INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed Journal Multi Disciplinary
Peer Reviewed

www.ijlra.com

ISSN: 2582-6433

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ISSN: 2582-6433

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ISSN: 2582-6433

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ISSN: 2582-6433

GOVERNING INFANT FOOD PRODUCTS: A COMPARATIVE STUDY OF INDIA, THE UNITED STATES, AND THE EUROPEAN UNION

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Abstract

Infant food occupies a uniquely sensitive position within food regulation, as formula and complementary foods frequently serve as the sole source of nutrition during a period of rapid physical and cognitive development, when the consumer is wholly incapable of assessing risk. This article offers a comparative examination of the legal regimes governing infant food products in India, the United States, and the European Union, situating each within the guiding principles of consumer protection and public health law—the precautionary principle, the vulnerable consumer, and information asymmetry. The study shows that India tends to put emphasis on encouraging breastfeeding as well as promoting ethical marketing mechanisms in view of the provisions of the 2006 Food Safety and Standards Act and the 1992 Infant Milk Substitutes Act, while the U.S. prefers an approach based on pre-market scientific controls and litigative responsibility as practised under the Food and Drug Administration and the European Union supports a coordinated and precautionary strategy based on the establishment of the European Food Safety Authority. Drawing on recent controversies—the Nestlé added-sugar dispute, the Beech-Nut heavy-metals litigation, and the cereulide contamination recalls—the study contends that the effectiveness of each framework depends less on legislative design than on enforcement, transparency, and the gradual harmonisation of global standards.

Keywords: infant food regulation; comparative law; consumer protection; precautionary principle; food safety; vulnerable consumers; public health law; marketing restrictions.

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1. Introduction

Infant nutrition is a highly sensitive area within the food regulation and public health sector[1]. Unlike any other food, infant formula and complementary foods can be the sole or primary nutrition source during a period of rapid physical growth, neurological development and immune system maturation in the first two years of life.[2] Inadequate nutrition at this stage could lead to irreversible stunting, and long-term cognitive impairments and disease susceptibility.

As a result governments around the world are all obligated to safeguard consumers against any potential nutritional deficits or food safety or quality concerns resulting from unsuitable infant nutrition products. Regulations for infant food products go well beyond those applicable to other food products, covering a wide range of aspects from nutritional composition and manufacturing processes, to labelling, marketing and distribution. India has developed one of the most robust and protective regulatory environments for infant nutrition.[3]

The Indian regulatory environment aims to strike a balance between three objectives: ensuring nutritional adequacy, protecting consumers and promoting breast feeding as the first choice feeding practice. The policy of promoting breast feeding as the gold standard of infant nutrition is at times an obstacle to the development and marketing of infant nutrition products. However, governments also recognise the need for scientifically regulated and safe infant nutrition products to be available as an alternative whenever breast feeding is not possible.

The regulatory equilibrium is maintained by a multi-tiered regulatory framework that is comprised of statutory bodies, technical standards and stringent marketing controls. The apex regulatory body is the Food Safety and Standards Authority of India (FSSAI)[4] under the Food Safety and Standards Act, 2006, supported by sector-specific legislation such as the Infant Milk Substitutes Act, 1992[5] and quality certification mechanisms through the Bureau of Indian Standards[6].

The infant nutrition market has expanded rapidly in recent years due to urbanisation, rising income levels and increased female participation in the workforce, and has presented new regulatory challenges such as misleading advertising, excessive sugar content, nutrient fortification and cross-border variations in standards. The regulatory framework has thus

[1] *The Food Safety and Standards Act, 2006*, No. 34 of 2006, § 16, India Code.
[2] World Health Organization, *Infant and Young Child Feeding: Model Chapter for Textbooks* 1–5 (2009).
[3] Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020, Gazette of India.
[4] *Food Safety and Standards Act, 2006*, § 4, India Code; Food Safety and Standards Authority of India, *About FSSAI*,https://www.fssai.gov.in/
[5] Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992, No. 41 of 1992, India Code.
[6] Bureau of Indian Standards Act, 2016, No. 11 of 2016, India Code.

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evolved significantly, most notably with the enactment of the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020.

2. Theoretical Background

The regulation of infant food products may be considered in the light of three fundamental concepts of consumer protection and public health law, i.e. the principle of precaution[7], the concept of vulnerable consumer[8] and information asymmetry[9]. Infants are the most vulnerable consumers, as they lack autonomy and are not capable of judging the risks of food consumption. Their vulnerability is compounded by the information asymmetry between manufacturers and caregivers, which creates a need for regulation to intervene in marketing and nutritional claims. In this light, regulation may proceed on a precautionary basis, which means that it operates with a lower burden of proof - in other words, without scientific evidence of harm - as a result of the potentially irreversible nature of any health consequences. In India, the FSSAI combines both safety regulation and a public health agenda, with a strong emphasis on the protection of infant consumers in terms of breastfeeding promotion and regulation of the marketing of commercial infant foods. The European Union adopts a more formalised theory of precaution through the European Food Safety Authority[10], whereby scientific risk assessment forms the basis of preventive regulation. The United States operates on an enforcement-based risk theory, through the U.S. Food and Drug Administration.[11] The latter relies on risk assessment as well as on post-market surveillance. Taken together, these different models illustrate the growing trend towards hybrid governance models, whereby paternalistic authorities and the private sector combine safety regulation, labelling and marketing controls in the interests of consumer protection.

3. Regulatory Framework in India

3.1 Legal Foundation and Institutional Structure

The Indian infant food products governance lies within the purview of the Food Safety and Standards Act, 2006[12], which provides a single, comprehensive legal framework for food

[7] Cass R. Sunstein, Beyond the Precautionary Principle, 151 U. Pa. L. Rev. 1003, 1005 (2003).
[8] World Health Organization, *Guiding Principles for Complementary Feeding of the Breastfed Child* (2003).
[9] George A. Akerlof, The Market for "Lemons": Quality Uncertainty and the Market Mechanism, 84 Q.J. Econ. 488 (1970).
[10] European Food Safety Authority, *About EFSA*,https://www.efsa.europa.eu/en
[11] U.S. Food & Drug Admin., *Infant Formula Guidance Documents & Regulatory Information*, https://www.fda.gov/
[12] *Food Safety and Standards Act, 2006*, § 18, India Code.

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safety. It established the FSSAI as the top regulatory body for food standards and food businesses, and for consumer protection.

The Act has a science-based regulatory framework that allows the FSSAI[13] to prescribe standards on composition, contaminants, additives, and labelling. Fundamental principles such as risk analysis, precautionary approach, and consumer protection are covered, and unsafe or misbranded food is prohibited, with the product makers bearing the responsibility.

3.2 Infant Specific Regulations

The Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020[14] is the most important legislation regulating the nutrition of infant. The infant food products regulated under this legislation span infant formula and follow-up formula to complementary foods and food for special medical purposes.

The specifications are made for infant food products based on age and nutrition. Infant formula is to be used only in place of breast milk during the first 6 months of infant life. Complementary food is to be introduced after 6 months for supplementing the nutrition of infant.

3.3 Composition, Safety and Manufacturing Controls

The Indian legislation requires stringent composition of the infant food products to be close to human breast milk. The infant food products are required to contain specific amounts of calorie, protein, fats and carbohydrates. It must also contain specific amounts of micronutrients like iron, calcium, vitamins, etc.

The safety and manufacturing controls for infant food products are equally stringent. The infant food products must be produced under strict hygienic conditions with free from any harmful contaminant and must be manufactured and packaged in hermetically sealed BPA free containers. The use of additives is strictly controlled and only those additives which are approved and within the specified limit are allowed. This is due to the classification of infant food products as high risk foods in the Indian legislation.

3.4 Labelling and Marketing Restrictions

India adopts a public health approach to labelling. The label statement that mother's milk is best for the baby[15] must be prominently displayed, as well as detailed instructions on

[13] Supra note 4.
[14] Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020, § 2.1.
[15] Infant Milk Substitutes Act, 1992, § 6.

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preparation, storage and use. The use of images or promotional claims that may influence the use of infant formula at the expense of breast feeding is also prohibited.

The Infant Milk Substitutes Act, 1992, imposes restrictions on the advertising and promotion of infant milk substitutes. The Act prohibits direct advertising, free sampling and unethical engagement with health professionals. The aim is to protect breastfeeding and to safeguard the markets for infant nutrition from commercial exploitation.

3.5 Enforcement and emerging issues

Enforcement is a challenge in India, despite a robust regulatory framework. Numerous violations in marketing practices and concerns about excessive sugar content have been reported. The controversy over CCPA v. Nestlé (2024) stems from allegations that Nestlé sold infant food products that contained higher sugar content, in developing countries, including India, than in European markets. This is based on a report released by the Swiss organization Public Eye, in collaboration with the International Baby Food Action Network (IBFAN), that some baby cereals and infant milk substitutes in India, Africa and Latin America contain added sugars and honey.[16]

Considering the circumstances, the Central Consumer Protection Authority (CCPA) sent notices to the FSSAI to look into the issue, and the National Commission for Protection of Child Rights (NCPCR) also sent notices pointing out the public health concerns.[17] The controversy has awakened concerns over nutritional inequality, deceptive practices and ethics in the global supply chain, especially for vulnerable consumers such as infants. While Nestlé argued that it adhered to the relevant regulatory standards and lowered the sugar content over time, the controversy revealed the regulatory gaps between nutritional quality and mere compliance with the law. This case is more significant as a regulatory intervention rather than an adjudicated final judgement. It is significant because it signals the underlying trend towards substantive regulation of infant nutrition products in India in the consumer protection and food safety regime. A regulatory review has been triggered-without contravention of extant standards-that suggests a concern about quality of nutrition and equity and indicates the shift towards substantive regulation.

[16] Public Eye & Int'l Baby Food Action Network, *Sweetening the Deal: How Infant Food Companies Target Developing Countries* (2024).
[17] Central Consumer Protection Authority, Press Release on Nestlé Infant Food Products (2024).

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4. Regulatory Framework in the United States

4.1 Legal Framework and Regulatory Authority

The regulatory framework in the U.S. is very structured and science-based, and is largely governed by the Federal Food, Drug, and Cosmetic Act and the Infant Formula Act of 1980.[18] The U.S. Food and Drug Administration is responsible for regulatory oversight of infant food. The Infant Formula Act[19] was established to meet safety concerns and includes specific requirements for nutrient content, manufacturing and quality control. Unlike in India, there is less emphasis on promoting Breast feeding and more emphasis on safety and nutritional adequacy.

4.2 Pre-Market Controls and Nutritional Requirements

A unique feature of the U.S. system is that manufacturers are required to notify the FDA[20] of a new infant formula and to show that it satisfies all the requirements. The FDA specifies the minimum and maximum levels of key nutrients.

Manufacturing facilities are inspected rigorously and are required to follow Good Manufacturing Practices (GMP) to avoid contamination.

4.3 Contamination concerns: Heavy metals in baby food

In spite of a strong regulatory framework, studies recently found the presence of unexpected levels of toxic heavy metals (arsenic, lead, cadmium and mercury)[21] in a number of baby foods widely used by the population. This is of particular concern for public health because of the potential impact on infant development.

4 4. Litigation and Enforcement: Re Beech-Nut Baby Food Litigation (2025)

The In re Beech-Nut Nutrition Company Baby Food Litigation (2025)[22] is perhaps the largest consumer class action to arise in the United States from allegations that a food company made false claims about the safety of its products. In this case, the plaintiffs alleged that Beech-Nut unfairly represented its baby foods as "safe," "natural," and "healthy" even though the products may have contained or been at risk of containing toxic levels of heavy metals (arsenic, lead,

[18] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2018).
[19] Infant Formula Act of 1980, Pub. L. No. 96-359, 94 Stat. 1190.
[20] Supra note 11.
[21] H.R. Comm. on Oversight & Reform, Subcomm. on Econ. & Consumer Pol'y, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (2021).
[22] See *In re Beech-Nut Nutrition Co. Baby Food Litigation*, No. 2:22-cv-____ (U.S. Dist. Ct. filed 2022) (alleging misleading marketing of baby food products containing heavy metals).

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cadmium, and mercury). The public disclosure of a U.S. Congressional report that found high levels of these metals in commercial baby foods led to widespread concern that the contaminants may cause long-term developmental harm in infants.

Plaintiffs in the Re Beech-Nut Baby Food Litigation claimed fraud[23], breach of warranty and consumer protection violations, that they too paid a premium for a product they had been assured was safe and of high quality. In March 2025, the court dismissed the claims[24], finding that the plaintiffs had failed to demonstrate a particularised injury, especially in terms of economic loss or demonstrable harm. The court also found general marketing terms such as "natural" and "healthy" to be too vague to constitute actionable misrepresentation in the absence of specific guarantees that the products were free of contaminants.

The Re Beech Nut case illustrates a major flaw in the U.S. legal system, namely that consumer protection is based on the necessity to prove an actual injury rather than the mere presence of a risk, which creates a gap between science and law. The case also illustrates the reality of the challenges of addressing a latent health risk in infant food products in a regulatory system in which liability is based on litigation. The Re Beech Nut case exemplifies the limitations of the legal and political systems in the United States in addressing pervasive food safety risks. The Re Beech Nut case arises from a class action lawsuit filed by consumers who alleged that Beech-Nut misrepresented "natural," "healthy" and "safe" products despite the presence of toxic heavy metals.

Even though the lawsuit was brought on the ground of misleading advertising, the court ultimately dismissed the case because the plaintiffs failed to prove actual injury or tangible economic loss, both of which are prerequisites under U.S. law. The court rejected the plaintiffs' argument that general marketing terms such as "natural" or "healthy" were misleading, because such terms were too vague to be actionable and did not specifically promise that heavy metals were absent from the supplement.

This case is illustrative of an important limitation in the U.S. regulatory and legal systems: where legal remedies are predicated upon proof of injury, rather than the presence of a risk or regulatory concern. As a result, there is sometimes a disconnect between scientific data indicating potential harm and the ability of consumers to obtain legal recourse.

4.5 Enforcement and recall mechanisms

The FDA has broad enforcement powers, including authority to conduct inspections, monitor

[23] Id.
[24] Id.

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adverse events, and require product recalls, but it depends heavily on post-market surveillance and litigation, and corrective measures may be triggered only after harm has been observed.

Thus, the U.S. system is strong in its scientific regulation and enforcement mechanisms, but may be less effective in dealing with latent or long-term risks, such as may affect infant food.

5. Regulatory Framework in the European Union

5.1 Legal Framework and Institutional Oversight

In the European Union, food for infants is regulated by Regulation (EU) No. 609/2013[25], which covers foods for specific groups (including infants, young children). Scientific risk assessment and standard setting are undertaken by the European Food Safety Authority[26], ensuring that regulatory decisions are underpinned by science.

The EU system is highly harmonised, ensuring that regulatory standards are applied consistently across all member states. Fragmentation of regulation is minimized and protection of the consumer is, therefore, maintained at a consistently high level. Rather than relying on post-market intervention, the system places a heavy burden of burden on manufacturers to regulate the product prior to it being placed on the market.

5.2 Precautionary principle and safety.

One feature of the EU regulatory system is the precautionary principle, which enables the regulators to implement measures to protect against possible contamination in the absence of complete scientific confidence, and therefore, it is more restrictive than many other jurisdictions regarding contaminants, additives and pesticide residues.

The composition of infant food products is subject to specific standards, in accordance with international standards such as Codex Alimentarius, and of strict environmental contaminant limits, as well as continuous monitoring of the manufacturing process. Overall, it is a regulatory approach that tends to prevent risks rather than dealing with them.

5.3 Labelling and Consumer Protection

The EU requires detailed labelling on food, which provides consumers with all the information needed for making an informed choice. This includes nutritional composition, preparation instructions and safety warnings on infant food products. False or misleading claims are not

[25] Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013 on Food Intended for Infants and Young Children, 2013 O.J. (L 181) 35.
[26] Supra note 10.

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allowed, and claims made about health benefits must be supported by evidence.

While the EU does not have a law like the IMS Act in India, the focus on consumer protection and ensuring products are accurately represented is high enough that parents will not be misled by dubious, unsubstantiated claims.

5.4 Rapid Alert and Recall Mechanisms

Rapid Alert System for Food and Feed (RASFF)[27] is the most valuable component of the EU system, as it ensures rapid identification and removal of potentially hazardous foods from the market. This system has the ability to enable rapid, real-time communication and coordination between member states.

The precautionary recall of infant nutrition after the detection of Bacillus cereus is a clear example of this. Even though no mass harm was reported, the authorities took the precautionary approach and immediately recalled the products in question. This illustrates the EU's zero-tolerance policy and proactive approach to infant food.

The recent crisis with infant formula recall has revealed weaknesses in the European Union's otherwise strong food safety system. The problem involved a toxin, cereulide, produced by Bacillus cereus, contaminating a widespread ingredient, arachidonic acid (ARA) oil, sold to multiple manufacturers. As a result, multiple top infant nutrition brands were affected with a single contamination point at the cutting edge of globalised supply chains in infant nutrition.

It is problematic that the recall and regulatory response was delayed; certain products were on the market and available for months after the detection of contamination. The EU's precautionary approach was undermined by this incident. Although the RASFF is designed to quickly notify each member state of potential food safety hazards, the recall incident showed a lack of coordination between member states, with some authorities not acting quickly enough. The crisis also exposed regulatory uncertainty, as no safety thresholds for cereulide existed and responses varied from country to country. More generally, it highlighted that the EU framework is robust by design, but its efficacy depends on the effectiveness, transparency and coordination of national actions, and on rapid recalls, tighter controls of shared ingredients and clearer standards for emerging contaminants, in high risk products such as infant formula.

5.5 Global Case Study: Foodwatch Complaint on Toxin in Baby Milk

The strengths and weaknesses of the EU system are further highlighted by a major global issue

[27] European Commission, *Rapid Alert System for Food and Feed (RASFF)*,https://food.ec.europa.eu/index_en

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surrounding the presence of toxins in infant formula, for which the consumer organisation Foodwatch has taken legal action. The presence of the toxin cereulide, produced by Bacillus cereus, was found in infant milk products in several countries.[28]

The alleged source of contamination was a shared ingredient: arachidonic acid (ARA) oil, used by several multinational companies including some of the largest global brands. The use of a common supply chain for this ingredient meant that the contaminated product was present in many different markets, resulting in extensive recalls covering over 60 countries. The incident highlighted the potential dangers of a globalised food supply, in which the presence of a single contaminated ingredient can have global implications.[29]

Foodwatch has taken criminal action against French authorities, alleging that manufacturers had not acted responsibly in ensuring the safety of their products and had failed to call for a public recall even after they had been warned of the possible risk, and that the authorities had been slow to communicate and were not exercising enough oversight. The use of a complaint against "unknown persons" means that the investigation can look into the responsibilities of all actors involved, including manufacturers, suppliers and regulatory authorities.

The Foodwatch case was the product of a single contaminant discovered in a huge supply chain of chemicals and food products. Though we do not know who the custodian of the contaminant was, the Foodwatch case does underscore a few of the challenges in the current food regulatory regime. The need for more robust and faster communication between regulators and industry is obvious, as is the need for precautionary action, since the Foodwatch case revealed that it was impossible to completely rule out the risk until the contaminant was found. Though the recall of the affected products was done quickly once the contaminant was discovered, this case also shows that there are often many days between risk discovery and the implementation of public recalls. Finally, the Foodwatch case also shows the limitations of corporate responsibility and supply chain transparency. The contaminant was found in many different products, but we do not know the source. We have to insist that companies maintain control over their supply chain and take responsibility for the substances that enter their products. The Foodwatch case proves that even in the EU, which has one of the best food safety regimes in the world, it is possible to have gaps and overlaps in the regulatory regime.

[28] Foodwatch, *Complaint Concerning Contaminated Infant Formula Products Filed with French Authorities* (2024).
[29] European Commission, *RASFF Notification on Bacillus cereus Contamination in Infant Formula Products* (2023–2024).

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6. Comparative Analysis of Regulatory Frameworks

A comparison of food regulation in India, USA, and the EU.

This article examines the current regulatory systems of infant food in India, the U.S. , and the EU. The IMS Act, the FDA regulations, and the EU regulations cover the same issues but they vary in emphasis. The Indian system is corporately developed and implemented with a strong emphasis on public health, particularly on the promotion of breastfeeding and strict restrictions on marketing[30]. The FDA regulations are based on pro-active regulation and enforcement of product safety and nutrient adequacy. The EU system is most similar to the Indian system and places high emphasis on contamination limits. Consumer protection can be enhanced in each system if enforcement authorities have sufficient power and resources. The American system in particular could be improved if the courts had the power to award general damages in cases of consumer harm. The Indian system could be strengthened by tighter enforcement of marketing restrictions and a clearer legal enforcement regime. The EU would be enhanced by a system that is more balanced between pre-market controls and post-market surveillance.

7. Conclusion

Regulation of infant food products is a fascinating interface of law, public health and ethics. The regulatory approaches in India, the US and the EU are reflective of the dominant legal cultures and policy priorities. India focuses on breastfeeding and ethics of marketing, the United States focus on scientific evidence and liability, while the European Union adopts a precautionary and harmonised approach.

All three systems are changing to accommodate new challenges such as altered sugar content, contamination risks, and complexity of global supply chains. The future of regulation of infant nutrition will be the product of stronger enforcement, better transparency and harmonisation of global standards.[31]

The governance of infant nutrition is only as good as the enforcement of the law and the ethics of the industry, and so the most vulnerable require the best protection.

[30] World Health Organization, *International Code of Marketing of Breast-milk Substitutes* (1981).
[31] FAO & World Health Organization, *Food Safety Risk Analysis: A Guide for National Food Safety Authorities* (2006).