

September 10, 2025

Attention: Docket ID No. FDA-2025-N-1134

Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Re: Infant Formula Nutrient Requirements; Request for Information (Published May 14, 2025)

To Whom It May Concern,

The National Oilseed Processors Association (NOPA) appreciates the opportunity to respond to the Department of Health and Human Services (HHS) and Food and Drug Administration's (FDA) request for information on infant formula nutrient requirements. As the leading trade association for U.S. oilseed crush, NOPA represents over 99% of soybean crushing capacity. Our member companies are proud to contribute to the U.S. food supply chain and are deeply invested in producing the highest-quality ingredients to support the health and development of the next generation of Americans.

NOPA supports the administration's efforts to conduct the first comprehensive review of infant formula ingredients in more than two decades. We strongly encourage that every recommendation be grounded in rigorous, evidence-based science to protect infant health. As these guidelines are revised, regularly updating dietary recommendations to reflect the latest, most robust scientific findings is essential.

### **Nutritional Importance of Seed Oils**

As this review relates to U.S. oilseed and seed oils, it's important to note that every infant formula on the U.S. market contains omega-6 fatty acids from seed oils because they are the most effective and bioavailable sources of essential fatty acids for infant development.

Consider the role of essential fatty acids in infant neural development. Long-chain polyunsaturated fatty acids—particularly docosahexaenoic acid (DHA, an omega-3 fatty acid) and arachidonic acid (ARA, an omega-6 fatty acid)—cannot be produced by the body in sufficient amounts, therefore they must be obtained through diet.<sup>1</sup> Vegetable oils, or “seed oils,” as they are sometimes called, such as soybean, canola, and sunflower oil, are the primary sources of essential omega-3 fatty acids and omega-6 fatty acid precursors— $\alpha$ -linolenic acid (ALA) and linoleic acid (LA)—which are foundational to infant nutrition

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<sup>1</sup> Carlson, S. E., & Colombo, J. (2016). Docosahexaenoic Acid and Arachidonic Acid Nutrition in Early Development. *Advances in pediatrics*, 63(1), 453–471. <https://doi.org/10.1016/j.yapd.2016.04.011>

and help maintain appropriate amounts of fatty acids in the body.<sup>2</sup> Seed oils are essential because they provide the required levels of linoleic acid (LA, omega-6 fatty acid) and  $\alpha$ -linolenic acid (ALA, omega-3 fatty acid), which the body cannot synthesize. While infant formulas are supplemented with DHA and ARA to ensure neural and visual development, seed oils remain the most foundational, bioavailable sources of LA and ALA. This requirement is explicitly recognized in the CODEX Alimentarius international standards for infant formula, as well as in EPSA scientific options, which establish minimum and maximum levels for LA and ALA.<sup>3</sup>

Research consistently demonstrates that infants who receive adequate levels of DHA and ARA exhibit stronger visual and cognitive development.<sup>4,5,6,7,8</sup> Randomized controlled trials confirm that formulas enriched with these fatty acids lead to measurable improvements in visual acuity and neurodevelopment compared to unsupplemented formulas.<sup>9,10</sup> Following the conclusions of this body of research, it is patently clear that seed oils provide essential omega-3 and omega-6 precursors, alongside direct DHA and ARA supplementation, and are vital to ensure infant formula jumpstarts lifelong development.

### Retaining Essential Fatty Acids

Importantly, omega-6 fatty acids should not be viewed as mere fillers to meet caloric requirements; they are functional nutrients that support infant growth, immune system maturation, intestinal health, and overall development.<sup>11,12</sup> Retention of these sources of essential fats are pivotal to replicating the nutritional complexity of breast milk, as there are no other oils currently available that offer the same requirements necessary for healthy infant development.<sup>13</sup> Additionally, providing more specificity to the balance of essential fatty acids, such as the levels of DHA and ARA, to align with other countries would

<sup>2</sup>Einerhand, A. W. C., et al. (2023). "The Impact of Linoleic Acid on Infant Health in the Absence or Presence of DHA in Infant Formulas." *Nutrients* 15(9).

<sup>3</sup> Codex Alimentarius Commission. (2007). Standard for infant formula and formulas for special medical purposes intended for infants (CX572-1981, rev. 2007) [PDF]. Food and Agriculture Organization of the United Nations & World Health Organization. Retrieved from <https://acrobat.adobe.com/id/urn:aaid:sc:US:b31fc185-1fbb-4af0-bbbd-f4e260dfc756>

<sup>4</sup> Zhang Y, Chadaideh KS, Li Y, et al. Butter and Plant-Based Oils Intake and Mortality. *JAMA Intern Med.* 2025;185(5):549–560. doi:10.1001/jamainternmed.2025.0205

<sup>5</sup> Miles EA, Childs CE, Calder PC: Long-Chain Polyunsaturated Fatty Acids (LCPUFAs) and the Developing Immune System: A Narrative Review. *Nutrients* 2021, 13.

<sup>6</sup> Yu, J., et al. (2025). "A review on lipid inclusion in preterm formula: Characteristics, nutritional support, challenges, and future perspectives." *Compr Rev Food Sci Food Saf* 24(2): e70099.

<sup>7</sup> Li, Y., Hruby, A., Bernstein, A. M., Ley, S. H., Wang, D. D., Chiuve, S. E., Sampson, L., Rexrode, K. M., Rimm, E. B., Willett, W. C., & Hu, F. B. (2015). Saturated fats compared with unsaturated fats and sources of carbohydrates in relation to risk of coronary heart disease. *Journal of the American College of Cardiology*, 66(14), 1538–1548. <https://doi.org/10.1016/j.jacc.2015.07.055>

<sup>8</sup> Marklund, M., Wu, J. H., Imamura, F., Del Gobbo, L. C., Fretts, A., De Goede, J., Shi, P., Tintle, N., Wennberg, M., Aslibekyan, S., Chen, T., De Oliveira Otto, M. C., Hirakawa, Y., Eriksen, H. H., Kröger, J., Laguzzi, F., Lankinen, M., Murphy, R. A., Prem, K., . . . Risérus, U. (2019). Biomarkers of dietary omega-6 fatty acids and incident cardiovascular disease and mortality. *Circulation*, 139(21), 2422–2436. <https://doi.org/10.1161/circulationaha.118.038908>

<sup>9</sup> Birch, E. E., Hoffman, D. R., Uauy, R., Birch, D. G., & Prestidge, C. (1998). Visual acuity and the essentiality of docosahexaenoic acid and arachidonic acid in the diet of term infants. *Pediatric Research*, 44(2), 201–209. <https://doi.org/10.1203/00006450-199808000-00011>

<sup>10</sup> Birch, E. E., Carlson, S. E., Hoffman, D. R., Fitzgerald-Gustafson, K. M., Fu, V. L., Drover, J. R., Castañeda, Y. S., Minns, L., Wheaton, D. K., Mundy, D., Marunycz, J., & Diersen-Schade, D. A. (2010b). The DIAMOND (DHA Intake And Measurement Of Neural Development) Study: a double-masked, randomized controlled clinical trial of the maturation of infant visual acuity as a function of the dietary level of docosahexaenoic acid. *American Journal of Clinical Nutrition*, 91(4), 848–859. <https://doi.org/10.3945/ajcn.2009.28557>

<sup>11</sup> Yu, J., et al. (2025). "A review on lipid inclusion in preterm formula: Characteristics, nutritional support, challenges, and future perspectives." *Compr Rev Food Sci Food Saf* 24(2): e70099.

<sup>12</sup> Miles EA, Childs CE, Calder PC: Long-Chain Polyunsaturated Fatty Acids (LCPUFAs) and the Developing Immune System: A Narrative Review. *Nutrients* 2021, 13.

<sup>13</sup> *Your questions answered about infant formula* | Abbott Newsroom. (2025, August 8).

<https://www.abbott.com/corpsnewsroom/nutrition-health-and-wellness/your-questions-answered-about-infant-formula.html>

be positive. Many formulas have varying amounts of DHA and ARA added, while labeling does not make this clear for the consumer.<sup>14</sup>

Seed oils offer a unique and vital nutritional profile, which is especially important to remember when distinguishing infant formula from toddler formula. While toddler formulas are designed to supplement an established diet, infant formula must be nutritionally complete and capable of serving as an infant's sole source of nourishment during the most crucial months of brain and body development.<sup>15</sup> Every infant formula on the global market—not only in the U.S.—contains omega-6 fatty acids from seed oils to meet essential fatty acid needs. In some markets, such as China, milk fat is included in blends for flavor; however, even when milk fat is maximized, seed oils remain necessary to achieve the correct fatty acid profile.<sup>16</sup>

## Public Health and Supply Chain Considerations

The widespread use of formula in the U.S. further underscores the importance of preserving its nutritional integrity. In 2019, only 24.9% of infants in the U.S. were exclusively breastfed, with 74% of parents using formula in some capacity.<sup>17, 18</sup> Given this reliance, any changes to the nutritional makeup, price, or availability of infant formula could disrupt supply chains, increase costs, and threaten accessibility, potentially recreating scenarios like the 2022 Abbott *Cronobacter* outbreak. During the shortage, out-of-stock rates spiked from approximately 43% to 70%, and nearly half of surveyed parents resorted to unsafe feeding practices such as diluting formula, preparing homemade substitutes, or engaging in informal milk sharing.<sup>19, 20, 21</sup> Ensuring that formula remains safe, accessible, and nutritionally complete is not just a matter of infant health, but also public health security.

The overall economic impact of seed oils cannot be overstated—removing seed oils from the U.S. economy would not only result in an increase of up to 25.1% in the consumer price index for fats and oils, but also a \$2 billion annual reduction of farm income.<sup>22</sup> While the effect would be smaller in scale for infant formula specifically, the consequences for families would still be significant. For households already coping with the stress and stigma of being unable to provide enough, or any, breast milk, making formula unaffordable is not the solution to improving the health of our most vulnerable. Moreover, there

<sup>14</sup> Abrams, S. A. and N. Du (2025). "Perspective: operation stork speed: strategies for reviewing and advising on infant formula." *Am J Clin Nutr* 121(6): 1220-1223.

<sup>15</sup> Program, H. F. (2025, May 13). *Infant Formula*. U.S. Food And Drug Administration. <https://www.fda.gov/food/resources-you-food/infant-formula>

<sup>16</sup> Jeske H.J. Hageman, Marianne Danielsen, Arie G. Nieuwenhuizen, Anouk L. Feitsma, Trine K. Dalsgaard, Comparison of bovine milk fat and vegetable fat for infant formula: Implications for infant health, *International Dairy Journal*, Volume 92, 2019, Pages 37-49, ISSN 0958-6946, <https://doi.org/10.1016/j.idairyj.2019.01.005>.

<sup>17</sup> *Breastfeeding Report card*. (2025, February 24). Breastfeeding Data. <https://www.cdc.gov/breastfeeding-data/breastfeeding-report-card/index.html>

<sup>18</sup> *The state of feeding*. (n.d.). <https://stateoffeeding.com/>

<sup>19</sup> Genovese, D. (2022, May 27). Baby formula shortage: Out-of-stock rates surge to 70%. *Fox Business*. <https://www.foxbusiness.com/lifestyle/baby-formula-shortage-abbott-fda>

<sup>20</sup> Sharp, S. (2022, May 13). As baby formula shortage worsens, families take desperate steps. *Yahoo News*. <https://www.yahoo.com/news/baby-formula-shortage-worsens-families-215613961.html>

<sup>21</sup> *Unsafe feeding methods spiked during infant formula shortage*. (2023, June 27). College of Agricultural and Environmental Sciences. [https://caes.ucdavis.edu/news/unsafe-feeding-methods-spiked-during-infant-formula-shortage?\\_gl=1\\*rvr2rt\\*\\_ga\\*NDUwNzYwODAsLjE3NTI3NzYxODA.\\*\\_ga\\_2N9JP0W2PC\\*cze3NTI3ODc4NDckbzlkZzAkDDE3NTI3ODc4NTYkajUxJGwwJGgw](https://caes.ucdavis.edu/news/unsafe-feeding-methods-spiked-during-infant-formula-shortage?_gl=1*rvr2rt*_ga*NDUwNzYwODAsLjE3NTI3NzYxODA.*_ga_2N9JP0W2PC*cze3NTI3ODc4NDckbzlkZzAkDDE3NTI3ODc4NTYkajUxJGwwJGgw)

<sup>22</sup> Kruse, J., Foreman, M., Denny, S., & WAEES. (2025). US seed oil ban scenario. In *WAEES* [Report]. [https://sniglobal.org/wp-content/uploads/2025/04/CA5734\\_033125\\_Seed-Oil-Ban-Report-3-27-2025\\_USDAApproved.pdf](https://sniglobal.org/wp-content/uploads/2025/04/CA5734_033125_Seed-Oil-Ban-Report-3-27-2025_USDAApproved.pdf)

are no widely available alternative oils sources capable of providing the requisite balance of omega-6 and omega-3 fatty acids at the scale, quality, and affordability required for infant nutrition.<sup>23, 24</sup>

## Barriers to Breastfeeding

While breastfeeding remains the optimal nutritional choice when possible, exclusive breastfeeding is not a feasible option for all families due to economic constraints, limited access to donor milk banks, medical considerations, and personal circumstances.<sup>25</sup> NIH research confirmed that workplace inflexibility, lack of private spaces, and inadequate maternity leave remain major barriers to breastfeeding.<sup>26</sup> Furthermore, mothers are often unable to find childcare near their office and have limited maternity leave benefits.<sup>27, 28</sup> For low income and single mothers, returning to work after having a child is imperative, and if formula makes it possible for them to return to work to provide for their family, then it has to remain an option.

Economic issues aside, there are a plethora of personal and medical reasons women cannot or choose not to breastfeed. Frequently cited are issues with not producing enough milk, insufficient gland tissue, clogged ducts, mastitis, inflammation, and latching issues. Psychologically, breastfeeding can be incredibly stressful, as mothers never know how much milk their baby is consuming and can be consumed with anxiety due to the cultural stigmas surrounding the practice. Breastfeeding can also compound the already rampant phenomenon of post-partum depression. Additionally, there are some medications that prevent mothers from breastfeeding, as certain drugs can affect the quality of breastmilk.<sup>29</sup>

A supposed option for filling the gap between mothers breastfeeding and purchasing formula is pasteurized donor breast milk. While invaluable in certain medical contexts, donor milk often costs \$3 to \$5 per ounce, several times the price of standard infant formula which typically ranges from \$0.50 to \$1.50 per ounce.<sup>30, 31, 32, 33, 34, 35</sup> These price disparities make universal access to breastmilk impractical;

<sup>23</sup> National Institutes of Health. (2023, February 15). *Omega-3 Fatty Acids*. Nih.gov.

<https://ods.od.nih.gov/factsheets/Omega3FattyAcids-HealthProfessional/>

<sup>24</sup> Murphy, K. (2015). *The Role of Seed Oils in Baby Formula*. Bobbie.

<https://www.hibobbie.com/blogs/bobbie/the-role-of-seed-oils-in-baby-formula?srsltid=AfmBOoqmSwaImXEIqV2PjrYp2UO7f7sLjs58AZ-Kyxf>

<sup>25</sup> User, G. (2025, April 10). *Milk Banks & Milk Donor FAQs* | Mamava. Mamava.

<https://www.mamava.com/mamava-blog/milk-banks-and-donor-milk-faqs>

<sup>26</sup> Moret-Tatay, A., Pérez-Bermejo, M., Asins-Cubells, A., Moret-Tatay, C., & Murillo-Llorente, M. T. (2025). A Systematic Review of Multifactorial Barriers Related to Breastfeeding. *Healthcare (Basel, Switzerland)*, 13(11), 1225. <https://doi.org/10.3390/healthcare13111225>

<sup>27</sup> General, O. O. T. S. (2011). *Barriers to breastfeeding in the United States*. The Surgeon General's Call to Action to Support Breastfeeding - NCBI Bookshelf.

<https://www.ncbi.nlm.nih.gov/books/NBK52688/#:~:text=Lactation%20Problems,latch%20on%20by%20the%20infant.&text=Women%20who%20encounter%20these%20problems,unless%20they%20get%20professional%20assistance>

<sup>28</sup> Sriraman, N. K., & Kellams, A. (2016). Breastfeeding: What are the Barriers? Why Women Struggle to Achieve Their Goals. *Journal of Women's Health*, 25(7), 714–722. <https://doi.org/10.1089/jwh.2014.5059>

<sup>29</sup> Odom, E. C., Li, R., Scanlon, K. S., Perrine, C. G., & Grummer-Strawn, L. (2013). Reasons for earlier than desired cessation of breastfeeding. *PEDIATRICS*, 131(3), e726–e732. <https://doi.org/10.1542/peds.2012-1295>

<sup>30</sup> *How much does baby formula cost?* (n.d.). <https://smartasset.com/financial-advisor/the-cost-of-baby-formula>

<sup>31</sup> Carlson, J. (2024, February 1). *How much does baby formula cost?* TrustedCare. <https://trustedcare.com/costs/baby-formula-cost>

<sup>32</sup> C, N. (2025, August 5). *Request milk for families - the New York Milk Bank*. The New York Milk Bank - Give. Nourish. Thrive.

<https://nymilkbank.org/request-milk-for-families/>

<sup>33</sup> User, G. (2025b, April 10). *Milk Banks & Milk Donor FAQs* | Mamava. Mamava.

<https://www.mamava.com/mamava-blog/milk-banks-and-donor-milk-faqs>

<sup>34</sup> Aparicio, Z. (2021, May 25). *Donor human milk Processing fee - Mothers' Milk Bank at Austin*. Mothers' Milk Bank at Austin.

<https://milkbank.org/processing-fee/>

<sup>35</sup> Rubio, A. (2022, May 17). *Breast milk cost: How much will you pay at a milk bank?* GoodRx. Retrieved August 19, 2025, from

[https://www.goodrx.com/conditions/pregnancy/breast-milk-bank-cost?srsltid=AfmBOoo2tmL3WGbvNXKb7QaTMaJbWag\\_DHG1bN-pmCzu2Zfgk5Wnh9&](https://www.goodrx.com/conditions/pregnancy/breast-milk-bank-cost?srsltid=AfmBOoo2tmL3WGbvNXKb7QaTMaJbWag_DHG1bN-pmCzu2Zfgk5Wnh9&)

therefore, families must have access to safe, affordable, and nutritionally complete infant formula as a critical alternative.

Breastmilk is truly the “gold standard” that infant formula technology has been developed to successfully replicate its nutritive profile. Both regulatory and policy efforts should focus on enhancing and safeguarding these formula options. Respecting and supporting parental choice, whether breastfeeding or formula feeding, is essential to ensuring optimal health outcomes for both infants and mothers, while recognizing the diverse realities and needs of families across the U.S.

In light of this information, we would like to offer the following recommendations for the administration’s consideration:

1. Maintain requirements that reflect the vast body of science proving omega-6 fatty acids are essential for infant brain and retinal development.
2. Reinforce the complementary roles of omega-6 and omega-3 fatty acids.
3. Advocate for policies that would allow flexibility to use readily available essential fatty acid sources, helping to lower costs for families and safeguard the U.S. formula supply.
4. Continue allowing the use of a variety of domestically-sourced, safe and nutritious vegetable oils to ensure reliable supply chains for U.S. growers.
5. Bolster public information campaigns communicating the safety and nutritional content of infant formula and its equivalence to breast milk as the best alternative.
6. Emphasize the difference between infant formula and toddler formula.<sup>36</sup>
7. Align U.S. regulations with international standards CODEX Alimentarius and EFSA, recognizing the necessity of LA and ALA from seed oils.

## Conclusion and Call to Action

In conclusion, NOPA stands ready to collaborate with the administration, offering our technical expertise to ensure that any revised guidelines are firmly grounded in sound science and serve to protect the health, well-being, and economic stability of all Americans. We agree that periodic review of infant nutritional requirements is both necessary and prudent, as the earliest years of life are critical in shaping lifelong physical and cognitive outcomes.

As we move forward, we urge the FDA and HHS to keep families at the center of decision-making, ensuring affordable access to nutritionally complete infant formula and recognizing the vital role of U.S. soybean, sunflower, and canola producers.

By protecting the essential role of plant-based oils in infant formula, we can uphold this priority by putting families at the heart of our guidelines and policies, bolstering our country’s health and economic resilience, and supporting the farmers who sustain the American people. We appreciate the opportunity to contribute to this important discussion and look forward to the continued application of rigorous science in advancing a goal so clearly worthy of its merit.

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<sup>36</sup> Program, H. F. (2025b, May 13). *Infant Formula*. U.S. Food And Drug Administration. <https://www.fda.gov/food/resources-you-food/infant-formula>



Best Regards,

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