2025	7%	2027-2036	
		$17.57	$8.31	$31.58	2025	3%	2027-2036	
	Annualized Quantified							
	Qualitative							
Transfers	Federal Annualized Monetized ($millions/year)					7%		
						3%		
		From:			To:			
	Other Annualized Monetized ($millions/year)					7%		
						3%		
		From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Distributional: Benefits are expected to accrue disproportionately to WIC-enrolled infants, who represent approximately 50 percent of formula-fed infants in the United States and are more likely to be exclusively formula-fed. Costs are borne by manufacturers.							

In line with Executive Order 14192, in Table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. We estimate that this proposed rule would generate $7.08 million in 2024 dollars in annualized net costs at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

Table 2. Executive Order 14192 Summary Table (millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate)

	Primary Estimate	Low Estimate	High Estimate
Present Value of Costs	$101.11	$47.85	$181.76
Present Value of Cost Savings			
Present Value of Net Costs	$101.11	$47.85	$181.76
Annualized Costs	$7.08	$3.35	$12.72
Annualized Cost Savings			
Annualized Net Costs	$7.08	$3.35	$12.72

We request comment on our estimates of benefits, costs, and transfers of this proposed rule.

II. **Preliminary Economic Analysis of Impacts**

A. Background

Infant formula is the sole or primary source of nutrition for many U.S. infants during the first year after birth: a period of rapid growth, organ development, and neurological maturation. Because infant formula must independently sustain all physiological functions of a developing infant, the nutritional stakes of its composition are categorically higher than for any other regulated food product.

Federal law and FDA's implementing regulation specify binding minimum and maximum nutrient levels that all infant formulas marketed in the U.S. must meet. An infant formula that does not comply with those requirements is adulterated under the Federal Food, Drug and Cosmetic Act (FD&C Act) and may not be sold in the U.S. Because infant formula may serve as the sole source of nutrition for a developing infant, these specifications are the primary nutritional safeguard for formula-fed infants. Formulas that meet the specifications are presumed nutritionally adequate; formulas that do not may expose infants to deficiency, toxicity, or both.

The only substantive update to the list of required nutrients since 1985 was the 2015 final rule adding selenium as a required nutrient.[1] As a result, many current specifications, including the iodine minimum of 5 µg/100 kcal and the iodine and vitamin A maximums, date to the 1985 rulemaking and have not been revised in over 40 years.[2]

Since the last comprehensive review in 1998, the scientific evidence base has expanded substantially, including updated Dietary Reference Intakes from National Academies of Sciences, Engineering, and Medicine (NASEM), new large-scale human milk composition studies, and revised infant formula standards from major international regulatory bodies. These developments have progressively widened the gap between U.S. specifications and the international regulatory consensus as to some nutrients. A full review of the scientific evidence is provided in the notice of proposed rulemaking (NPRM) and supporting materials are in the docket.

Section 3401(g)(4) of the Food and Drug Omnibus Reform Act of 2022 (FDORA) amended section 412(i)(1) of the FD&C Act to require FDA to review the infant formula nutrient table every four years, as appropriate, providing an ongoing statutory mandate for periodic reassessment of the nutrient requirements.[3] In March 2025, HHS and FDA announced Operation Stork Speed, initiating a comprehensive review of infant formula nutrient requirements. FDA issued a Request for Information in May 2025, receiving 446 comments from manufacturers, scientific experts, and consumer organizations.[4]

B. Need for Federal Regulatory Action

After comprehensive review, some of the binding nutrient specifications governing infant formula need to be updated to align with current science. Absent an act of Congress, federal rulemaking is

1 80 FR 35834 (June 23, 2015).

2 50 FR 45106 (October 30, 1985)

3 Pub. L. 117-328, § 3401(g)(4) (December 29, 2022)

4 90 FR 20475 (May 14, 2025)

the only mechanism to do this. This NPRM assesses 8 of the 30 required infant formula nutrients and is one part of a phased approach to a comprehensive review of infant formula nutrients. As described in Section A, the scientific evidence base has expanded substantially since the last comprehensive review in 1998, and international regulatory bodies have updated their standards accordingly. The current U.S. specifications reflect the science available at the time they were established. For iodine, vitamin A, vitamin D, and manganese, more recent evidence suggests that the current specifications would benefit from revision. Without federal government intervention, there are no mechanisms to update those minimums and maximums as the scientific evidence base evolves. In addition, section 412(i)(1) of the FD&C Act, as amended by FDORA, requires FDA to review the nutrient table every four years as appropriate.

An underlying need for federal regulatory action stems from an information asymmetry. FDA has access to the latest scientific data and information related to infant formula nutrients, including international infant formula standards, as well as the expertise to evaluate this information and the authority to revise binding federal nutrient specifications to reflect the latest scientific data and information. Caregivers purchasing infant formula reasonably rely on the existence of federal nutrient requirements as an assurance that a lawfully marketed infant formula meets their infant's nutritional needs. When the underlying specifications no longer reflect the most recent science, that assurance may no longer be fully reliable, yet caregivers have limited means of identifying this gap. Consumers may lack the expertise needed to identify where binding federal nutrient specifications may be inadequate and there may be a need for nutrient supplementation. This problem is particularly acute for vitamin D. Current minimum specifications allow infant formula to be marketed with vitamin D levels that may be insufficient for infants, yet caregivers who are aware that infant formula is a regulated, nutritionally complete food are unlikely to suspect a need for vitamin D supplementation. The complexity of infant nutritional science and regulation places this judgment beyond the reach of most consumers.

C. Purpose of the Proposed Rule

This proposed rule would, if finalized, update the infant formula nutrient specifications to reflect the best available current scientific evidence on infant nutritional requirements and safe intake levels. Specifically, the proposed rule would:

- Increase the required minimum level of iodine from 5 µg/100 kcal to 15 µg/100 kcal and decrease the required maximum level from 75 µg/100 kcal to 50 µg/100 kcal;
- Decrease the required minimum level of vitamin A from 75 µg RAE (250 IU)/100 kcal to 70 µg RAE (225 IU)/100 kcal and decrease the required maximum level from 225 µg RAE (750 IU)/100 kcal to 120 µg RAE (400 IU)/100 kcal;
- Change the unit of measure for vitamin A from International Units (IU) to microgram retinol activity equivalents (µg RAE);
- Limit the permitted forms of vitamin A that contribute to the minimum and maximum vitamin A content from both preformed vitamin A and beta-carotene to preformed vitamin A only;

- Increase the required minimum level of vitamin D from 1 µg (40 IU)/100 kcal to 2 µg (80 IU)/100 kcal and increase the required maximum level from 2.5 µg (100 IU)/100 kcal to 3 µg (120 IU)/100 kcal;
- Change the unit of measure for vitamin D from IU to micrograms (µg); and
- Decrease the required minimum level of manganese from 5 µg/100 kcal to 1 µg/100 kcal and establish a maximum level of 50 µg/100 kcal.

For those reviewed nutrients where the current specifications remain consistent with the best available evidence (chloride, selenium, sodium, and potassium) no changes are proposed.

D. Baseline Conditions

The baseline describes the state of the infant formula market and the population of formula-fed infants in the absence of this proposed rule.

1. Infant Formula Market

Infant formula is the sole or primary source of nutrition for the majority of U.S. infants during the first year after birth. This is particularly true in the first six months, when roughly 30 percent of U.S. infants are exclusively breastfed.[5] The nutrient specifications governing its composition are binding requirements that every manufacturer must meet before a formula may be lawfully marketed in the United States.

FDA maintains a web registry of all infant formulas marketed in the U.S.[6] As of the date of this analysis, the registry contains 222 unique formulations, comprising 147 non-exempt and 75 exempt formulations. To support this analysis, FDA's Nutrition Center of Excellence (NCE) Monitoring Team conducted an analysis of current infant formula label data to estimate the number of formulations and unique packaging labels on the U.S. market and to identify the number of formulations potentially requiring reformulation under the proposed specification changes [Ref. 1]. For purposes of this analysis, each product sold in a distinct format, for example, powder, ready-to-feed, and liquid concentrate versions of the same product line, is counted as a separate formulation, consistent with the approach used in the NCE analysis. The market includes products from major domestic manufacturers as well as a substantial number of private-label products.

Of the 222 registered formulations, 46 formulations were excluded from the nutrient label analysis because their nutrition data was not provided in a per-100-kcal format compatible with the analytical approach used. Specifically, the excluded formulations are human milk fortifiers for preterm infants, whose compositional requirements and on-package labeling formats differ materially from standard infant formula, and products requiring medical supervision that are not sold directly to consumers and are packaged with nutrition data provided in a per-100-gram powder format rather than per 100 kcal.

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[5] See https://www.cdc.gov/breastfeeding-data/survey/results.html, accessed July 14, 2026, and described in more detail in Section D.2. Population of Interest.

[6] See https://www.fda.gov/food/infant-formula-homepage/infant-formulas-marketed-us, accessed July 14, 2026.

These 46 formulations are not assumed to be exempt from reformulation requirements; rather, their label format precluded direct inclusion in the nutrient-level screening step. The rates observed among the 176 analyzed formulations are applied proportionally to all 222 registered formulations to estimate the total number potentially requiring reformulation under each condition. Table 3 presents the results.

Table 3. Formulations potentially requiring reformulation

Nutrient	Flagging Condition	Number of Formulations (of 176)	Estimated Total (of 222)
Vitamin D	< 80 IU or > 120 IU per 100 kcal	176	222
Iodine	< 15 µg or > 50 µg per 100 kcal	16	20
Vitamin A	> 400 IU per 100 kcal	10	13
Manganese	> 50 µg per 100 kcal	1	1

Note: A single formulation may be flagged for more than one nutrient.

The proposed vitamin D minimum increase is the dominant driver of reformulation burden: we expect that all 222 formulations may reformulate to meet the required levels, if the rule finalizes as proposed. Iodine, vitamin A, and manganese affect a much smaller subset of products.

We estimate that there are 326 unique packaging labels (UPCs) for infant formula products, reflecting the variety of product sizes and formats in which individual formulations are sold [Ref. 1]. Because the proposed rule includes a mandatory unit change for vitamin A (from IU to µg RAE) and vitamin D (from IU to µg) that applies to all infant formula products regardless of whether nutrient levels change, all 326 UPCs would be subject to relabeling. Table 3 below summarizes the baseline counts of formulations, manufacturers, and UPCs used throughout this analysis.

Table 4. Number of infant formula formulations, manufacturers, and unique packaging labels

	Total	Domestic	Foreign
Registered formulations	222	198	24
Unique packaging labels (UPCs)	326	291	35
Total manufacturers	19	10	9

Source: FDA web registry of infant formulas marketed in the United States; NCE Monitoring Team, 2026 [Ref. 1].

We consider three factors that suggest we may overestimate the number of expected reformulations. First, because private-label products may share common formulations and manufacturing processes, the total formulation count may overstate the number of independent reformulation efforts required. Second, some exempt infant formulas may not require reformulation, as their alternative nutrition profiles designed to address specific medical conditions may not be affected by the proposed specification changes. Third, the NCE analysis is based on labeled nutrient values, which reflect the minimum amount guaranteed in the product rather than the actual formulated level. Thus, actual vitamin D content at the time of manufacture may already meet or exceed the proposed minimum for a substantial proportion of products flagged based on their labeled values.

We invite comment on the baseline infant formula market, including:

- whether actual formulated vitamin D levels would already meet the proposed minimum for products flagged based on labeled values;
- which exempt formulations would and would not require reformulation; and
- the extent to which manufacturers of multiple private-label formulas at the same facility would consolidate reformulation activities.

2. Population of Interest

This proposed rule affects all U.S. infants who consume any infant formula during the first year after birth. Based on CDC National Immunization Survey-Child (NIS-Child) data for infants born in 2023, 29.8 percent (95% confidence interval = [28.6, 31.0]) of infants were exclusively breastfed through 6 months of age and are therefore not exposed to infant formula nutrient specifications during that period.[7] The remaining 70.2 percent of infants consume infant formula at some point during the first year after birth and represent the population to whom this rule's nutrient specifications are relevant.

In 2027, U.S. Census projects 3.65 million births, with an average 0.36 year-to-year percent change over the analytical period, 2027 and 2036.[8] Thus, the rule's nutrient specifications are annually relevant to approximately 2.6 million infants (=3.65 million × 70.2%) who consume infant formula at some point during the first year after birth. We acknowledge that this estimate may underestimate the population of interest, as it does not account for infants who were exclusively breastfed through 6 months but subsequently supplemented or replaced breastfeeding with infant formula between 6 and 12 months of age. The 70.2 percent figure therefore represents a lower bound on total infant formula exposure during the first year after birth.

The population-level implications of the proposed changes differ by nutrient, reflecting differences in the direction of the proposed specification changes, the prevalence of inadequate or excessive intake under current specifications, and the availability of alternative nutrient sources.

Iodine. The proposed increase in the iodine minimum from 5 to 15 µg/100 kcal would benefit exclusively and predominantly formula-fed infants, for whom formula is the primary dietary source of iodine. At the current minimum, formula-fed infants receive only approximately 24 percent of the NASEM Adequate Intake (AI) for infants 0–6 months at typical consumption volumes. The NASEM AI represents the most directly applicable threshold for this analysis because it is established specifically for the U.S. population based on experimentally derived intake levels or observed mean nutrient intakes in healthy infants, providing a scientific benchmark for assessing nutritional adequacy. Additionally, the proposed decrease in the maximum from 75 to 50 µg/100 kcal would reduce the risk of excessive iodine exposure across all formula-fed infants.

Vitamin A. U.S. dietary intake data from multiple national surveys consistently show that 21 to 39 percent of U.S. infants have preformed vitamin A intakes exceeding the NASEM Tolerable Upper

[7] See https://www.cdc.gov/breastfeeding-data/survey/results.html, accessed October 21, 2026.

[8] See Table 1. Projected Population and Components of Change, "Births" and "Percent change since prior year," accessed October 22, 2026.

Intake Level (UL) of 600 µg RAE/day. The NASEM UL is the most relevant safety threshold for this analysis because it represents the highest average daily intake level likely to pose no risk of adverse health effects for the U.S. infant population, providing a scientific benchmark for assessing the safety of nutrient exposure. The proposed decrease in the maximum from 225 to 120 µg RAE/100 kcal would reduce unnecessary preformed vitamin A exposure across all formula-fed infants, with the greatest benefit for high consumers.

Manganese. The primary concern as to manganese for formula-fed infants is excess exposure rather than deficiency. Manganese deficiency has not been documented in healthy formula-fed infants. The proposed decrease in the minimum from 5 to 1 µg/100 kcal and establishment of a maximum of 50 µg/100 kcal would reduce aggregate manganese exposure, particularly for infants consuming soy protein-based formulas.

Vitamin D**.** Formula-fed infants are dependent on infant formula as their primary dietary source of vitamin D. At the current minimum of 1 µg (40 IU)/100 kcal, infants consuming typical formula volumes receive only approximately 53 percent of the NASEM AI of 10 µg (400 IU)/day. U.S. dietary intake data indicate that vitamin D is one of the few nutrients for which mean intakes among formula-fed infants do not exceed the AI. Low rates of vitamin D supplementation among formula-fed infants, reported at 4 to 5 percent in a longitudinal study of WIC-enrolled infants [Ref. 2], mean that formula vitamin D content is the primary determinant of vitamin D adequacy for most formula-fed infants. The quantified benefits of the proposed vitamin D minimum increase are assessed in Section E.

For all four nutrients, the population of affected infants is not uniform. Formula feeding rates, consumption volumes, supplementation practices, and dietary exposures vary across demographic groups, geographic regions, and socioeconomic strata. Distributional effects, including the disproportionate impact of this rule on WIC-enrolled infants, who represent a larger share of formula-fed infants in the United States, are discussed in Section H.

E. Benefits of the Proposed Rule

This proposed rule would generate health benefits to formula-fed infants through reformulation across all four nutrients for which specification changes are proposed: vitamin D, iodine, vitamin A, and manganese. However, the scope of reformulation differs substantially across nutrients. While the proposed vitamin D minimum increase is expected to require reformulation of all infant formulas, the proposed changes to iodine, vitamin A, and manganese specifications are expected to require reformulation of only a small number of products: approximately 9 percent of registered formulations for iodine, 6 percent for vitamin A, and less than 1 percent for manganese.

We lack information on the market share of the specific formulations requiring reformulation for iodine, vitamin A, or manganese, or the share of formula-fed infants consuming them. Therefore, we cannot estimate the size of the population that would benefit from those changes. For this reason, the benefits of the iodine, vitamin A, and manganese specification changes are described qualitatively. For vitamin D, we quantify benefits using the best available data, recognizing that the resulting estimate is subject to substantial uncertainty, as described below.

Vitamin D is essential for calcium absorption and bone development. Without adequate vitamin D, infants' bones may not form or harden properly. Clinical manifestations include hypocalcemia (i.e., low blood calcium), hypophosphatemia (i.e., low blood phosphorus), tetany (i.e., involuntary spasms, muscle cramps, and twitching), rickets, skeletal deformities, and muscle weakness and pain [Ref. 3, 4]. Vitamin D deficiency may also manifest as hypocalcemic seizures. Although most commonly reported in breastfed infants, case reports have documented this outcome in formula-fed infants when compounding risk factors are present, including limited sun exposure, poor maternal vitamin D status during pregnancy, and low formula intake volumes [Ref. 4, 5, 6]. Because the periods of infancy and childhood represent critical windows of skeletal development, ensuring adequate vitamin D intake during these stages is essential to prevent these clinical outcomes [Ref. 3, 4, 7].

Among the clinical manifestations of vitamin D deficiency described above, we focus the quantitative benefit analysis on avoided healthcare costs from late-onset hypocalcemia (LOH). LOH is an acute clinical event that typically presents in the first days or weeks of life with neuromuscular irritability, seizures, apnea, or cardiac conduction abnormalities, and in severe cases requires inpatient management in a neonatal or pediatric intensive care unit (NICU or PICU). We selected LOH as the quantified outcome because it was the most tractable given available data, not because we believe it represents the full scope of benefits attributable to this proposed rule nor the proposed changes to minimum and maximum vitamin D levels. The quantified estimate and its limitations are described below.

1. Avoided Healthcare Costs from Vitamin D-Induced Late-Onset Hypocalcemia

The quantified benefit analysis focuses on formula-fed infants who are at risk of vitamin D deficiency under the current minimum specification and who would benefit from the proposed increase. We define the at-risk population in three steps.

First, we begin with our at-risk population estimated in the baseline: approximately 2.6 million infants annually consume infant formula at some point during the first year after birth and represent the population to whom this rule's nutrient specifications are relevant. (=3.65 million × 70.2%)

We then exclude infants who already meet the NASEM AI for vitamin D under the current specification and would not necessarily benefit from additional vitamin D. Simon and Ahrens (2020) estimated that between 27.6 and 34.5 percent of non-breastfeeding infants meet vitamin D intake guidelines, with a midpoint of 31.1 percent [Ref. 8]. Thus, an average 68.9 percent of non-breastfeeding infants do not meet the vitamin D intake guidelines (=1-31.1%). Applying this exclusion, we estimate an at-risk population of approximately 1.8 million infants annually (=2.6 million × 68.9%), representing formula-fed infants who do not currently meet the AI and would benefit from the proposed minimum increase. Table 5 below shows the projected at-risk population over the 10-year analytical period, reflecting CDC birth rate projections.

Table 5. Projected number of formula-fed infants not meeting Vitamin D AI, primary estimates 2027-2036

	Total Births	Formula-fed infants (70.2%)	Formula-fed infants not meeting Vit D AI (68.9%)
2027	3,645,000	2,558,790	1,763,006
2028	3,648,000	2,560,896	1,764,457
2029	3,651,000	2,563,002	1,765,908
2030	3,653,000	2,564,406	1,766,876
2031	3,654,000	2,565,108	1,767,359
2032	3,654,000	2,565,108	1,767,359
2033	3,653,000	2,564,406	1,766,876
2034	3,650,000	2,562,300	1,765,425
2035	3,645,000	2,558,790	1,763,006
2036	3,639,000	2,554,578	1,760,104

Note: Proposed benefits begin accruing in 2032, reflecting the proposed three-year compliance date following an assumed effective date in 2029. Years 2027–2031 are shown for reference.

As described above, severe LOH may require inpatient management in a NICU or PICU, and the associated hospitalization costs are estimable from available data. Longer-term consequences of sustained vitamin D deficiency, including nutritional rickets and impaired bone mineralization, are discussed qualitatively in Section E.2, as they are difficult to attribute specifically to infant formula vitamin D content and may manifest beyond the formula-feeding period.

We do not know the prevalence rate for LOH in the general population or the at-risk population. We also lack information on the effectiveness of this proposed rule, if finalized, on the number of avoided hospitalizations. Without more information, to estimate the number of LOH hospitalizations avoided annually under the proposed rule, we assume that between 0.1 and 1 percent of the at-risk population (primary estimate 0.55%) experiences vitamin D deficiency severe enough to result in LOH requiring hospitalization. We assume that this range incorporates the expected avoided hospitalizations due to this rule. Applying the primary estimate to the at-risk population of approximately 1.76 million infants in 2032 yields approximately 9,723 avoided LOH hospitalizations annually (=1,767,787 × 0.55%), or 0.27 percent of all births in 2032 (=9,723/3,654,000).

We estimate that intensive care for acute LOH will last between two and four days. This reflects that LOH-related hospitalizations are likely to be brief and at a lower intensity of care than premature birth NICU admissions or higher-level of care PICU admissions, and is consistent with the medical literature [Ref. 9]. We estimate the cost of a LOH hospitalization between $9,227 and $30,828, with an average cost of $20,027 per case. This is based on a reported average daily facility cost of $4,613 for NICU care [Ref. 10] and $7,707 for PICU care [Ref. 11].[9] The low estimate represents a NICU stay of two days and the upper estimate represents a PICU stay of four days. The average cost of $20,027 is the midpoint of the low and high estimates. Table 5 shows the projected stream of avoided cases and undiscounted benefits at the mean over the analytical period.

[9] Estimated costs have been inflated to 2025 dollars using the GDP implicit price deflator.

Table 6. Projected avoided LOH cases and undiscounted benefits, primary estimates 2027–2036 (2025$)

	At-Risk Population	Avoided Cases (0.55%)	Undiscounted benefit
2027	1,763,006	0	$0
2028	1,764,457	0	$0
2029	1,765,908	0	$0
2030	1,766,876	0	$0
2031	1,767,359	0	$0
2032	1,767,359	9,720	$194,671,988
2033	1,766,876	9,718	$194,618,712
2034	1,765,425	9,710	$194,458,883
2035	1,763,006	9,697	$194,192,501
2036	1,760,104	9,681	$193,872,842
Total	17,650,378	48,525	$971,814,925

Note: Benefits begin accruing in 2032, reflecting the proposed compliance date. Years prior to 2032 are pre-compliance and generate no benefits.

Table 7 summarizes the present and annualized values of quantified benefits at 3 and 7 percent discount rates across low, primary, and high estimates. The range reflects uncertainty in two key assumptions: the incidence of LOH requiring hospitalization in the at-risk population (0.1% to 1.0%, with a primary estimate of 0.55%) and the average length of a LOH-related hospital stay (2 to 4 days, with a primary estimate of 3 days). The values were derived using Monte Carlo simulations across the low and high inputs described above. At the primary estimate, the proposed vitamin D minimum increase would generate annualized benefits of $80.9 million at a 7 percent discount rate and $90.0 million at a 3 percent discount rate over the 10-year period.

Table 7. Present and Annualized Values of Quantified Benefits (millions of 2025$)

Value	**Low**	**Primary**	**High**
PV (7%)	$131.97	$568.43	$1,205.62
PV (3%)	$178.32	$768.08	$1,629.08
AV (7%)	$18.79	$80.93	$171.65
AV (3%)	$20.90	$90.04	$190.98

Quantified benefits of this rule are subject to substantial uncertainty, as no national surveillance system tracks LOH incidence at the required level of specificity. In the absence of data, we assume that between 0.1 and 1.0 percent of the at-risk population experiences vitamin D deficiency severe enough to result in LOH requiring hospitalization. This range is intended to reflect that LOH is a rare outcome, and that not all vitamin D-deficient infants will progress to LOH requiring hospitalization. An analysis of the national population between 2007 and 2010 indicate that approximately 0.7 percent of children have blood vitamin D levels low enough to be considered deficient [Ref. 12], which falls near the upper bound of this range. Furthermore, whether a given infant develops LOH severe enough to require hospitalization depends on many factors beyond

the vitamin D content of their formula. These include individual variation in vitamin D metabolism, calcium intake, sun exposure, and maternal vitamin D status during pregnancy.

Additional sources of uncertainty include:

- The proposed specification change doubles the minimum vitamin D content in infant formula but does not guarantee that all at-risk infants will achieve the adequate intake, particularly those consuming the lowest formula volumes.
- Serum 25(OH)D concentration alone does not accurately predict health outcomes across all populations, and interpretation should account for age, ethnicity, genetics, calcium intake, and inflammation.
- This analysis captures only the direct healthcare cost of acute inpatient treatment and does not capture costs of follow-up care, caregiver time, or longer-term developmental consequences of sustained vitamin D deficiency.
- The unit cost estimate combines NICU and PICU daily facility costs, but the incidence assumptions underlying the estimated number of avoided hospitalizations are drawn from NICU-specific data. Because the distribution of LOH hospitalizations between NICU and PICU settings is not known, the analysis cannot precisely align incidence and cost inputs; this introduces uncertainty into both the estimated number of cases and the per-case cost.

2. Qualitative Benefits Analysis

Vitamin D: Benefits Beyond the Primary At-Risk Population

The quantified benefit analysis above focuses on the most vulnerable subpopulation: formula-fed U.S. infants who receive no supplemental vitamin D drops. However, the proposed minimum increase would raise vitamin D content across all infant formula products, generating potential benefits for a broader population, including partially formula-fed infants, older infants transitioning to less formula as complementary foods are introduced, and higher-risk subgroups such as infants with dark skin pigmentation, limited sun exposure, northern geographic residence, or preterm birth status [Ref. 3, 4]. The proposed rule would also improve the reliability of infant formula as a vehicle for meeting the vitamin D AI without supplementation, reducing caregiver burden and the risk of deficiency in settings where supplementation recommendations are not followed. Nutritional rickets is a metabolic bone disease resulting from sustained vitamin D deficiency [Ref. 3, 4], and helping to reduce its incidence represents an additional non-quantified benefit. Because rickets typically does not become clinically apparent until infants begin bearing weight around 12 months of age, it is not included in the primary quantified estimate but is a real consequence of sustained deficiency that the proposed rule would help prevent.

Iodine: Reduced Risk of Inadequate Intake

The proposed increase in the iodine minimum from 5 to 15 µg/100 kcal would substantially improve iodine adequacy for formula-fed infants, raising estimated iodine intake at the minimum from approximately 24 percent of the NASEM AI to approximately 72 percent for infants 0–6 months of age. Additionally, the proposed decrease in the maximum from 75 to 50 µg/100 kcal would reduce the risk of excessive iodine exposure, which has been associated with subclinical hypothyroidism in populations with high iodine intake due to environmental exposure or supplementation [Ref. 13, 14]. Because iodine deficiency disorders, including impaired

neurodevelopmental outcomes, are difficult to attribute to infant formula iodine content specifically, and because U.S. iodine status data for formula-fed infants are limited, these benefits are described qualitatively.

Vitamin A: Reduced Risk of Excessive Preformed Vitamin A Intake

The proposed decrease in the vitamin A maximum from 225 to 120 µg RAE/100 kcal would meaningfully reduce the share of formula-fed infants with preformed vitamin A intakes exceeding the NASEM UL of 600 µg RAE/day. At typical intake volumes, the proposed maximum would result in estimated vitamin A intakes representing 106 percent of the UL for infants 0–6 months of age and 81 percent of the UL for infants 6–12 months of age from infant formula alone, compared to substantially higher percentages under the current maximum. Reducing unnecessary exposure to preformed vitamin A above the UL decreases the risk of hypervitaminosis A, including acute manifestations such as bulging fontanelle and vomiting, and potential longer-term consequences, including bone pain and liver effects [Ref. 4, 15, 16]. These benefits are described qualitatively because no dose-response data are available to link current formula vitamin A levels to specific adverse outcomes in U.S. infants. The proposed modest decrease in the minimum from 75 to 70 µg RAE/100 kcal is not expected to meaningfully affect the prevalence of vitamin A deficiency, which is rare in healthy U.S. infants.

Manganese: Reduced Aggregate Exposure

The proposed establishment of a manganese maximum of 50 µg/100 kcal would limit manganese exposure from infant formula, particularly for infants consuming soy protein-based formulas, which naturally contain substantially higher manganese concentrations than cow milk-based formulas. Given that formula-fed infants may be exposed to manganese through multiple concurrent pathways (e.g., formula, reconstitution water, prenatal transfer) and that the developing brain is vulnerable to manganese excess during early infancy, the establishment of a maximum is expected to reduce aggregate manganese exposure for some formula-fed infants [Ref. 17, 18, 19, 20]. The proposed decrease in the minimum from 5 to 1 µg/100 kcal is not expected to affect adequacy, as manganese deficiency has not been documented in healthy formula-fed infants. These benefits are described qualitatively because no dose-response data are available to monetize the reduction in neurodevelopmental risk associated with the proposed maximum.

We invite comment on our estimates of the benefits of this proposed rule, including:

- Whether the 6-month exclusive breastfeeding rate is the appropriate basis for excluding breastfed infants from the at-risk population and whether alternative approaches would better capture the population of infants exposed to infant formula vitamin D specifications;
- Whether the assumed incidence range of 0.1 to 1.0 percent is appropriate for estimating the share of at-risk infants who develop LOH severe enough to require hospitalization, and whether there is any surveillance data or clinical evidence that would support a more precise estimate;
- Whether a 3-day average hospital stay is an appropriate basis for the unit cost estimate, and whether alternative cost data better reflect the typical cost of a LOH-related hospitalization;
- Whether additional health benefits not captured in this analysis can be quantified, including outcomes associated with vitamin D deficiency beyond LOH, and benefits of the iodine, vitamin A, or manganese specification changes.

- Information related to the costs of follow-up care and caregiver time savings associated with reduced supplementation burden such as medical costs, out of pocket costs, and caregiver time burden.

F. Costs of the Proposed Rule

The proposed rule would, if finalized, impose costs on domestic and foreign infant formula manufacturers. The three main cost categories are: (1) relabeling costs, representing the costs to all manufacturers of updating infant formula labels to reflect the proposed specification changes, including new numeric values and new units of measure for vitamin A and vitamin D; (2) reformulation costs, representing the costs incurred by manufacturers whose current formulations do not comply with the proposed specifications and who therefore must adjust nutrient levels or ingredient sourcing to achieve compliance before the rule's compliance date; and (3) administrative costs, representing the costs to manufacturers and FDA associated with BFP notification submissions required when a manufacturer reformulates an existing infant formula product.

Costs incurred by foreign manufacturers are included in this analysis. To the extent that foreign producers pass compliance costs through to U.S. consumers, those costs are borne domestically. We assume that 50 percent of foreign manufacturer costs are passed through to U.S. consumers and estimate domestic and foreign manufacturer costs separately to identify these potential passthrough costs.[10]

1. Labeling Costs

As described in Section D, the FDA infant formula web registry contains 222 unique formulations and 326 UPCs. Because the proposed rule includes mandatory unit changes for vitamin A (from IU to µg RAE) and vitamin D (from IU to µg) that apply to all infant formula products regardless of whether nutrient levels change, all 326 UPCs are subject to relabeling.

Relabeling costs were estimated using FDA's Labeling Cost Model [Ref. 22], updated to 2025 dollars. The model estimates per-UPC costs across labor, materials, inventory, and recordkeeping activities[11] associated with a label change. All proposed label changes in this analysis are classified as minor changes, that is, changes confined to the Nutrition Facts panel that do not require multi-color redesign or modification of the principal display panel. The proposed changes, including

[10] We estimate passthrough costs from foreign entities to be between 0-100% with a midpoint of 50%, which is consistent with the broad scope of the literature on this topic. While there are many peer-reviewed papers that look at cost pass-through, the majority cannot be extrapolated for general purposes, because they tend to be specific to the structure of a single industry and type of cost. We rely on a report called "Cost pass-through: theory, measurement, and potential policy implications" by RBB Economics (2014) for broad conclusions on this literature. While this report is not peer-reviewed, it summarizes the peer reviewed literature. The report concludes, "In summary, the available evidence reveals a wide range of pass-through rates or elasticities. Absolute industry-wide pass-through can be as low as 20% but can also reach well over 100%. Pass-through elasticities may fall close to zero but in some cases they come close to one. However, there is not enough empirical evidence to tie these variations in pass-through to specific market features, as predicted by the theory described in the preceding chapters. In sum, we are able to draw little by way of solid conclusions in this respect" [Ref. 21, page 126].

[11] The labeling model includes administrative and recordkeeping costs associated with understanding the regulation, determining their responses, tracking the required change throughout the labeling change process, and reviewing and updating their records of product labels. These costs are in addition to the administrative costs we estimate manufacturers will incur to submit BFP notifications to FDA.

updating declared values for vitamin D, vitamin A, iodine, and manganese and converting vitamin A and vitamin D declarations from IU-based to weight-based units, satisfy this definition.

The model distinguishes between coordinated and uncoordinated label changes. A coordinated change occurs when a manufacturer aligns a required regulatory label change with a planned voluntary relabeling cycle, avoiding prepress, design, and plate costs that would have been incurred regardless. An uncoordinated change occurs when a manufacturer must make a required label change outside of its normal voluntary cycle, incurring the full cost independently. Consistent with the model's empirical data showing that most products are voluntarily relabeled on a two-to-five-year cycle, we assume all label changes in this analysis are coordinated. Even under a coordinated change, manufacturers still incur administrative and recordkeeping costs associated with understanding the regulation, determining their response, and tracking the required change throughout the labeling process.

The estimated cost of a label change is $836 per UPC, with a 90 percent confidence interval between $226 and $1,942. We assume domestic and foreign entities incur the same per-UPC cost. Table 8 shows total estimated labeling costs by domestic and foreign origin.

Table 8. Total labeling costs (2025$)

	Number of UPCs	Low	Primary	High
Domestic	291	$65,696	$243,392	$565,145
Foreign	35	$7,902	$29,274	$67,973
Total	326	$73,598	$272,666	$633,118

Note: Domestic UPCs estimated as 89.2% of total UPCs, consistent with the ratio of domestic to total formulations.

2. Reformulation Costs

Reformulation costs were estimated using the 2014 FDA Reformulation Cost Model [Ref. 23], updated to 2025 dollars. The model estimates per-formula costs across eight reformulation activities: (1) project management; (2) product reformulation and process modification; (3) packaging assessment; (4) packaging development, where needed; (5) product and package performance testing; (6) production scale-up; (7) recordkeeping; and (8) analytical and consumer testing costs where applicable. The model separates cost estimates by company size, distinguishing between small companies (defined here as less than $10 million in annual sales) and large companies. Given the capital-intensive nature of infant formula manufacturing, most registered infant formula manufacturers are expected to fall in the large company category.

All proposed nutrient specification changes in this rulemaking are classified as minor functional ingredient substitutions under the model's definitions. The nutrients at issue are present in infant formula at trace quantities and do not approach the two percent by weight threshold that would trigger a more complex classification. Table 9 shows the per-formula cost estimates by company size under the Reformulation Cost Model.

Table 9. Per-formula reformulation cost estimates (2025$)

	Average per formula cost	
Reformulation Activity	Small Company	Large Company
Determine response to regulation	$2,780	$20,395
Project management	$6,385	$101,861
Product reformulation/process modification	$17,887	$187,238
Packaging assessment	$872	$13,389
Packaging development	$37	$3,848
Product and package performance testing	$6,816	$114,706
Production scale-up testing	$4,767	$195,922
Recordkeeping	$729	$174,396
Analytical tests	$3,008	$3,008
Consumer tests	$0	$35,518
Total	$43,280	$850,280

Note: Small companies are defined as having less than $10 million in annual sales.

Total reformulation costs are estimated by applying the per-formula cost to the 222 formulations requiring reformulation, weighted by the assumed share of small and large companies. We apply small company costs to 13 formulations produced by domestic (6 formulations) and foreign (7 formulations) firms. Table 10 shows total estimated reformulation costs by domestic and foreign origin.

Table 10. Total reformulation costs, (millions of 2025$)

	# of Formulas	Low	Primary	High
Domestic	198	$76.13	$163.51	$295.78
Foreign	24	$6.88	$14.76	$26.68
Total	222	$83.01	$178.27	$322.46

Note: Low, primary, and high estimates reflect the range of per-formula costs under the Reformulation Cost Model, not variation in the number of formulations requiring reformulation.

3. Administrative Costs

The proposed rule would generate administrative costs for both manufacturers and FDA. These costs arise from the regulatory notification requirements triggered when a manufacturer reformulates an existing infant formula product. Under section 412(d)(3) of the FD&C Act and FDA's implementing regulation, a manufacturer that reformulates an existing infant formula by making a non-major change in formulation that may affect whether the formula is adulterated under section 412(a) of the FD&C Act must submit a BFP notification to FDA before commercially distributing the reformulated product. BFP submissions require manufacturers to provide documentation of the reformulated product's nutrient composition, quality control procedures, and compliance with applicable specifications. Each reformulation generates one BFP submission, and the costs of preparing and reviewing those submissions are borne by manufacturers and FDA, respectively. We estimate administrative costs separately for manufacturers and FDA.

Preparing a BFP submission requires manufacturer staff time for compiling nutrient composition data, quality control documentation, and regulatory correspondence. We estimate the cost of a BFP submission at $510 per formulation, based on an assumed 6 hours of staff time at a fully loaded wage rate of $84.96 per hour (6 hours × $84.96/hour = $509.76).[12] The fully loaded wage rate reflects the median wage for a food scientist or related regulatory affairs professional, adjusted for benefits and overhead.[13] Under baseline conditions, FDA receives approximately 61 BFP submissions annually. We expect that each updated formulation will submit a BFP before the compliance date, if finalized. The incremental cost attributable to the proposed rule is the difference between the after-rule and before-rule totals. Table 11 shows the estimated manufacturer costs of BFP submissions before and after the proposed rule.

Table 11. Manufacturer costs of BFP submissions (2025$)

	Before Rule	After Rule	Change
Annual submissions (total)	61	176	+115
Domestic	*54*	*157*	*+103*
Foreign	*7*	*19*	*+12*
Fully loaded wage ($/hr)	$84.96	$84.96	No change
Hours per submission	6	6	No change
Cost per submission ($)	$510	$510	No change
Total industry cost ($)	$30,993	$89,718	$58,724
Domestic	$27,629	$80,032	$52,403
Foreign	$3,364	$9,685	$6,321

FDA will incur costs associated with reviewing BFP submissions from reformulating manufacturers. FDA review of each BFP submission requires staff time from reviewers in the Office of Critical Foods, Human Foods Program, to assess nutrient composition data, verify compliance with proposed specifications, and document the review. We estimate the cost of reviewing a single BFP submission at $21,856, based on an estimated 140 hours of staff time at a fully loaded FDA wage rate of $156.50 per hour. The approximately 140-hour estimate reflects the typical staff time required to review a BFP submission under current practice. Table 12 shows the estimated FDA review costs before and after the proposed rule.

[12] See PRA Supporting Statement 0256.

[13] See BLS Wage Estimate: Food Scientists and Technologists: https://www.bls.gov/oes/2023/may/oes191012.htm

Table 12. FDA review costs of BFP submissions (2025$)

	Before Rule	After Rule	Change
Submissions in the first year	61	176	+115
FDA wage rate ($/hr)	$156.50	$156.50	No change
Total review hours	8,491	24,579	+16,088
Cost per submission ($)	$21,856	$21,856	No change
Total FDA review cost ($)	$1,328,845	$3,846,657	$2,517,812

Note: All BFP reviews are assumed to occur in the compliance year.

4. Summary of Costs

Table 13 summarizes the estimated costs of the proposed rule by category over the 10-year analytical period. For purposes of this analysis, we assume an effective date of 2029 if the rule is finalized as proposed, followed by a proposed three-year compliance date of 2032. All costs are assumed to occur in 2031, the year leading up to the projected compliance date, reflecting the one-time nature of relabeling, reformulation, and BFP submission activities. Total undiscounted costs, assuming a 50 percent passthrough adjustment for foreign costs, is about $173.7 million. Reformulation costs are the largest single cost category, accounting for approximately 98 percent of total primary costs. Labeling and administrative costs account for the remainder.

Table 13. Undiscounted primary cost stream by category (2025$)

	Labeling	Reformulation	BFP Submission	FDA Review
2027	$0	$0	$0	$0
2028	$0	$0	$0	$0
2029	$0	$0	$0	$0
2030	$0	$0	$0	$0
2031	$258,029	$170,892,321	$55,564	$2,517,766
2032	$0	$0	$0	$0
2033	$0	$0	$0	$0
2034	$0	$0	$0	$0
2035	$0	$0	$0	$0
2036	$0	$0	$0	$0

Note: All costs reflect primary estimates; 50 percent passthrough adjustment for foreign costs is applied.

Table 14 below presents the present and annualized values of total costs at 3 and 7 percent discount rates across low, primary, and high estimates. The values were derived using Monte Carlo simulations across the low and high inputs described above. The large range primarily reflect the range of per-formula reformulation costs under the Reformulation Cost Model.

Table 14. Present and annualized values of total costs (millions of 2025$)

	Low	Mean	High
PV 7%	$58.62	$123.86	$222.66
PV 3%	$70.92	$149.86	$269.38
AV 7%	$8.35	$17.64	$31.70
AV 3%	$8.31	$17.57	$31.58

We invite comment on our estimates of the costs of this proposed rule, including:

- The number of infant formulas that would require reformulation, particularly whether using labeled nutrient values overstates the number of products whose actual formulated nutrient levels would not already meet the proposed minimum;
- Whether the $10 million annual sales threshold appropriately distinguishes small from large company reformulation costs, or whether a different threshold, or no size distinction, would better reflect cost differences across infant formula manufacturers;
- To what extent the proposed reformulations could affect optimal packaging or storage practices and whether treating vitamin D reformulation as a one-time cost is appropriate, given that the proposed rule both raises the minimum and narrows the acceptable range, potentially generating recurring costs as nutrient levels shift with ingredient sourcing and production variability;
- Whether the appropriateness of classifying all the proposed specification changes as minor functional ingredient substitutions under the Reformulation Cost Model and estimating a single per-formula cost is appropriate when some manufacturers may need to address up to four nutrients simultaneously;
- Whether changing the input amount of vitamin D, iodine, vitamin A, and manganese could change the flavor or other aspects of sensory experience, thus affecting amounts or quality of other inputs as manufacturers attempt to maintain palatability; and
- The extent to which manufacturers of multiple private-label formulas at the same facility would consolidate reformulation activities, reducing per-formula costs relative to the estimates presented above.

G. Transfers Caused by the Proposed Rule

This proposed rule is not expected to generate transfers.

H. Summary of Benefits and Costs

Table 15 summarizes the primary estimated costs and benefits of the proposed rule over the 10-year analytical period. We propose a compliance date of three years after the effective date of the final rule completing our phased, comprehensive infant formula nutrient review to provide industry time to reformulate and relabel infant formula while recognizing the importance of updating the infant formula nutrient specifications. We invite comment on the proposed compliance date.

Costs are incurred in 2031, the year leading up to the projected compliance date of 2032, and consist of relabeling, reformulation, and administrative costs borne by domestic and foreign infant formula manufacturers. Benefits begin accruing in 2032 and consist of avoided healthcare costs

from vitamin D deficiency-induced late-onset hypocalcemia in formula-fed infants. Additional benefits from the proposed iodine, vitamin A, and manganese specification changes are described qualitatively in Section E and are not reflected in the figures below.

Table 15. Primary undiscounted costs and benefits of the proposed rule, (2025$)

	Costs	Benefits
2027	$0	$0
2028	$0	$0
2029	$0	$0
2030	$0	$0
2031	$173,723,726	$0
2032	$0	$194,671,988
2033	$0	$194,618,712
2034	$0	$194,458,883
2035	$0	$194,192,501
2036	$0	$193,872,842
Total Undiscounted	$173,723,726	$971,814,925

Table 16 below presents the present and annualized values of costs and benefits at 3 and 7 percent discount rates.

Table 16. Present and annualized primary values of costs and benefits (millions of 2025$)

	Costs	Benefits	Net Benefits
PV (7%)	$123.86	$568.43	$444.56
PV (3%)	$149.86	$768.08	$618.22
AV (7%)	$17.64	$80.93	$63.30
AV (3%)	$17.57	$90.04	$72.47

Note: Cost present and annualized values reflect primary estimates only. The full range of benefits and costs are shown in Table 6 and Table 14, respectively.

I. Analysis of Regulatory Alternatives to the Proposed Rule

FDA considered one regulatory alternative to the proposed rule: shortening the compliance period from three to two years. All proposed specification changes are identical under both scenarios. The shorter compliance period would increase reformulation costs by triggering the 1.5 cost multiplier under the Reformulation Cost Model and would advance benefit accrual by one year. The costs and benefits of this alternative are assessed in turn below.

Under the two-year compliance alternative, the earlier compliance date would advance the year in which benefits begin accruing by one year (from 2032 to 2031) generating one additional year of avoided LOH hospitalizations within the 10-year analytical period. Also, all 222 formulations requiring reformulation would face an accelerated timeline, triggering the 1.5 cost multiplier applied under the Reformulation Cost Model for compliance periods of two years or fewer. This multiplier reflects the additional costs manufacturers incur under compressed timelines, including overtime labor, additional staffing, and vendor rush charges. Relabeling and administrative costs

are assumed to be unchanged relative to the proposed rule, as these activities are not expected to be materially affected by a one-year reduction in the compliance period. Table 17 shows the undiscounted cost stream and present and annualized values of costs under the two-year compliance alternative.

Table 17. Undiscounted Cost Stream, Two-Year Compliance Alternative, 2027–2036 (2025$)

	Primary Cost	Primary Benefits
2027	$0	$0
2028	$0	$0
2029	$0	$0
2030	$258,706,277	$0
2031	$0	$194,722,968
2032	$0	$194,722,968
2033	$0	$194,669,677
2034	$0	$194,509,806
2035	$0	$194,243,355
2036	$0	$193,923,612
Total Undiscounted	$258,706,277	$1,166,792,386

Table 18 presents the present and annualized values of costs and benefits. The two-year compliance alternative generates higher net benefits than the proposed rule in present value terms, approximately $78 million higher at a 7 percent discount rate ($138.8 million in additional discounted benefits offset by $60.6 million in additional discounted costs), reflecting the value of one additional year of avoided LOH hospitalizations. However, this modest net benefit advantage comes at the cost of a 49 percent increase in total compliance costs, which would be borne by manufacturers in the compliance year.

Table 18. Regulatory alternative, present and annualized values of costs and benefits (millions of 2025$)

Costs			
	Low	Primary	High
PV 7%	$86.86	$184.45	$332.17
PV 3%	$105.09	$223.16	$401.88
AV 7%	$12.37	$26.26	$47.29
AV 3%	$12.32	$26.16	$47.11
Benefits			
PV 7%	$164.20	$707.26	$1,500.09
PV 3%	$217.32	$936.05	$1,985.34
AV 7%	$23.38	$100.70	$213.58
AV 3%	$25.48	$109.73	$232.74

J. Distributional Effects

Benefits, costs, and transfers rarely accrue to the same individuals or entities and may accrue differentially across populations, demographic groups, and socioeconomic strata. This section describes the distributional effects of the proposed rule across the populations most likely to be differentially affected.

The most significant distributional effect of this proposed rule concerns WIC-enrolled infants. The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) provides federal nutrition assistance to low-income pregnant, postpartum, and breastfeeding women, infants, and children under five years of age, including issuing infant formula for formula-fed infants. WIC participants use their food benefits, often issued in the form of an electronic benefits transfer (EBT) card, to purchase WIC-approved foods including infant formula at WIC authorized retailers.[14] Infants participating in WIC account for approximately 56 percent of all infant formula consumed domestically.[15] A longitudinal study of WIC-enrolled infants found that vitamin D supplementation was reported in only 4 to 5 percent of formula-fed participants, meaning that formula vitamin D content is the primary determinant of vitamin D adequacy for this population [Ref. 2]. Because WIC participants are more likely to be exclusively formula-fed than higher-income populations, the nutrient specifications at 21 CFR 107.100 function as a particularly critical nutritional safeguard for this population. The proposed rule would generate larger benefits for WIC-enrolled infants relative to the general formula-fed population because WIC-enrolled infants are more likely to be exclusively formula-fed and to consume formula as their sole source of nutrition, making them more dependent on formula nutrient content to meet their nutritional needs. [Ref. 24]

The costs of the proposed rule are borne by manufacturers, not by WIC participants directly. To the extent that manufacturers pass compliance costs through to consumers in the form of higher infant formula prices, WIC program costs could increase over time. These effects are not quantified in this analysis due to insufficient data on the pass-through of manufacturer compliance costs to retail formula prices but are noted here as a potential distributional effect.

Several subgroups of formula-fed infants face elevated risk of vitamin D deficiency under the current baseline and would benefit disproportionately from the proposed vitamin D minimum increase. These include:

- Infants with dark skin pigmentation, who synthesize vitamin D less efficiently from sunlight exposure and are therefore more dependent on dietary sources.
- Infants with limited sun exposure, including those in northern geographic regions, those born in winter months, and those whose caregivers limit outdoor exposure for cultural or practical reasons.
- Preterm infants, who have lower vitamin D stores at birth and higher nutritional requirements relative to body weight than term infants.

[14] WIC Program funds may not be used to purchase or issue dietary supplements, including vitamin D supplements.

[15] See USDA Economic Research Service report, "Infants in USDA's WIC Program consumed an estimated 56 percent of U.S. infant formula in 2018," at https://www.ers.usda.gov/data-products/charts-of-note/103970.

- Infants born to mothers with vitamin D deficiency during pregnancy, who are born with lower hepatic vitamin D stores and are at elevated risk of deficiency in the early postnatal period.

These subgroups are not uniformly distributed across the U.S. population. If infants that face these risk factors for vitamin D deficiency are disproportionately represented among WIC participants, the distributional benefit of the proposed minimum increase is amplified for these populations.

K. International Effects

This proposed rule would apply to all infant formulas marketed in the United States, including those produced by foreign manufacturers. As described in Section F, foreign manufacturer costs are included in this analysis. The proposed rule does not impose additional regulatory requirements on foreign entities beyond those applicable to domestic manufacturers and is not expected to have a material effect on U.S. imports or exports of infant formula.

The proposed rule would bring U.S. infant formula nutrient specifications into closer alignment with international standards for several nutrients. Specifically, the proposed iodine minimum of 15 µg/100 kcal aligns with the European Union (EU) and China; the proposed iodine maximum of 50 µg/100 kcal falls within the range of international standards; the proposed vitamin A maximum of 120 µg RAE/100 kcal is consistent with the EU maximum of 114 µg RE/100 kcal; and the proposed manganese maximum of 50 µg/100 kcal aligns with the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition recommendation. Foreign manufacturers who already produce infant formula meeting EU, Codex Alimentarius, or Health Canada specifications may face lower compliance costs than those estimated in the primary analysis, as their existing formulations may already meet or approach the proposed U.S. specifications for one or more nutrients. This potential cost reduction is not quantified but represents a source of downward bias in the foreign cost estimates.

Manufacturers who currently produce formula for both U.S. and international markets under divergent specifications may also realize cost savings from simplified formulation management and reduced need to maintain separate product lines. These savings are not quantified in the primary analysis due to insufficient data on the share of U.S.-marketed formulas also sold internationally. We invite comment on the magnitude of these potential savings and the extent to which foreign manufacturers currently marketing formula in the United States already meet the proposed specifications.

L. Uncertainty and Sensitivity Analysis

This section assesses the robustness of the primary net benefit estimate to key sources of uncertainty in the benefits and costs analysis. We first present the primary net benefit estimate, then assess uncertainty in the vitamin D formulation estimates, and finally present a sensitivity analysis using willingness to pay (WTP) for vitamin D infant drops as an alternative measure of the benefit of the proposed vitamin D minimum increase.

1. Net Benefits

Table 19 presents the net benefit estimate at 3 and 7 percent discount rates, calculated as the difference between the present value of quantified benefits and the present value of total costs. As described in Section E, the quantified benefits reflect avoided healthcare costs from vitamin D deficiency-induced late-onset hypocalcemia only and represent a lower bound on the rule's total social benefits.

Table 19. Net Benefits of the Proposed Rule (millions 2025$)

	Low	Mean	High
PV 7%	$73.35	$444.56	$982.96
PV 3%	$107.40	$618.22	$1,359.70
AV 7%	$10.44	$63.30	$139.95
AV 3%	$12.59	$72.47	$159.40

2. Nutrient Formulation Uncertainty

The primary cost estimate assumes that all 222 formulations require reformulation to meet the proposed vitamin D minimum of 2 μg (80 IU)/100 kcal and 45 of those formulations also require reformulation of manganese, iodine, or vitamin A. These assumptions are based on two uncertain inputs: the number of exempt formulas requiring reformulation and labeled nutrient values. First, as described in the baseline section above, some exempt infant formulas may not require reformulation, as they may need to deviate from the standard nutrient requirements specified for routine, healthy full-term infants due to the specific medical condition for which the exempt formula is used. These formulas still require FDA notification and regulation for their specific intended uses but have alternative nutrition profiles that may not be impacted by the proposed changes.

Second, labeled nutrient values, which represent the minimum amount of a nutrient guaranteed in the product at the end of its shelf life, are not the same as actual formulated levels. Because many nutrients degrade over a product's shelf life, manufacturers routinely formulate above their label claims, a practice known as “overage,” to ensure that the labeled minimum is still met when the product reaches the consumer.

The extent of overage varies across products and depends on several factors, including the stability of the nutrient in the infant formula matrix, the target shelf life of the product, and how frequently the product is manufactured. Nutrients that are less stable over time, such as water-soluble vitamins, typically require larger overages than more stable nutrients such as minerals. Products with longer shelf lives, such as formulas for generally healthy infants with shelf lives of up to 36 months, may require substantially larger overages than products with shorter shelf lives, such as certain exempt infant formulas targeting smaller populations, which may have shelf lives of 12 months or less and are often manufactured less frequently. As a result, the actual vitamin D content of a product at the time of manufacture is typically higher than the labeled value.

Of the 222 formulations flagged as potentially needing reformulation to comply with the proposed rule, we estimate 87 percent have labeled vitamin D values between 60 and 78 IU/100 kcal, below

the proposed minimum of 80 IU/100 kcal based on the label, but potentially above it at actual formulated levels. If actual formulated levels for these products are approximately 150 percent of the labeled value, a plausible assumption given typical manufacturing overage practices, their actual vitamin D content would range from approximately 90 to 117 IU/100 kcal, which meets or exceeds the proposed minimum of 80 IU/100 kcal. Under this assumption, these formulations would not require reformulation to meet the proposed vitamin D minimum and would incur no reformulation costs attributable to this rule.

This practice is not without tradeoffs: manufacturers who meet the proposed minimum with overages would face a choice between reformulating and reducing their product's shelf life. While reducing shelf life may avoid reformulation costs, it carries operational implications that this analysis does not estimate, such as more frequent production runs and reduced inventory flexibility.

Eight percent of the formulations were flagged for one or more nutrients other than vitamin D and would require reformulation regardless of their actual vitamin D content. Combining these two adjustments yields an alternative reformulation count of 45 formulations (222 total − 193 assumed to already meet the vitamin D minimum at actual formulated levels + 16 flagged for other nutrients = 45).

Table 20 presents the total costs of this alternative reformulation assumption. If fewer infant formulas needed to reformulate in order to comply with the rule as proposed, total costs to industry and FDA would be smaller and thus net benefits would be larger.

Table 20. Uncertainty analysis, total costs (millions of 2025$)

	Low	Primary	High
Total Undiscounted	$51.24	$107.08	$191.60
PV 7%	$36.53	$76.35	$136.61
PV 3%	$44.20	$92.37	$165.28
AV 7%	$5.20	$10.87	$19.45
AV 3%	$5.18	$10.83	$19.38

We invite comment on the prevalence and magnitude of manufacturing overages for vitamin D in infant formula, and on whether the 150 percent overage assumption is representative of current industry practice.

3. Sensitivity Analysis: WTP for Vitamin D Infant Supplements

The primary benefit analysis values the proposed vitamin D minimum increase in terms of avoided healthcare costs from late-onset hypocalcemia hospitalization. A way to potentially extend the primary benefit estimate is to observe the market value of vitamin D infant drops, which reflects the aggregate amount U.S. caregivers spend annually to ensure their infants receive adequate vitamin D through supplementation. To the extent that the treatment costs estimated above (which become savings attributed to the proposed rule) are paid by entities or individuals *other* than

caregivers, the value of vitamin D drops would provide insight into a separate benefit—associated with, among other effects, quality-of-life gains accruing to infants as they grow.[16]

We use proprietary data from market research firm Circana to evaluate the market value.[17] Based on Circana retail scanner data, the total annual market value of vitamin D infant drops in the United States was approximately $33.9 million in 2025, shown in Table 21.

Table 21. Retail Market for Vitamin D Infant Drops, 2022–2025

	Dollar Sales	Units Sold	Price Per Unit
2022	$34,349,724	2,787,268	$12.32
2023	$32,506,566	2,446,738	$13.29
2024	$33,485,703	2,384,396	$14.04
2025	$33,942,880	2,456,429	$13.82

This figure represents the revealed willingness of U.S. caregivers to pay for infant vitamin D supplementation in the current baseline, in a world where infant formula vitamin D content is insufficient to meet the NASEM AI at typical consumption volumes for most formula-fed infants. We do not know what share of this market is attributable to formula-fed infants specifically, how consistently caregivers administer the drops, what proportion of at-risk infants are currently being supplemented, or the extent to which market value of vitamin D drops is suppressed by minor adverse reactions that have sometimes been observed among infant recipients. Accordingly, we do not use this figure as a direct benefit estimate.

[16] By contrast, to the extent that treatment costs are paid by infants' caregivers, there is overlap between the two quantitative approaches.

[17] See https://www.iriworldwide.com/en-US/Company/About-Us for details.

III. **Initial Small Entity Analysis**

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we cannot determine with certainty the magnitude of reformulation costs that small infant formula manufacturers would incur under this proposed rule, we find that that the proposed rule may have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document and the Preamble of the proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

Affected entities are domestic infant formula manufacturers subject to the proposed nutrient specification and labeling changes. We identify small entities using the SBA size standard effective March 17, 2023 applicable to NAICS code 311514 (Dry, Condensed, and Evaporated Dairy Product Manufacturing), which defines a small business as one with fewer than 1,000 employees.[18]

To characterize the size distribution of firms in this industry, we draw on 2022 Census Bureau Statistics of U.S. Businesses data for NAICS 311514.[19] Table 22 and Table 23 below present the number of firms and average annual receipts per firm by enterprise employee size and enterprise receipt size, respectively, for all firms in this NAICS code.

Table 22. NAICS 311514: Dry, Condensed, and Evaporated Dairy Product Manufacturing, by Enterprise Employee Size (2025$)

Enterprise Size (Employees)	Firms	Average Annual Receipts per Firm
<500	90	$74,711,607
750–999	4	$184,793,420
1,000–1,499	7	$347,516,649
2,500–4,999	5	$1,091,088,450
5,000+	11	$637,486,110
Total	122	$195,966,480

Note: The 500–749 employee size category is not separately reported in the 2022 Census Bureau Statistics of U.S. Businesses data for this NAICS code. Source: https://www2.census.gov/programs-surveys/susb/tables/2022/us_state_naics_detailedsizes_2022.xlsx

[18] See https://www.sba.gov/document/support-table-size-standards

[19] See https://www.census.gov/data/tables/2022/econ/susb/2022-susb-annual.html

Table 23. NAICS 311514: Dry, Condensed, and Evaporated Dairy Product Manufacturing, by Enterprise Receipt Size (2025$)

Enterprise Size (Receipts)	Firms	Average Annual Receipts per Firm
$100K–$499K	8	$288,433
$500K–$999K	8	$923,210
$1,000K–$2,499K	7	$1,733,259
$2,500K–$4,999K	11	$4,121,315
$5,000K–$7,499K	4	$6,988,768
$7,500K–$9,999K	3	$9,135,297
$10,000K–$14,999K	4	$12,970,423
$15,000K–$19,999K	4	$16,547,438
$30,000K–$34,999K	5	$36,490,638
$50,000K–$74,999K	8	$55,973,138
$75,000K–$99,999K	4	$94,731,008
$100,000K+	49	$458,708,210
Total	122	$195,966,480

Source: https://www2.census.gov/programs-surveys/susb/tables/2022/us_6digitnaics_rcptsize_2022.xlsx

These data cover all firms in NAICS 311514 and are not limited to infant formula manufacturers. The infant formula manufacturing industry is substantially more concentrated than the broader NAICS code suggests. Based on our review of the FDA infant formula web registry and publicly available information on manufacturer size, we identify 3 domestic manufacturers as small entities under the applicable SBA size standard. The remaining domestic manufacturers have more than 1,000 employees.

B. Description of the Potential Impacts of the Rule on Small Entities

In the main analysis, we estimated costs to industry to be reformulation, labeling, and administrative costs associated with BFP submissions. For small domestic firms, per-formula total costs range from $22,449 to $78,768.

We are unable to determine whether costs to small domestic firms would exceed 3 percent of revenue for the following reasons. First, the number of small entity products requiring reformulation is uncertain, as described in the baseline and shown in Table 3. Second, the per-formula cost of reformulation is uncertain. As shown in Table 9, the reformulation cost model provides separate cost estimates for small firms, defined as having annual revenues less than $10 million. If actual total costs for small infant formula manufacturers are closer to the large firm range ($396,000 to $1,540,571 per formula), the cost burden could be substantially higher than the small firm estimates suggest. We request comment and data on the difference in reformulation cost small and large manufacturers face.

To assess the potential magnitude of the cost burden, we use average annual receipts per firm from 2022 Census Bureau data for NAICS 311514. Table 24 shows the number of formulas a small firm with less than 1,000 employees would need to reformulate, at the high end of both the small firm and all firm cost ranges, in order for total reformulation costs to reach 3 percent of average annual receipts.

Table 24. Number of Formulas Required to Reach 3% of Average Annual Receipts at High-End Reformulation Costs (2025$)

			Number of formulas to reach 3% if per formula cost equals	
Enterprise Size (Employees)	Average Annual Receipts	3% Revenue Threshold	$78,768	$1,540,571
<500	$74,711,607	$2,241,348	28.5	1.5
750–999	$184,793,420	$5,543,803	70.4	3.6

Under small firm cost estimates, a firm would need to reformulate approximately 28 or more formulas before costs would approach 3 percent of average annual receipts which is well above the number of infant formulas marketed by small manufacturers. However, if actual costs are closer to the large firm range, a single reformulation could potentially exceed the 3 percent threshold for the smallest establishments.

Of the small domestic infant formula manufacturers, we are unable to determine how many would experience a significant economic impact because we lack data on firm revenue and the number of products requiring reformulation. Given this uncertainty, we find that the proposed rule may have a significant economic impact on a substantial number of small entities and have prepared this Initial Regulatory Flexibility Analysis accordingly. We invite comment on the revenues of small domestic infant formula manufacturers, the number of their products that would require reformulation, and the reformulation costs they would expect to incur.

FDA is not aware of any federal rules that duplicate, overlap with, or conflict with the proposed rule.

C. Alternatives to Minimize the Burden on Small Entities

The Regulatory Flexibility Act requires FDA to consider alternatives that would minimize the significant economic impact of the proposed rule on small entities. We consider two alternatives: an extended compliance period and an exemption for small entities. We invite comments on these alternatives to minimize the significant economic impact on small entities, including ways to better streamline reformulation requirements.

1. Extended Compliance Period for Small Entities

Under this alternative, small domestic manufacturers would be granted a four-year compliance period, one year longer than the three-year compliance period proposed for all manufacturers. A longer compliance period would not reduce per-formula reformulation costs but could provide small manufacturers with additional time to plan and align compliance activities with their normal production cycles. We are unable to quantify the benefits under this alternative due to lack of data on market share but expect they would be smaller than estimated in the primary analysis, resulting in fewer net benefits. FDA does not adopt this alternative at this time but invites comment on whether an extended compliance period for small entities would be appropriate.

2. Exemption for Small Entities

Under this alternative, small domestic manufacturers would be exempt from all proposed nutrient specification changes, eliminating reformulation costs entirely. We are unable to quantify the benefits under this alternative due to lack of data on small manufacturer market share and are uncertain whether the net benefits under this alternative would be smaller or larger than estimated in the primary analysis. FDA does not adopt this alternative because the public health rationale for updating nutrient specifications applies to all infant formula products regardless of manufacturer size, and an exemption could result in formula-fed infants consuming products that do not meet current scientific standards for nutrient adequacy.

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