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ASPEN Statement on Contaminants in Infant Formula

The American Society for Parenteral and Enteral Nutrition (ASPEN) is aware of concerns about contaminants in many infant formulas available in the US market. These concerns could potentially influence clinical practice, caregiver decisions, and advice given to consumers. ASPEN is committed to the provision of safe, effective, and high-quality nutrition care for all patients and urges clinicians and caregivers to consider the following information regarding the safe feeding of infants.

Adequate Nutrition (Human Milk and/or Infant Formula) is Critical to Infant Health

Appropriate nutrition in infancy is paramount to supporting health, growth, and cognitive development. Human milk is the gold standard of infant feeding; however, infant formula, which by definition is formulated to mimic human milk,[1] is an appropriate alternative or supplement.[2] **Infants should exclusively be fed human milk and/or infant formula for the first six months of life, and they require human milk and/or infant formula alongside complementary feeding from six to twelve months of life to meet their nutritional requirements.**[2] Note that other kinds of milk, such as whole cow or goat milk that has not been formulated into infant formula, as well as homemade infant formulas, are inappropriate for infants, do not meet their nutritional requirements, and may cause serious harm.[3] Therefore, infant formula is critical to the health of infants who do not receive adequate human milk.

All Foods, Including Human Milk and Infant Formula, Contain Contaminants

All foods, including infant formula and human milk, contain contaminants, including heavy metals and other chemicals.[4] Contaminants result from natural processes and events, such as volcanic eruptions, or human industrial activities, such as fracking. Groundwater and soil contain these contaminants in varying amounts, and packing materials may also contain chemicals. Therefore, contaminants can enter infant formulas and all foods in a variety of ways, including sources of water, ingredients used in production, and/or storage of ingredients.

Unfortunately, it is virtually impossible to eliminate exposure to contaminants, and even safe drinking water standards allow for some presence of these substances.[5] Despite their pervasiveness, it is important to limit infant exposure to heavy metals, such as arsenic and lead, and other contaminants, such as PFAS and BPA, as infants are more vulnerable to their consequences on health and cognition. ASPEN supports continuous testing of infant formulas for contaminants known to impact human health and the institution of regulations to limit the amounts to safe standards.

Infant Formula is Regulated by the FDA

The Food and Drug Administration (FDA) regulates infant formula legally sold in the US as a food with additional statutory and regulatory requirements.[1] The FDA monitors infant formula manufacturers for quality, labeling, and nutrient levels. Minimum levels for 29 nutrients and maximum levels for 9 nutrients are established, and manufacturers are required to analyze all batches of infant formula to verify that they contain the essential nutrients declared on the label. Manufacturer records are monitored by the FDA, and the FDA also performs additional testing on infant formula products. The FDA is taking steps to implement measurement of contaminants in infant formula.

Safely Feed Infant Formula in the Absence of Adequate Human Milk

In the absence of adequate human milk, ASPEN strongly recommends the use of infant formula. Homemade formulas and milk that has not been formulated into infant formula are inappropriate for infants and should not be used in children under 1 year of age. Additionally, toddler formulas are not appropriate for infants and do not meet their nutritional requirements. ASPEN encourages clinicians and caregivers to recognize that contaminants exist in all food sources, and replacements for human milk outside of infant formula are nutritionally inadequate and inappropriate for infant consumption.

Recommendations for the Safe Preparation and Use of Infant Formula:[6-8]

1. In regions where tap water has been deemed safe, infants who: 1) have intact gastrointestinal tracts, 2) have normally functioning immune systems, and 3) are appropriate to feed orally can be fed infant formula prepared with tap water. If appropriate tap water is not available, bottled water and "infant/nursery water" can be used. It is recommended that tap water and bottled water be boiled prior to use for sterilization, whereas "infant/nursery water" does not need to be boiled prior to use. Chemically softened water is not appropriate for the preparation of infant formula due to the higher sodium content, and well water is not appropriate for the preparation of infant formula due to concerns for sanitation and contaminants.
2. Caregivers must carefully read and follow the manufacturer's instructions on the container for preparing infant formulas. Instructions may vary by manufacturer and by product. Caregivers should only use the measuring scoop supplied with the specific product, as measuring scoops vary in size and can cause errors in formula concentration if used across products.
3. Ideally, caregivers should wash their hands with soap and water for at least 20 seconds before preparing infant formula and before feeding an infant. If this option is not available, hand sanitizer with at least 60% alcohol content is acceptable.
4. Infant formula should be prepared on a clean surface. Caregivers should clean and sanitize feeding items, such as bottles and nipples, and store cleaned items safely.
5. Caregivers must carefully read and follow manufacturer instructions for safe storage of prepared infant formula. For infants receiving nutrition orally, the Center for Disease Control (CDC) recommends infant formula be prepared and used within 1 hour of starting oral feeding and within 2 hours of preparation if maintained at room temperature. Caregivers should discard any formula left in the bottle after feeding.[7] For infants receiving infant formula via an enteral access device, a prepared formula can hang for 4 hours. For infants over 30 days of age with normally functioning immune systems given sterile ready-to-feed formulas enterally, a hang time of 8 hours can be considered.[8] The CDC recommends that infant formula prepared in larger quantities be stored in the refrigerator and discarded after 24 hours.
6. If an infant formula is in an active recall, caregivers must stop using it and discard it immediately. Caregivers must select an infant formula that is not in an active recall.

ASPEN Resources for the Appropriate Selection of Infant Formula:

Navigating the selection of appropriate infant formulas may be stressful for caregivers. The choice is influenced by the child's health, caregiver beliefs and attitudes, and cost. All families want to nurture their children's health through feeding. Clinicians can support caregivers to make appropriate selections and to feel confident in their feeding method. ASPEN provides the following resources for clinicians on the appropriate selection of infant formula:

1. Corkins KG, Lee L. Chapter 12: Infant Formulas and Complementary Feeding. In: *ASPEN Pediatric Nutrition Support Core Curriculum*. 3rd ed. American Society for Parenteral and Enteral Nutrition; 2025:215-229. Print, eBook, Bundle
2. Enteral Nutrition Formula Guide
3. Hypoallergenic Formulas for Infants and Children: When to Use Extensively Hydrolyzed Formula vs Amino Acid-Based Formula
4. Resources for Human Milk and Human Milk Fortifiers

References

1. Questions & Answers for Consumers Concerning Infant Formula. US Food & Drug Administration. May 17, 2023. Accessed March 31, 2025. https://www.fda.gov/food/people-risk-foodborne-illness/questions-answers-consumers-concerning-infant-formula#1.
2. Kleinman RE, Greer FR, eds. Pediatric Nutrition. 8th ed. American Academy of Pediatrics; 2019.
3. Fuchs G, DeWier M, Hutchinson S, Sundeen M, Schwartz S, Suskind R. Gastrointestinal blood loss in older infants: impact of cow milk versus formula. *J Pediatr Gastroenterol Nutr*. 1993;16(1):4-9.
4. Chemical Contaminants & Pesticides. US Food and Drug Administration. March 20, 2025. Accessed March 31, 2025. https://www.fda.gov/food/chemical-contaminants-pesticides.
5. Drinking Water Regulations. United States Environmental Protection Agency. December 10, 2024. Accessed March 31, 2025. https://www.epa.gov/dwreginfo/drinking-water-regulations.
6. Corkins KG, Lee L. Chapter 12: Infant Formulas and Complementary Feeding. In: *ASPEN Pediatric Nutrition Support Core Curriculum*. 3rd ed. American Society for Parenteral and Enteral Nutrition; 2025:215-229.
7. Infant formula preparation and storage. Centers for Disease Control and Prevention. December 19, 2024. Accessed March 31, 2025. https://www.cdc.gov/infant-toddler-nutrition/formula-feeding/preparation-and-storage.html#:~:text=When%20tap%20water%20is%20safe,mixed%20with%20powdered%20infant%20formula.&text=Boil%20the%20water%20and%20then%20wait%20about%205%20minutes%20before,t%20burn%20your%20baby's%20mouth.
8. Steele C, Collins EA. *Infant and Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. 3rd ed. Academy of Nutrition and Dietetics; 2019.