REAGAN-UDALL FOUNDATION FOR THE FDA

Infant Formula Roundtable Series

Report on Cross-sector Stakeholder Insights

Summary of Roundtable Discussions

OCTOBER 2025

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The Reagan-Udall Foundation for the FDA (Foundation) is an independent 501(c)(3) created by Congress to advance the mission of the FDA to modernize product development, accelerate innovation, and enhance product safety. The Foundation works to advance regulatory science, support development and dissemination of reliable information, and facilitate engagement and information exchange.

This activity is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of $510,000 in federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.

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Overview

Many infants in the United States rely on infant formula for some or all of their nutrition. Ensuring that the youngest and most vulnerable individuals have access to safe and nutritionally adequate formula products is a top priority for the U.S. Food and Drug Administration (FDA). The agency regulates the production of infant formulas to help ensure that these products are safe and support healthy growth in infants who consume them. FDA's regulatory requirements address, among other issues, the safety, nutritional adequacy, packaging, and labeling of these products. All infant formula manufacturers must meet the FDA's nutritional quality and safety standards in order to have their products sold in the U.S.

In 2022, safety concerns with powdered infant formula led to a voluntary recall of specific lots of powdered infant formula products manufactured at Abbott Nutrition's facility in Sturgis, Michigan. This recall, combined with the overall strains on supply chains experienced during the COVID-19 pandemic, led to a powdered infant formula shortage that revealed several vulnerabilities and underscored the importance of strengthening systems to safeguard the safety and availability of this essential product. In response, the FDA has implemented measures to improve powdered infant formula safety, including the development of a comprehensive prevention strategy, enhanced inspection protocols, increased collaboration with the infant formula industry, and the pursuit of regulatory actions as warranted.

Building on these efforts, in 2025, Operation Stork Speed was launched jointly between FDA and the U.S. Department of Health and Human Services (HHS). This initiative includes several key priorities: a comprehensive nutrient review, increased testing for heavy metals and other contaminants in infant formula, enhanced scientific and research collaboration with the National Institutes of Health (NIH), and additional measures to expand infant formula safety.

To support this ongoing work and the Agency's commitment to safe and nutritious infant formula, the Reagan-Udall Foundation for the FDA (Foundation), convened a series of four moderated roundtable discussions in September 2025 to gather insights and perspectives from a wide range of experts and cross-sector stakeholders engaged in or impacted by FDA's infant formula policies and actions. The four roundtable discussions included the following groups (1) public health experts, state officials, and advocacy organizations; (2) infant formula manufacturers; (3) academics and researchers; and (4) parents, caregivers, and healthcare providers, such as pediatricians, nurses, and registered dietitians.

The roundtables were designed to gather perspectives from a diverse range of views on infant formula, aiming to identify strengths, gaps, and opportunities within the current system. While FDA has deep scientific knowledge and regulatory expertise, the agency's work is enhanced through sessions such as these roundtables, where diverse experiences offer an opportunity to further inform its work and to tailor responses and policies in a meaningful and evidence-based fashion. The discussions yielded valuable insights into opportunities to improve communication and trust, and the need for transparency and a call to address misinformation.

Several themes emerged consistently across the discussions, underscoring support for breastfeeding as the gold standard for infant nutrition, as well as a shared commitment to maintaining and communicating the already high bar of safety and quality that all U.S. infant formula must meet as the next best alternative to breastmilk. Participants echoed the desire for

updates to nutrient standards grounded in science and informed by innovation, as well as a call for better tools, education, and messaging to support families and providers in making informed choices. Participants emphasized that the FDA's leadership and regulatory foundation are critical—but they are even more effective when informed by multi-stakeholder dialogue and community-level insights. This report summarizes the key insights and cross-cutting themes from the full roundtable series, aligns those insights with FDA's role in Operation Stork Speed, and presents actionable opportunities identified in the stakeholder roundtable discussions.

Key Insights and Cross-Cutting Themes

Maintain and Build on a Solid Foundation of Quality, Safety, and Availability of Infant Formula in the U.S.

Maintaining the availability of safe, high-quality, nutritious, and widely available infant formula for all families was a consistent theme throughout the roundtable series. Emphasizing that all U.S. infant formula products adhere to stringent safety, quality, and nutrition standards can help reassure providers, caregivers, and parents in their choices. Participants succinctly emphasized that FDA is the leader in infant formula scientific review and rigor, and effectively communicating this is critical. This sentiment resonates through these participant comments: "the level of scientific rigor in the approval process for the US is among the highest, if not the highest, in the world" and "FDA's pre-market review program that they have in place for infant formula today is the most scientifically rigorous and robust review that's done to bring an innovative infant formula to the market."

The potential impacts of any proposed regulatory changes need to be carefully considered to understand any downstream effects or unintended consequences on infant formulas, notably availability and cost. There was broad agreement that the infant formula ingredient supply chain must remain strong, resilient, and responsive to meet the needs of all families.

Nutrient Review is Supported

Across stakeholder groups, participants expressed strong support and consensus around the necessity for a comprehensive infant formula nutrient review, including the evaluation of required nutrients and the required amounts of those nutrients, as well as support for enhancements to promote innovation in this area. Moving beyond traditional safety and growth measures, participants advocated for regulatory and scientific frameworks that incorporate functional outcomes, such as cognitive, neurodevelopmental, metabolic, and microbiome measures, as key considerations for the review of infant formula nutrient requirements. A holistic approach, grounded in emerging science and the implications for long-term health, was supported with caution to avoid oversimplifying developmental measures. Participants urged that any changes be grounded in robust scientific evidence, with defined and meaningful outcomes, and consideration of appropriate nutrient needs.

Regulatory Clarity is Welcome

Participants expressed support for regulatory clarity across key topic areas, including nutrient levels, contaminants, labeling, and claims. Examples with broad consensus included defined maximum levels for nutrients, innovative and accelerated approval pathways for infant formula submissions, and the need for criteria for claims that ensure they are backed by scientific evidence. Improvements in regulatory clarity in these areas may lead to enhanced compliance, reduced confusion, and ultimately benefit consumers by providing clear information to enable them to make informed choices about formulas.

Further Transparency in Communication

Transparency emerged as a critical theme vital to building and maintaining trust in infant formula. Consumers expect clear information regarding ingredients, claims, and contaminants. Participants stressed the need to clearly communicate about potential risks, such as from contaminants and heavy metals and any impact to infant formula products, as well as to provide context for consumers. The importance of communicating safe preparation methods, including considerations for consumers around different water sources, was noted as an area of ongoing need.

The discussions emphasized the need for coordination, consistency, and clarity from regulators and other key stakeholders in the infant formula industry. Participants called for consistent messaging and transparency and suggested that the FDA take the lead in providing information in plain language—such as decoding technical ingredient names into understandable terms or providing accessible evidence for specific claims.

To be effective, infant formula information needs to be visually clear, transparent, and accessible in a variety of formats. Participants encouraged FDA and other stakeholders to take a proactive role in leading these communication efforts to build trust and to counter misinformation. The importance of using a variety of methods, particularly social media (e.g., TikTok and YouTube), is critical for reaching the younger generation of parents and caregivers.

Increase Collaboration Among Stakeholders

Participants highlighted the value of continuous dialogue and engagement opportunities with a broad array of stakeholders. They noted the usefulness of these Foundation-convened roundtables and similar activities as an example to replicate, moving towards scientific advancement and progress in all aspects of infant formula product development. Cross-sector shared knowledge and problem-solving are crucial for countering the spread of misinformation and confusing product recommendations from unofficial sources. A unified approach involving manufacturers, healthcare providers, professional/advocacy organizations, and regulatory groups can foster a more robust, transparent infant formula ecosystem, leading to more effective solutions.

While there was general agreement on the need for collaboration, some participants pointed out the challenges of aligning diverse interests and priorities.

Leverage Trusted Sources by Providing Accessible Education, Tools, and Information

Another consistent theme participants underscored was the need for trusted, authoritative sources of information, alongside practical, easy-to-access tools for the public and professionals who support them. The myriad infant formula choices and conflicting claims highlighted the emotional burden that families face when making decisions about infant nutrition. This uncertainty can add stress to those making product decisions, as one healthcare participant described:

> "Parents are trying to do the right thing, but they feel like they have to pick one priority over another—do I want the formula that says it helps brain development, or the one that supports the immune system? There's no guidance on which matters more or whether it even matters at all."

Healthcare professionals (such as pediatricians, nurses, and community-based providers) called for more education investment and resources to better equip them when answering detailed questions about ingredients, safety standards, and how to interpret marketing claims. These "trusted messengers" highlighted the importance of and need for current resources to use in real-world settings to help families make informed choices.

Participants suggested that providing clear, reliable resources—such as infographics, Quick Response (QR) codes, and digital labels—could enhance understanding and alleviate some of this confusion. Participants urged organizations like the FDA and professional associations to take the lead in creating and sharing these resources. Partnering with trusted messengers to make information accessible across various platforms and in multiple languages was suggested as a way to effectively reach all families.

Aligning Insights to FDA's Infant Formula Priorities

The roundtable discussions addressed three key areas and organized the conversations around these cross-cutting topics: comprehensive nutrient review; heavy metals and contaminants; and labeling and marketing claims. These align with priority areas in Operation Stork Speed and were designed to highlight regulatory opportunities and gaps, understand public concerns, and elucidate areas to continue building consumer trust.

① Nutrient Review

Framing: *The current FDA nutrient requirements are available in Title 21 of the Code of Federal Regulations (CFR) 21 CFR § 107.100. FDA also issued a Request for Information (RFI) which closed on September 11, 2025, to determine if existing nutrient requirements need revision to ensure nutritional adequacy and improve infant health outcomes, considering international standards and the latest scientific information. The roundtable participants provided insights and thoughts on opportunities for FDA to consider in undertaking the comprehensive review of infant formula nutrient requirements to ensure consistent, evidence-based decision-making that reflects current science and public health priorities.*

Standards and Limits

There was a strong consensus across all stakeholder groups that current nutrient requirements for infant formula need to be updated given that the last comprehensive review occurred in 1998. Although the FDA regularly reviews individual nutrient requirements, the lengthy interval since the previous comprehensive review, combined with the rapid pace of scientific advancements, underscores the urgency of this review and the opportunity to incorporate advancements in nutritional science. Many stakeholders advocated for the establishment of maximum limits for specific nutrients such as manganese, calcium, and phosphorus. Without maximums, participants cited concerns that excessive amounts of these nutrients could pose health risks to infants and may far exceed the typical amounts that infants get through breastfeeding.

Considering all sources of exposure to nutrients was also a common theme, including infant formula, supplements, and water sources (for products that require reconstitution). Evidence from currently available data, such as the National Health and Nutrition Examination Survey (NHANES), should also be utilized to support any revisions.

While there was alignment on the need for updated standards, it was also highlighted that there are complexities involved, and considerations need to be balanced between innovation and affordability. Participants noted that any changes should not compromise the availability of U.S.-based infant formula ingredients or the stability of the infant formula supply, particularly for programs like the U.S. Department of Agriculture (USDA) Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) that serve vulnerable populations. This concern was echoed by various stakeholders, who emphasized the need for a careful approach that ensures both safety and accessibility.

Evaluation Approach

There were numerous recommendations for FDA's approach to the comprehensive nutrient review process, including a need for FDA to consult with groups of experts for each nutrient as no single expert exists for all nutrients as well as a systematic approach to the scientific literature focusing on clinical outcomes rather than solely breast milk composition. Other recommendations included utilizing an external expert panel to conduct the comprehensive review, examining physiological and biochemical outcomes between formula-fed and breastfed infants, reviewing expert scientific opinions published since 1998, and considering global standards such as those developed by Codex Alimentarius.

The discussions revealed a clear desire to move beyond traditional metrics of growth and safety in evaluating infant formula. Functional outcomes, such as neurodevelopment, immune function, and microbiome health, were suggested as expanded areas for inclusion in the nutrient review as well as the regulatory review of infant formula products. This shift reflects a growing understanding of the impacts of nutrition on developmental milestones and short and long-term health outcomes.

Process and Research Needs

Participants agreed that the currently mandated FDA timeframe to review required infant formula nutrients every four years, as appropriate, provides a predictable cycle that helps ensure requirements remain current and relevant while helping to drive innovation. Another suggestion was to enhance post-market surveillance to monitor any short and long-term impacts from updates to nutrient requirements.

Another suggestion included establishing separate regulatory pathways for ingredients with established safety profiles versus novel ingredients. This approach may support innovations and ensure new ingredients are rigorously evaluated for safety and efficacy. Participants continued to acknowledge and recognize the importance of balancing innovation with the realities of cost and ingredient availability.

Some participants highlighted the necessity of funding research in infant and childhood nutrition. The approach varied across participants, weighing time and cost across evidence generation methods, including the cost and burden of randomized controlled trials and innovative study designs. Regardless, participants agreed that robust scientific evidence is the bedrock for FDA decision-making and vital for understanding the outcomes associated with both established nutrients and novel ingredients.

Communication and Clarity

Stakeholders stressed the importance of a transparent comprehensive nutrient review process to ensure clarity regarding the basis for any changes to infant formula nutrient requirements. Across the roundtables, participants emphasized the importance of simplifying labeling to clearly communicate that all FDA-approved formulas meet rigorous, established safety and nutritional standards. The need for clarity in the understanding and labeling of nutrients was a recurring theme, with stakeholders advocating for regulations that focus on supporting evidence-based differences between products while regulating claims that were deemed vague or marketing-driven.

2 Contaminants and Heavy Metals in Infant Formula

Framing: *Recognizing that contaminants occur naturally in the environment and through human activities and acknowledging that it is impossible to achieve zero presence of heavy metals in infant formula, there is a need for ongoing efforts to develop effective risk communication strategies and methods for reaching groups such as parents, caregivers, and health professionals. This discussion topic elucidated perspectives on a challenging yet important issue for stakeholders and illuminated pathways to consider for reducing gaps and improving timeliness in communications.*

Regulatory Standards

A significant concern raised during the roundtables was the lack of enforceable limits for many heavy metals in infant formula. Participants strongly supported establishing clear, evidence-based limits to protect infants from potential harm. Many participants stated that current regulations do not adequately address the presence of harmful substances such as lead, arsenic, and cadmium, which can pose serious health risks. There were requests to establish a clear legal pathway to intervene. A state public health participant highlighted the regulatory gap by sharing "we sometimes see concentrations of lead in infant formula that are concerning, but we have no legal authority to act."

FDA's *Closer to Zero* initiative is designed to help reduce dietary exposure to harmful contaminants to as low as possible in foods commonly eaten by babies and young children, yet does not currently include infant formula. This was framed as a gap with a suggestion for FDA to consider including infant formula. A counter perspective to this recommendation was that doing so could unintentionally fuel public fear if not communicated carefully. This reflects the ongoing tension between transparency and potential misinterpretation in public health messaging.

International harmonization with standards such as those created by Codex Alimentarius, the European Food Safety Authority, and the World Health Organization (WHO), could provide a framework for reference and act as a starting point for establishing limits. However, participants expressed caution and stressed the need to align with U.S.-based exposure risks and to distinguish between toxicology-based thresholds and market-driven standards, ensuring that safety remains the top priority.

Nature of Exposure

Participants acknowledged that heavy metals are naturally occurring in the environment and can also be present in breast milk and water, but this does not diminish the need for enhancements to infant formula regulatory oversight. This complexity necessitates a nuanced understanding of exposure risks. Parents need clarity around these risks, noting that while they are real, they can be managed effectively and mitigated to alleviate fear or alarm. Many solutions were shared, including educational campaigns that alleviate confusion and provide context about heavy metal levels, focus on reassuring parents about the rigorous regulatory evaluation process, and emphasize that all FDA-approved formulas undergo stringent ongoing testing and must meet established safety standards.

Special attention was drawn to meeting the needs of families using well water or other non-standard reconstitution sources, as these may pose an additional risk of exposure to heavy metals and contaminants. Educating parents about safe mixing practices, testing their water supply, and providing filters to families on wells were all surfaced as opportunities to enhance infant formula safety and limit potential exposure to contaminants or heavy metals.

Risk Communication

Effective risk communication emerged as a critical theme throughout the discussions, along with the need to simplify information and provide visual tools to quickly convey complex data. For example, technical metrics, such as parts per billion (ppb), may not be well understood by consumers or be hard to understand when assessing the safety of an infant formula. Many

participants suggested a clear visual information-based approach potentially using well-understood colors, such as green, yellow, and red, to indicate safety levels, making it easier for families to assess the safety of infant formula at a glance.

Transparency from the FDA and infant formula manufacturers regarding contaminant testing and established limits was deemed essential for building trust among parents and caregivers. Messaging must be consumer-tested and credible, aiming to minimize undue alarm while effectively communicating the risks associated with contaminants. As one industry participant shared:

> The FDA has a lot of work to do on building the muscle of trust, and we absolutely here can be partners in that, but it is not one manufacturer or one voice alone. It is really a coalition or a collective of voices because we all have really the same goals here.

Trusted Sources

Participants repeatedly emphasized the value of "trusted messengers" – especially pediatricians, NICU/pediatric nurses, dietitians, and public health programs – as the most effective avenues for educating families about contaminants and heavy metals. However, several participants noted a lack of accessible and current resources to explain risks, safe preparation methods, and how to interpret claims such as "all natural" or "clean label" on formula labels. The discussions highlighted opportunities to collaborate and develop straightforward, evidence-based information on heavy metals and contaminants, thereby enhancing understanding and supporting informed recommendations to parents and caregivers. There was strong support for public-private collaboration to develop ready-to-use fact sheets, videos, and social media content campaigns to counter misleading influencer content and other online misinformation, and to more effectively reach the younger generation of parents and caregivers.

3 Labeling and Claims

Framing: *This topic focused on gathering input on opportunities to better understand the perspectives of different stakeholders involved in decisions around infant formula, including purchasing, ingredient understanding, and other labeling and claims. Participants shared a range of viewpoints and identified areas for collaboration and improvement to enhance transparency and trust in infant formula.*

Oversight & Regulation

Across stakeholder groups, participants consistently and repeatedly called for enhanced oversight and regulation of labeling claims for infant formula products. Concerns raised around claims on infant formula—such as "gentle," "closer to breast milk," "sensitive," and "all natural"—are often vague or misleading, lack standard regulatory definitions, and/or are not supported by sufficient scientific backing. Participants suggested that these claims can create confusion for parents and caregivers who are trying to make informed choices about infant nutrition and may lead to an interpretation of the terms as evidence of superior health outcomes.

> When parents see these claims on the packaging, they assume there's regulatory meaning behind them, but often there isn't. This can mislead them into thinking they are making the best choice for their child.

> The marketing language used on infant formula labels can create a false sense of security for parents, leading them to believe that certain products are inherently better without understanding the lack of evidence behind those claims.

There was a strong call for the FDA to extend the same rigorous oversight standards to efficacy claims (e.g., "reduces spit up") that currently exist for safety-related labeling requirements (e.g., "hypoallergenic"). It was also proposed that FDA require substantiation of efficacy-related claims, particularly those associated with cognitive, immune, or digestive health benefits. By establishing clear guidelines, this can help ensure that claims are not only meaningful but also backed by robust scientific research, ultimately benefiting both consumers and manufacturers alike. While there was a strong call for oversight of efficacy claims, participants also acknowledged that the infant formula market is highly competitive with limited opportunities for product differentiation.

Extending regulations to toddler formula-type products (e.g., toddler nutritive drinks, toddler drinks) was highlighted as an important step to close the gap in inconsistent standards between infant formulas and toddler drinks. The claims made in these toddler drinks can lead to confusion and make it appear as if these products must meet the same standards and undergo the same FDA evaluation as infant formulas, when in fact they do not. Participants referred to an AAP clinical report on toddler 'formulas' as a useful resource for further insights on this group of products.

Finally, participants called for consistent and unified federal labeling standards. The current labeling landscape is complicated by a patchwork of varying state regulations, adding confusion and uncertainty to infant nutrition.

Label Accuracy & Transparency

Participants raised concerns around the reliability and accuracy of infant formula labeling. Several participants noted that nutrient levels, such as those of manganese, selenium, and iron, can vary significantly and often exceed the values listed on labels. This level of variance raised concerns, and participants emphasized the importance of ensuring accuracy in labeling to align with what is "inside the can."

To address these concerns, it was suggested to have mandatory third-party label audits with a requirement to publish ranges of anticipated variation, instead of single-point lab values.

Using clear and plain language on labels and in nutrient information was another area of need to enhance consumer understanding. Education is needed to highlight the rigorous review process each nutrient undergoes to be included on the label, and how each one serves a specific purpose for supporting infant health and development. Participants felt this was an important area of opportunity for building trust in the safety and nutritional adequacy of these products.

Consumer Tools & Access

Participants expressed support for creating a public FDA-managed online database listing all approved formulas, including ingredients, nutrient ranges, and any added functional components. They described this resource as a valuable tool for parents seeking to understand the nutritional profiles of different products and endorsed the need for it to be searchable and mobile-friendly to ensure practical use by consumers and other stakeholders.

The use of QR codes was highlighted as a low-cost, high-impact consumer-facing solution. For example, the code could be placed on the infant formula packaging, directly linking to FDA fact sheets and resources in plain language. This type of communication could facilitate easier access to information about the safety and nutritional content of infant formulas, explaining complex or confusing ingredients such as lactoferrin or docosahexaenoic acid (DHA), and provide evidence supporting claims. The importance of visual tools and mobile apps was raised frequently and is well-articulated in one participant: "accessible communication methods, like mobile apps and visual summaries, are key to helping diverse audiences understand the safety and nutritional content of infant formulas, ensuring that no family is left behind."

Global and Industry Role

The role of the industry in promoting safety and quality was also a focal point of discussion. Manufacturers were encouraged to align on core label principles while allowing for responsible product differentiation. Opportunities raised included aligning on what qualifies as a "*functional ingredient*" and avoiding claims like "*brain boosting,*" unless supported by rigorous scientific evidence. Participants highlighted the importance of supporting global collaboration to harmonize standards, and label transparency could help counter perceptions of European superiority in infant nutrition products.

Trusted Messengers and Education Needs

Pediatricians, other clinical specialists (such as NICU staff, dietitians, and nurses), and organizations like the American Academy of Pediatrics (AAP) and WIC were cited as the most

credible sources of information for parents and caregivers when making formula decisions. One participant remarked, "pediatricians play a crucial role in helping families navigate the complexities of infant nutrition."

> There's a significant gap in training for those of us who are on the front lines. Continuing education modules developed by the FDA and AAP would empower us to better support families in understanding infant formula labels.

However, many of these trusted messengers shared that there is a lack of formal training to understanding the range of ingredients and claims on infant formula. Participants recommended continuing education modules for healthcare providers, developed by authoritative sources such as the FDA and AAP, to provide education on how to interpret labels and confidently address parent and caregiver questions and concerns.

Participants pointed to trusted sources—such as the AAP's HealthyChildren.org and public health or WIC counselors—as effective channels for sharing reliable and trusted information about infant formula to support informed decisions that promote infant health.

Summarized Actionable Opportunities

These actionable opportunities were identified during the roundtable discussions. While not all fall directly within the FDA's purview, they offer a series of suggestions for the Agency to consider for enhancing the safety, quality, nutrition, and resiliency of all U.S.-marketed infant formula products.

Prioritize Accessible and Usable Infant Formula Data and Information Tailored to Relevant Audiences

- **Create an FDA-Managed Public Database of Approved Formulas**
  - Include product names, ingredient lists, nutrient levels or ranges, and evidence supporting functional claims
  - Ensure the database is searchable and mobile-friendly
  - Co-design data tools with input from stakeholders who use them most
  - Implement QR codes on packaging that could be linked to this new database or other FDA-created information

- **Enhance Data Communication Pipelines**
  - Improve, or establish, data pipelines between FDA and key stakeholder groups (e.g., WIC, providers, states, and public health professionals) to communicate timely updates on product changes, recalls, or nutrient changes
- **Training for Clinicians**
  - Provide training and tools for clinical users (e.g., pediatricians, nurses, dietitians) to interpret data and communicate with families effectively

Infant Formula Nutrient Requirements Must Reflect Modern Science and Real-World Exposure Risks

- **Review and Update Nutrient Standards**
  - Incorporate advances in nutrition science in reviewing updates to the current nutrient requirements (21 CFR 107.100)
- **Add Functional Health Outcomes**
  - Evaluations should incorporate functional health outcomes like neurodevelopment, immune function, and microbiome health
- **Establish Maximum Levels for Certain Nutrients**
  - Maximum levels should be set for specific nutrients (e.g., manganese, calcium, phosphorus) to prevent excess intake
  - Consider all nutrient exposure sources—formula, supplements, and water
  - Utilize existing real-world nutrient intake data sources (e.g., NHANES)
- **Routine Review Cycles**
  - Implement a standard cadence for regular nutrient reviews (e.g., every 4 years) and require post-market monitoring of new nutrient standards
- **Create Regulatory Pathways for Novel Ingredients**
  - Develop different approval pathways for novel versus established ingredients as a means to foster innovation
- **Increase Research Funding**
  - Commit more research funding and broader acceptance of alternative evidence models beyond randomized controlled trials (RCTs)

Improving Clarity in Claims and Labeling

- **Standardize Efficacy Claims**
  - FDA was urged to standardize efficacy claims and require substantive evidence for terms like “gentle,” “closer to breast milk,” “sensitive,” and “all natural” which can be misleading.
- **Align Regulations for Infant Formulas and Toddler Nutritive Drinks**
  - Close regulatory gaps to ensure toddler drinks undergo similar regulatory scrutiny as infant formula

- **Ensure Nutrition Label Accuracy**
  - Provide clear, accessible regulatory guidance specifying nutrient minimums and maximums to support accurate labeling and improve compliance
  - Permit the use of consumer-friendly ingredient names in the label ingredient list
  - Consider third-party audits to verify label accuracy

Build Trust through Transparent Communication and Outreach Strategies

- **Develop Clear and Actionable Communication**
  - Create plain-language messaging about formula safety, label claims, ingredients, and potential concerns (such as safe preparation and naturally occurring contaminants and heavy metals) for families
  - Create relevant and actionable information, striking a balance between generating necessary insights and avoiding unnecessary fear around contaminants and heavy metals
  - FDA should spearhead public education efforts around heavy metals and contaminants and the safe preparation of infant formula
- **Use a Variety of Communication Tools and Methods**
  - Develop infographics, videos, multilingual fact sheets, and mobile-accessible formats for sharing information
  - Creating visual frameworks (e.g., color-coded risk indicators) to effectively communicate information about heavy metals and contaminants (e.g., limits, risks)
- **User-Testing**
  - Messaging should be tested with users and distributed through different means, such as digital and clinical settings
- **Provider Training**
  - Create continuing education modules in collaboration with FDA and AAP to help equip providers with timely information to assist families in understanding data and making informed choices
  - Formalize infant nutrition and formula training into medical and nursing school curricula
  - Create reference tools for providers to quickly access in clinical settings

Present Data through Simple, Visual, and Accessible Tools

- **Adopt Color-Coded Visuals**
  - Communicate complex information with easily interpretable visuals like a stoplight system (red-yellow-green)
  - Technical measures like “parts per billion” are not understood by most families and need to be translated into relevant points of reference
- **Link QR Codes to Information**
  - Add QR codes to labeling and link to plain-language information

- **Create Resources for Diverse Communities**
    - Tools and information should be available in multiple languages and mobile-friendly
    - Community-based education resources are needed, particularly to reach rural, immigrant, and low-income communities
    - Quick and easily digestible summaries are needed—usable on mobile phones
    - Parents want quick, digestible summaries – not detailed datasets – to support making decisions.

Encourage and Strengthen Collaboration Among Stakeholders

- **Increase Opportunities for Knowledge Sharing**
    - Need for more opportunities, such as these roundtable discussions, where stakeholders can come together to share knowledge, experiences, and best practices around infant formula safety and nutrition
- **Facilitate Durable Ongoing Dialogue**
    - Establish channels for stakeholders to communicate and address concerns, share insights, and develop coordinated strategies

Moving Forward

Roundtable participants were optimistic and shared in the commitment to continue building on the solid foundation that exists today to ensure that infant formulas meet and exceed the highest standards of safety and nutrition, ultimately fostering greater trust among families and providing a strong foundation for the health and well-being of infants in the United States.

Appendix A: Reference Documents

- U.S. Food and Drug Administration Infant Formula Resources https://www.fda.gov/food/resources-you-food/infant-formula
- Code of Federal Regulations for Infant Formula Nutrient Specifications 21 CFR § 107.100 https://www.ecfr.gov/current/title-21/section-107.100
- National Health and Nutrition Examination Survey (NHANES) https://www.cdc.gov/nchs/nhanes/index.html
- U.S. Food and Drug Administration – Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods. https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods
- U.S. Dept. of Agriculture (USDA) – Women, Infants and Children (WIC) Program https://www.fns.usda.gov/wic
- American Academy of Pediatrics (AAP) – clinical practice guidelines and public-facing tools are available at healthychildren.org
- AAP clinical report: Toddler 'formulas' offer no nutritional advantage https://publications.aap.org/aapnews/news/26436/AAP-clinical-report-Toddler-formulas-offer-no?autologincheck=redirected
- Codex Alimentarius Commission: Standard for Infant Formula and Formulas for Special Medical Purposes. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/es/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf
- World Health Organization - International Code of Marketing of Breast-Milk Substitutes https://www.who.int/publications/i/item/9241541601
- European Food Safety Authority: https://www.efsa.europa.eu/en

Appendix B: Acknowledgments

We appreciate the contributions of the individuals below to the roundtable series. While all had the opportunity to review the draft report, their inclusion does not represent their endorsement of or agreement with the content of this report, either individually or on behalf of their organization. The Reagan-Udall Foundation for the FDA retains sole responsibility for this report.

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