

*Submitted via Regulations.gov*

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Barbara Schneeman, PhD  
Chair, 2020-2025 Dietary Guidelines Advisory Committee  
c/o Kristin Koegel, MBA, RD Center for Nutrition Policy and Promotion, Food and Nutrition Service  
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RE: Docket Number FNS-2019-0001 titled "Meetings: 2020 Dietary Guidelines Advisory Committee."

Dear Dr. Schneeman and esteemed members of the 2020 Dietary Guidelines Advisory Committee,

The Infant Nutrition Council of America (INCA) is responding to the notice published March 12, 2019 in the *Federal Register* by the U.S. Department of Agriculture (USDA), Food and Nutrition Service (FNS); and Department of Health and Human Services (HHS) titled "Meetings: 2020 Dietary Guidelines Advisory Committee." INCA is an association representing companies<sup>a</sup> that research, develop, and market formulated nutrition products for infants, children and adults. INCA members produce over 95% of the infant formula consumed in the U.S., and we take our responsibility of providing optimal nutrition to infants very seriously. INCA supports the American Academy of Pediatrics' (AAP) position<sup>1</sup> that breast milk is the preferred infant feeding method. We also agree with the AAP, and other leading nutrition, health, and regulatory bodies that infant formula that has been submitted to, reviewed by, cleared by and registered with the U.S. Food and Drug Administration (FDA)--all of which is required by Section 412 of the Federal Food, Drug, and Cosmetic Act--is the only safe, nutritious and recommended alternative for infants who do not receive human milk.

INCA believes that the 2020-2025 Dietary Guidelines for Americans (DGAs) are a critical opportunity to clearly communicate to mothers, fathers, and caregivers the safest methods of infant feeding, as this is the first time the birth to 24 (B-24) month old population will be included in the DGAs. While there continue to be gaps in the scientific literature on infant nutrition,<sup>2</sup> it is justified to communicate that breastmilk and infant formula are the only safe and recommended infant feeding options. Today's parents and caregivers have access to more information on infant and young child feeding than previous generations. However, not all the information they are finding is grounded in science nor supported by the healthcare community. Additionally, there continues to be stigma surrounding the decision that parents, families, and caregivers make when it comes to infant feeding. The vast majority of mothers and caregivers feel judged for their infant feeding choices. This iteration of the Dietary Guidelines can help to lessen that stigma through the language used and recommendations made.

Detailed below are recommendations that INCA believes should be clearly addressed within the 2020-2025 DGAs to ensure that parents and caregivers can make the best feeding decision for themselves, their families, and their babies. To understand better the current practices, beliefs, and sources of information regarding infant feeding, INCA supported a Survey of mothers, fathers and other caregivers in 2019<sup>3</sup>. The Infant Feeding Survey was conducted as an online poll of 802 mothers who have given birth in the last 12 months. In addition, the online poll included an additional 400 caregivers – defined as individuals who spend more than 30 hours per week caring for a baby under 12 months old – to better

a. INCA members are Abbott Nutrition, Gerber Products Company, Perrigo Nutritionals, and Reckitt Benckiser.

represent today's diverse family units. The findings of that Survey are included throughout our recommendations below.

**1) INFANT FORMULA IS THE ONLY RECOMMENDED ALTERNATIVE TO BREAST MILK AND HOMEMADE INFANT FORMULA SHOULD BE IDENTIFIED AS DANGEROUS.**

As previously noted, INCA and its members support the AAP's position that breast milk is the preferred infant feeding method. INCA also aligns with AAP that infant formula is the only safe and recommended choice for infants who do not receive breast milk. Therefore, the 2020-2025 DGAs should clearly indicate that these are the only two recommended and safe infant feeding options. As demonstrated by the findings of the 2019 Infant Feeding Survey, mothers and caregivers view the government as an important source of information on infant feeding and believe the government should provide easy-to-understand guidance on both breastfeeding and infant formula. Recommendations should not stigmatize mothers or caregivers who cannot or chose not to breastfeed for any reason.

Furthermore, it is important to note that many U.S. mothers do not exclusively use one method of infant feeding during their infant's first year, but instead practice mixed feeding, such as supplementing breast milk with infant formula. According to the U.S. Centers for Disease Control and Prevention (CDC), 28% of mothers supplement breast milk with infant formula within the first 3 months of their infant's life, and 34% of mothers do so before six months.<sup>4</sup> Mothers' reasons for supplementing vary, from going back to work/school, to medical reasons, to personal choice. Thus, it is important the Dietary Guidelines provide parents with accurate information on appropriate infant feeding options to help ensure their baby's optimal nutrition and overall well-being, regardless of whether they choose to breastfeed, formula-feed, or use a combination of both.

If the DGAs recommendations appropriately identify breastfeeding and infant formulas that has been submitted to, reviewed by, cleared by, and registered with the FDA, as the only options for infant feeding, it will help to prevent mothers and caregivers from considering homemade infant formula as a viable option to feed their baby. The internet offers access to a plethora of infant formula "recipes" but often the many risks that can be harmful to a baby's health are not identified. Important nutrients can be overfed or underfed when using homemade formula, whereas commercial infant formula ensures babies receive the proper amount of protein, iron, and vitamins necessary for optimal health. There is also a safety risk with homemade formula and the possible exposure to contaminants when preparing the mixture. The FDA advises "The potential problems associated with errors in selecting and combining the ingredients for the [homemade] formula are very serious and range from severe nutritional imbalances to unsafe products that can harm infants. Because of these potentially very serious health concerns, FDA does not recommend that consumers make infant formulas at home."<sup>5</sup> Further, while FDA tests infant formula for quality, the quality of homemade formula is not assured. The 2019 Infant Feeding Survey indicated that 51% of moms do not view homemade formula as risky; making it clear that there is a need to identify homemade infant formula as a dangerous approach to infant feeding.

Finally, clearly and accurately communicating only the safe and nutritious feeding options will help to remove some of the stigma associated with infant feeding decisions. Our Survey revealed that more than two-thirds of moms indicated that they feel judged based on the method they choose to feed their infants, with mothers who do not exclusively breastfeed feeling the most judged. The 2020-2025 publication of the DGAs is an opportunity to remove some of the social stigma around infant feeding choice.

## **2) PARENTS AND FAMILIES SHOULD HAVE A CHOICE AND ACCESS TO ACCURATE INFORMATION ABOUT RECOMMENDED INFANT FEEDING METHODS.**

It is vital to ensure mothers and caregivers have access to information about recommended infant feeding options. Statistics from the 2018 CDC Breastfeeding Report Card indicate that breastfeeding rates continue to increase. The 2019 Infant Feeding Survey showed moms and caregivers strongly support having access to accurate, easy-to-understand information on both breastfeeding and infant formula in order to make informed infant feeding decisions. The Survey also underscored that mothers and caregivers understand the benefits of breastfeeding, yet still want access to accurate information about their options. The Survey found the top three reasons for not breastfeeding are health related including low breastmilk production, problems breastfeeding, and/or mothers felt their baby was not adequately gaining weight from breastfeeding alone. Mothers who face these issues are putting their child first, and in order to do so require the proper information, resources, and support to make the most informed decisions.

CDC data have also indicated that mixed feeding is extremely prevalent in the first year of life; well over half of U.S. mothers are breastfeeding infants at six months of age, but only 25% are exclusively breastfeeding through 6 months.<sup>4</sup> The 2019 Infant Feeding Survey documented 70% of infants receive at least some formula in the first year of life. Baby Friendly USA has recognized the importance of education on safe infant formula preparation, storage, and feeding, as their guidelines specify mothers who “have decided not to breastfeed, decided to “mixed-feed,” or will require supplementation with formula for their infants must receive written instruction and verbal information about safe preparation, storage, and feeding of formula.”<sup>6</sup> Thus, with the frequency of mixed feeding practices, the DGAs should give mothers and caregivers access to all relevant information regarding safe infant feeding practices, including recommendations on proper infant formula preparation, storage, and feeding. If all appropriate methods of infant feeding are not discussed, issues such as hazardous infant formula preparation could lead to poor infant health outcomes.

The 2019 Survey also indicated that the majority of moms oppose restricting access to information about infant formula, from both government sources and hospital settings. Eighty-two percent of mothers stated that both breastfeeding and infant formula information should be provided to new moms in the hospital and more than two-thirds of moms and caregivers agreed that the government should provide information on breastfeeding and infant formula. To understand the impact that the B-24 Dietary Guidelines may have, the Infant Feeding Survey asked participants to indicate how important certain sources were when it comes to receiving information about infant feeding. Sources including: WIC websites, CDC websites, and state health department websites ranked just behind health care professionals when it came to importance, above sources like friends, social media, and traditional media.

## **3) B-24 GUIDELINES SHOULD RECOMMEND PARENTS AND CAREGIVERS CONSULT THEIR HEALTHCARE PROVIDER ABOUT IDENTIFYING APPROPRIATE FEEDING METHODS, FOODS, AND DIETARY PATTERNS FOR INFANTS AND CHILDREN.**

The Dietary Guidelines are recommendations for healthy populations and not meant to be prescriptive for all individuals. A similar approach is important for B-24 recommendations; the recommendations should stress the importance of parents and caregivers discussing infant feeding options with their healthcare provider. Each infant and family unit is unique and different approaches may be needed to ensure healthy growth and development. There are often nutrient gaps in infants and children under

two years of age that should be addressed with dietary interventions. For example, infants who are exclusively breastfed should receive vitamin D as a supplement to prevent serious health and developmental consequences.<sup>2,7,16,17,8-15</sup> Vitamin E, iron, and fiber can often be nutrients of concern as well for the B-24 population<sup>7,18,19</sup>. Therefore, as complementary foods are introduced, products that contain these nutrients, such as follow-up formulas, can help children meet nutrient requirements. The Dietary Guidelines should encourage families and caregivers to discuss what is appropriate for their infant and young child with healthcare professionals.

#### **4) DIETARY GUIDELINES SHOULD NOT STIFLE INFANT FORMULA INNOVATION.**

Members of INCA are leaders in infant nutrition science, and their collective research has led to significant improvements in the health of formula-fed babies. Advancements and innovations are the result of decades of research and dedication to nutrition science, and represent INCA members' commitment to providing safe and nutritious options that support healthy growth and development for babies whose parents cannot or choose not to use breastmilk. INCA member companies develop infant formula using the latest scientific research to meet the nutritional and growth and development needs of infants (from healthy term infants to those who are premature or may require specialized products). As scientific knowledge evolves regarding the role of nutrients in optimizing growth and development, refinements supported by research are made to infant formulas in order to provide infants with the safe, quality nutrition when breast milk is not available. In order for moms and caregivers to receive the best possible products, it is critical that innovation is not hindered by the new Dietary Guidelines.

#### **ADDITIONAL 2019 INFANT FEEDING SURVEY FINDINGS**

The 2019 Infant Feeding Survey was conducted as an update to previous surveys conducted in 2009 and 2012 to gain current insights into infant feeding practices. The bipartisan polling group of Greenberg Quinlan Rosner Research (GQRR) and Public Opinion Strategies (POS) conducted an online poll of 802 mothers who have given birth in the last 12 months, as well as an additional 400 caregivers (who were defined as individuals spending more than 30 hours per week caring for a baby under 12 months old). The Survey was conducted between February 27- March 11, 2019 and asked mothers and caregivers a series of questions related to how they feed their infant, motivations behind their choices to feed, sentiments surrounding various feeding methods, and how they receive that information, among other topics. To ensure accurate representation, demographic controls were based on the American Community Survey by the U.S. Census Bureau of mothers who had a birth in the last 12 months.

Additional information on the 2019 Infant Feeding Survey is posted on INCA's website, including:

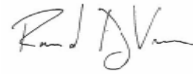
- [2019 Infant Feeding Survey Report](#)
- [2019 Infant Feeding Survey Presentation of Findings](#)
- [2019 Infant Feeding Survey Infographic](#)

Thank you for your consideration of our comments and for the opportunities to engage in the development of these important Guidelines. INCA commends the Agencies and the Committee for their work to maintain transparency in the DGA development process and we look forward to providing additional comments and feedback through the completion of the 2020-2025 DGAs. Please let us know if we can provide any further information about the Infant Feeding Survey or other information related to our comments.

Sincerely,



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