



Advocating for Infants: Ensuring the Safety of Infant Formula



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MCH Concern

Infant formula is a food product with unique safety considerations. Safety of infant formula is vital for the infant population because it is the sole or predominant source of nutrition for many infants and it is fed during a sensitive period of development. As a result, it has the potential for both short- and long-term consequences to infant health.

The Infant Formula Act of 1980 authorizes the Food and Drug Administration (FDA) to disseminate appropriate regulations to ensure the safety and nutrition of infant formulas. Today however, this legislation is having to address a diversity of potential new ingredients such as DHA/ARA, prebiotics, etc. which are proposed by manufacturers in order to mimic the composition and health benefits of human milk.

The existing guidelines and regulations of the Infant Formula Act of 1980 do not adequately function to address new scientific challenges created by the addition of new ingredients. In response to this concern the Institute of Medicine (IOM) convened a committee in 2004 charged with evaluating the current legislation and to make recommendations for its improvement; the Committee on the Evaluation of the Addition of Ingredients New to Infant Formula.¹ Unfortunately no action has occurred to implement these recommendations.

Prevalence of Formula Use in the US and WA²

■ Formula Use ■ Exclusive Breastfeeding



US: 3 months JS: 6 months WA: 3 months WA: 6 months

Findings

The following recommendations were made by the IOM Committee on the Evaluation of the Addition of Ingredients New to Infant Formula to improve evaluation and safety of new ingredients¹:

- Develop a hierarchy of decision-making steps for manufacturers
- Establish guidelines for selecting a qualified and unbiased expert panel to evaluate safety of potential new ingredients
- Establish guidelines for formal in-market surveillance
- Standardization of safety assessments (toxicity studies, risk assessment, etc.)
- Require that bioavailability, tolerance, allergenicity, impact on gastrointestinal flora, and nutrient imbalances be addressed in any evaluation
- Use of a two-level assessment approach to determine potential toxicity of the ingredient, its metabolites, and their effects on developing organ systems
- Preclinical studies must include an appropriate number and type of animal model at relevant developmental stages.

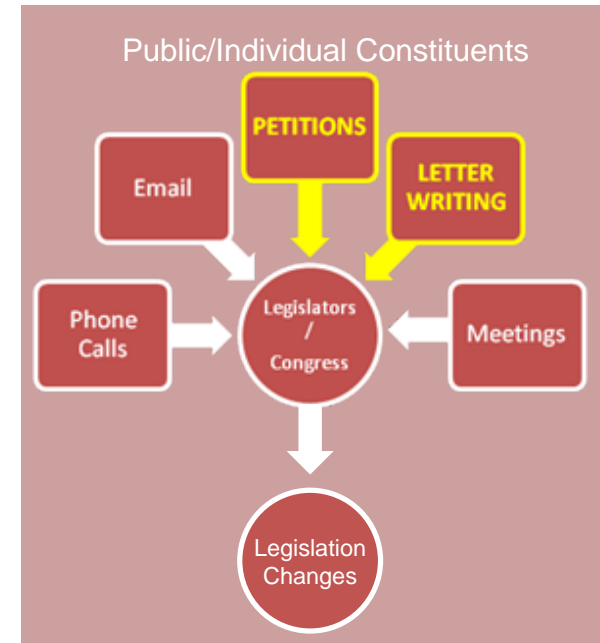
Recommendation

Direct "call to action" grassroots lobbying techniques will be employed to gain the attention of Congress on this MCH issue and the IOM committee's recommendations. A form letter and an online petition at www.thepetitionsite.com with the goal of 1,000 signatures will be circulated. These methods have the ability to reach the largest amount of constituents.

References

1. Institute of Medicine Committee on the Evaluation of the Addition of Ingredients New to Infant Formula. *Infant Formula: Evaluating the Safety of New Ingredients*. National Academy Press: Washington DC. (2004).
2. Centers for Disease Control and Prevention. (2008, August). *Breastfeeding Report Card, United States - 2008: Outcome Indicators*. Retrieved 11 May 2009, from DHHS: CDC: Data and Statistics: US National Health Survey: <http://www.cdc.gov/breastfeeding/data/index.htm>

Grassroots Lobbying



Implications

Infant formula is the significant and/or sole source of nutrition for the majority of infants in the United States. Reform of the Infant Formula Act to include recommendations provided by the IOM Committee will improve the evaluation and safety guidelines of infant formula manufacturing.

The goal of these grassroots advocacy efforts is to bring attention to legislators about how important the safety of infant formula is to constituents. It is by raising this public concern before legislators and Congress that the reform process can begin.