A BALANCING ACT: THE FINANCIAL IMPLICATIONS OF USING FOOD ADDITIVES BY AMERICAN COMPANIES

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I. INTRODUCTION 215
II. TRACING THE DEVELOPMENT AND CHALLENGES OF FOOD ADDITIVES 217
III. LEGAL AND REGULATORY LANDSCAPE 219
  A. Recent Litigation Involving Food Additives 220
  B. Potential Future Legislation 221
IV. ECONOMIC RISKS AND BUSINESS IMPLICATIONS 223
  A. Associated Costs with Compliance 224
  B. Associated Costs with Non-Compliance 224
  C. Impacts of a Damaged Reputation 225
  D. Global Compliance and Multinational Challenges 227
V. BALANCING PROFITABILITY AND COMPLIANCE 229
  A. Corporate Governance and Risk Mitigation 229
  B. Proactive Planning for Stricter Regulations 230
VI. CONCLUSION 231

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I. INTRODUCTION

The continued use of food additives in the United States, motivated by financial incentives like cost savings and market positioning, presents potential economic risks for businesses. If regulations tighten at the same rate public scrutiny intensifies, these practices could disrupt profitability and compel companies to reshape their business strategies in the food industry. To address these challenges, American businesses should prioritize reformulating products with safer, natural alternatives, adopt more transparent labeling to reduce litigation risks, and align with stricter international standards to mitigate future regulatory impacts while maintaining market competitiveness. Today, few companies pursue formal review by the U.S. Food and Drug Administration (FDA) for the introduction of new chemicals into food products.[1] Many circumvent the approval process by exploiting gaps within the existing regulatory regime, even despite recent initiatives seeking to bolster food safety regulations and strengthen oversight.[2] The evasion of regulation streamlines an easier and faster process for companies to incorporate additives into food without compliance delays, allowing them to cut costs to maintain a competitive edge in the market.[3] Furthermore, companies are driven to leverage consumer values when using food additives because the additives extend the shelf life of food and lower product costs, thereby elevating the product's convenience.[4]

Accordingly, the use of additives presents companies with the opportunity to generate inventory in compliance with consumer demand while optimizing profitability. However, limited regulation has led to widespread scrutiny and litigation, which has created a growing concern and a rising professional inquiry as to the extent to which stricter regulations will be implemented in the U.S.[5] As scrutiny increases, companies relying on additives may be vulnerable to significant financial and legal risks. Given food safety norms are used strategically by food companies to secure competitive advantages, a shift in regulatory standards, heightened public scrutiny, an influx of

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1. Thomas Galligan, Jensen N. Jose & Adrienne Crezo, *How Food Companies Sneak New Ingredients Past the FDA*, CENTER FOR SCIENCE IN THE PUBLIC INTEREST (Mar. 4, 2024), https://www.cspinet.org/ cspi-news/how-food-companies-sneak-new-ingredients-past-fda.

2. *Id.*; *See* Alana Semuels, *Why Some Food Additives Banned in Europe Are Still on U.S. Shelves*, TIME (Feb. 3, 2025, 10:29 AM), https://time.com/7210717/food-additives-us-fda-banned-europe/.

3. Galligan, *supra* note 1.

4. Martha Dragich, *GRAS-Fed Americans: Sick of Lax Regulation of Food Additives*, 49 IND. L. REV. 305, 308 (2016).

5. Erin Quinn & Chris Young, *Why the FDA Has Never Looked At Some of the Additives in Our Food*, NPR (Apr. 14, 2015, 3:28 PM), https://www.npr.org/sections/thesalt/2015/04/14/399591292/why-the-fda-is-clueless-about-some-of-the-additives-in-our-food.

legal disputes, or a combination of all three can affect the way companies mold and form their business strategies.[6]

This paper argues that if public scrutiny and litigation surrounding food additives continue to intensify, U.S. businesses will need to adjust their strategies to mitigate growing legal, financial, and reputational risks. The first section traces the history of food additive regulation in the U.S., starting with the 1958 Food Additives Amendment, moving through to the "Generally Recognized as Safe" (GRAS) loophole, and ending with contrasting U.S. policies with the stricter regulatory approach of the European Union (E.U.).

The second section explores gaps in FDA regulations and the growing legal challenges surrounding misleading labeling and harmful additives. It highlights lawsuits that demonstrate the financial and reputational risks companies face due to deceptive practices and undisclosed additives.

Next, the third section explores the economic implications of relying on food additives, weighing their cost-saving advantages against the financial risks of regulatory noncompliance, class action lawsuits, and recalls. This section further examines the real costs associated with compliance and non-compliance, including case studies such as the class action against Food Lion and the long-term reputational fallout faced by companies like Kellogg's.

The fourth section will explore the impact of potential future legislation, such as the Ensuring Safe and Toxic-Free Foods Act of 2022, and the growing push for stricter FDA oversight. It also examines the evolving international regulatory landscape, and the challenges U.S. companies face in complying with differing safety standards in global markets.

Finally, the fifth section proposes strategic adjustments for businesses, recommending that they proactively reformulate products with safer, natural alternatives, enhance transparency in labeling and ingredient disclosures, and align with stricter international food safety standards. This section outlines practical steps companies can take, including strengthening corporate governance, conducting internal safety audits, and proactively preparing for inevitable regulatory tightening. By taking a pre-emptive approach, businesses can protect themselves from legal and financial pitfalls while maintaining consumer trust and long-term profitability in a rapidly changing food industry.

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6. Louis Augustin-Jean, *Introduction to the Special Section on Food Safety-Food Risks, Food Safety, and International Trade: An Assessment*, 11 ASIAN J. OF WTO & INT'L HEALTH L. & POL'Y 245, 246-47 (2016).

II. TRACING THE DEVELOPMENT AND CHALLENGES OF FOOD ADDITIVES

The 1958 Food Additives Amendment introduced a regulatory framework for food additives, requiring pre-market approval based on scientific testing.[7] However, the amendment also established the GRAS exception, which allows certain substances to bypass pre-market approval if deemed safe by qualified experts.[8] Over time, many new additives have entered the market through GRAS self-determinations and regulatory loopholes, reducing the use of the formal FDA approval process.[9] This led to a surge in additive use, and by 2019, more than half of all packaged food and beverage products purchased by U.S. households contained three or more additives, which highlights the growing dependence on these substances in the modern food supply.[10] A 2023 study shows that the trend continues toward increased use of food additives, revealing that 60% of foods purchased by Americans now contain technical additives.[11]

In contrast, the EU maintains a more cautious approach, restricting or banning many food additives and colorings that are permitted in the U.S.[12] These differences in food regulations significantly impact international trade, as businesses must navigate a complex web of standards to gain market access.[13] The stricter EU regulations on additives create potential barriers for U.S. companies looking to export their products to the European market.[14]

Nevertheless, the U.S.'s widespread use of food additives is largely fueled by strong economic incentives, as companies aim to cut costs and increase profitability. These savings are achieved by extending product shelf life, enhancing taste and appearance, and supporting large-scale

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7. Dragich, *supra* note 4, at 312–13.

8. *Id*. at 313–14.

9. *See id*. at 314.

10. Tom Neltner, *FDA Must Set Up Its Role as a Chemical Safety Regulator,* BLOOMBERG L. (Oct. 4, 2021, 3:00 AM), https://news.bloomberglaw. com/environment-and-energy/fda-must-step-up-its-role-as-a-chemical-safety-regulator. ; *Over Half of Foods and Beverages Purchased by Americans Contain Technical Food Additives—a 10% Increase Since 2001*, GLOBAL FOOD RESEARCH PROGRAM (March 13, 2023), https://www.globalfoodresearchprogram.org/over-half-of-foods-purchased-by-americans-contain-technical-food-additives-a-10-increase-since-2001/#:~:text=This%20represents%20a%2010%25%20increase,additives%20is%20on%20the%20rise.

11. Elsevier, *Food Additives on the Rise, Study Finds*, FOOD MFG. (Mar. 14, 2023), https://www.foodmanufacturing. com/ingredients/news/22766269/food-additives-on-the-rise-study-finds.

12. *EU vs. US Food Regulations: Understanding the Key Differences*, RDR GLOBAL PARTNERS (Dec. 15, 2023), https://rdrglobalpartners. com/blog/eu-vs-us-food-regulations-understanding-the-key-differences; WTHR, *Closer Look at American Food Banned in Other Countries*, (YouTube, Feb. 27, 2023), https://www.youtube.com/watch ?v=TD5JulK1Iyk (explaining the use of additives in American products make American Gatorade, Skittles, Ritz Crackers, and Frosted Flakes illegal in Europe).

13. RDR GLOBAL PARTNERS, *supra* note 12.

14. *See id*.

industrial production.[15] Leveraging high-volume production methods can grant companies the prospect of producing food in bulk and reducing waste while maintaining product freshness for longer periods.[16] As a result, these efficiencies can boost cost savings by curtailing the need for immediate distribution or refrigeration, ultimately lowering production, storage, and transportation expenses.[17]

When companies harness these cost-saving strategies that additives provide, they can maximize their market positioning and gain a competitive edge. The diverse selection of food products that additives offer provides benefits to consumers by allowing them to easily access and select items based on their preferences and budget.[18] In contrast, manufacturers, who understand the role of additives in enhancing product appeal and durability, leverage this knowledge to maintain their advantage in the marketplace.[19] Therefore, additives play a significant role in driving profitability for food companies, because their incorporation makes it technologically feasible to eliminate undesirable nutrients and manufacture the perfect flavor and texture, while also being able to carve out a lasting advantage in the market.[20]

Despite the positive financial implications, a rising tide of public scrutiny and legal action has cast a spotlight on the economic risks that come with continued reliance on food additives. In recent litigation, courts have examined the use of additives and their implications for standards on consumer transparency, particularly in product labeling and marketing practices. For example, in *Thompson v. Schwan's Consumer Brands Inc*., a New York district court considered whether additives such as sodium acid pyrophosphate (SAPP) and sodium tripolyphosphate (STPP) in a frozen pie product contradicted the "NO Preservatives" label and misled consumers under state consumer protection laws.[21]

The plaintiff argued that SAPP and STPP acted as preservatives by maintaining color, texture, and shelf life, making the "NO Preservatives" label deceptive.[22] The defendant countered that they served other

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15. Frank Dixon, *Poorly Regulated Food Additives Increase Chronic Disease and Corporate Profit*, T. COLIN CAMPBELL CTR. FOR NUTRITION STUD., (Oct. 24, 2024), https://nutritionstudies.org/food-additives-increase-obesity-chronic-disease-and-corporate-profits/.

16. *Id.*

17. INT'L FOOD ADDITIVES COUNCIL, *Food Additives: Supporting Food Affordability*, https://www.food ingredientfacts.org/food-additives-supporting-food-affordability/ (last visited Oct. 25, 2024).

18. Elly Hernawati, et al., *Responsibilities of Food Products Businessmen for Using of Food Additives to the Customer Who Experience Losses on His Health*, 53 J. L. POL'Y & GLOBALIZATION 173, 174 (2016).

19. *Id*.

20. Alison T. Burrows, *Nano-Fed Americans: Novel & Untested Food Additives Are Bypassing the Regulatory System into Consumers Mouths*, 36 SYRACUSE J. SCI. & TECH. L. 25, 28 (2019-2020).

21. *Thompson v. Schwan's Consumer Brands Inc.*, No. 24-CV-00831 (CM), 2024 WL 3862104, at *1-2 (S.D.N.Y. Aug. 19, 2024).

22. *Id*.

functions, like leavening and pH regulation, and did not violate labeling laws.[23] The court recognized some ambiguity regarding the dual-purpose nature of the additives and ultimately allowed the primary consumer fraud claims to proceed.[24] The case is illustrative of the legal dangers for U.S. companies that mislead consumers about the additives in their products. Thus, when labels make false claims that increase prices but do not reflect the actual ingredients, businesses risk facing litigation costs and the loss of consumer trust.

As the FDA's enforcement of labeling regulations remains lax, people are often misled into trusting products as 'natural' or 'safe' despite the presence of additives or other harmful substances.[25] With limited knowledge about the additives in the food they purchase, consumers face potential health risks, compounded by their weaker bargaining position compared to more informed businesses.[26] As consumer protection lawsuits proliferate and the consumers themselves are made more aware of the health risks and deceptions, companies may be vulnerable to reputational damage and financial liabilities, signaling a shift toward greater accountability in the use of food additives.

III. LEGAL AND REGULATORY LANDSCAPE

The existing regulatory framework set by the FDA enables many companies to sidestep safety checks when incorporating food additives into their products.[27] Since 1970, most new additives have entered the market "based upon producer or industry self-determinations of safety rather than by FDA evaluation and approval."[28] One of the most significant FDA loopholes, the GRAS designation, was originally intended to exclude common ingredients like flour or eggs from excessive regulation, but its broad interpretation has allowed companies to self-certify.[29] Today, most new chemical additives enter the market through GRAS self-determinations, bypassing the FDA's rigorous pre-market approval process, and are only scrutinized after reaching consumers and potentially causing harm.[30] This regulatory gap leaves consumers vulnerable to potential health risks, as researchers

23. *Id*. at 2-3.
24. *Id*. at 4-6.
25. Dragich, *supra* note 4, at 319.
26. Elly Hernawati, et al., *supra* note 18, at 175.
27. Dragich, *supra* note 4, at 307.
28. *Id*.
29. *Id*. at 313-14.
30. *Id*.

explain, "it is nearly impossible to identify whether there are health effects caused by long-term exposure to certain ingredients."[31]

A. Recent Litigation Involving Food Additives

Courts especially scrutinize companies for using additives when they are coupled with a lack of transparency in product labeling. Similar to the example in the *Thompson* case, where the Court decided whether the use of additives contradicted the "NO Preservatives" label, a Missouri district court considered in *Brunts v. Hornell Brewing Co., Inc.* whether the use of additives in AriZona beverages contradicted the company's labeling of its products as "All Natural" or "100% Natural."[32] While the Court ultimately dismissed the claim for procedural reasons, the case underscores how the inclusion of artificial additives such as ascorbic acid, high fructose corn syrup, malic acid, and various added colorings like beta carotene and annatto in products labeled as "All Natural" or "100% Natural" can lead to significant legal costs and scrutiny.[33]

Brunts and legal disputes, in the same vein, highlight the growing importance of transparency in labeling. Consumers are becoming more aware of food company deception tactics and may allege that companies have misled them into believing products are entirely natural when they truthfully include potentially harmful food additives. Hence, there are now more consumer protection lawsuits that call for increased transparency in labeling and greater accountability from companies, which has pushed companies to voluntarily remove misleading labels from their products.[34]

Looking ahead, there are growing calls for stricter regulations that would close the loopholes currently exploited by food companies.[35] Experts have suggested that reforming the GRAS designation and requiring more comprehensive safety evaluations could help restore consumer trust and minimize legal risks.[36] If future legislation enforces stricter oversight on food additives, businesses may face higher costs associated with reformulating their products or complying with new

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31. Erin Quinn & Chris Young, *Why the FDA Has Never Looked at Some of the Additives in Our Food*, NPR (Apr. 14, 2015), https://www.npr.org/sections/thesalt/2015/04/14/399591292/why-the-fda-is-clueless-about-some-of-the-additives-in-our-food.

32. *Thompson v. Schwan's Consumer Brands Inc.*, No. 24-CV-00831 (CM), 2024 WL 3862104, at *1-2 (S.D.N.Y. Aug. 19, 2024); *Brunts v. Hornell Brewing Co., Inc.*, No. 4:22CV648 HEA, 2024 WL 1383545, at *1-2 (E.D. Mo. Mar. 29, 2024).

33. *Id*.

34. Patrick Meyer, *The Crazy Maze of Food Labeling and Food Claims Laws*, 92 ST. JOHN'S L. REV. 233, 275-77 (2018).

35. Tom Neltner, *FDA Must Set Up Its Role as a Chemical Safety Regulator,* BLOOMBERG L. (Oct. 4, 2021) https://news.bloomberg law.com/environment-and-energy/fda-must-step-up-its-role-as-a-chemical-safety-regulator.

36. *Id*.

safety standards.[37] The impact of such regulations could also reshape the food industry as businesses adjust their strategies to comply with new rules while maintaining profitability.[38]

B. Potential Future Legislation

Furthermore, in response to growing public concern over the safety of food additives and the loopholes in the current regulatory framework, there has been a significant push for legislative reform to strengthen oversight and accountability within the FDA's food safety programs.[39] For instance, in 2022, Senator Edward J. Markey introduced the Ensuring Safe and Toxic-Free Foods Act of 2022, which aims to overhaul the FDA's current GRAS rule.[40] This bill would require companies to submit detailed information on additives, prohibiting self-determination of safety without first notifying the FDA and making this data publicly available for a ninety-day comment period.[41] Senator Markey emphasizes it is long overdue for the FDA to revise outdated safety measures and prevent manufacturers from using the current loophole.[42]

The vitality of legislation such as this is demonstrated through its potential to "finally fix a system that has allowed thousands of chemicals into our food that have never been scrutinized by the FDA."[43] The bill seeks to restore consumer confidence by ensuring that the food on their tables is genuinely safe, aligning U.S. food safety practices with public health demands and international standards.[44] Legislation of this nature could be a key turning point in strengthening regulatory oversight, potentially enhancing the safety and transparency of substances entering the American food supply.[45]

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37. Berkeley Lovelace Jr. & Mustafa Fattah, *FDA's 'hands-off approach' to additives may allow unsafe ingredients in food, experts suggest*, NBC NEWS (Aug. 8, 2024), https://www.nbcnews.com/health/health-news/fdas-hands-approach-additives-may-allow-unsafe-ingredients-food-expert-rcna165535.

38. Nick Edwards, *Food Additives Market Sees Growth with Increasing Global Consumption*, S&P GLOBAL COMMODITY INSIGHTS (Mar. 9, 2022), https://www.spglobal.com/commodityinsights/en/ci/research-analysis/food-additives-market-sees-growth-with-increasing-global-consu.html.

39. KELLER AND HECKMAN, *Senate Bill Seeks to Modify FDA's GRAS Program*, (June 10, 2022), https://www.packaginglaw.com/ news/senate-bill-seeks-modify-fdas-gras-program.

40. *Id*.

41. *Id*.

42. OFFICE OF SENATOR MARKEY | CLIMATE HUB, *With Thanksgiving Right Around the Corner, Senators Markey and Booker Announce Legislation to Improve Food Safety and Hold FDA Accountable*, (Nov. 21, 2023) https://www.markey.senate.gov/news/press-releases/with-thanksgiving-right-around-the-corner-senators-markey-and-booker-announce-legislation-to-improve-food-safety-and-hold-fda-accountable.

43. *Id*.

44. *Id*.

45. *Id*.

Opponents of increasing legislation may argue that the heightened scrutiny could inadvertently limit consumer choice because implementing new regulations results in higher compliance costs and pricier products.[46] Therefore, regulations intended to protect vulnerable consumers have the potential to drive up prices and have a disproportionate impact on low-income households.[47] Once beloved and reasonably priced products may become unattainable as removing additives can fail to maintain not only low production costs but also taste, texture, shelf-life, and other characteristics of food that motivate consumers to choose that product over others.[48] Thus, businesses could experience a significant decrease in sales if their products are mandated to be reformulated to comply with the FDA.[49]

However, the potential negative impacts could be outweighed if mandated reformulations successfully made a level playing field for all companies.[50] For example, when the FDA determined that partially hydrogenated oils (PHOs), the primary source of artificial trans fats, were not safe for human consumption in 2015, there was a nationwide mandate requiring food manufacturers to eliminate PHOs from their products by 2018.[51] To eliminate artificial trans fats from the food system, companies were required to reformulate their products in three years.[52] By requiring all manufacturers to meet the same food safety standards, mandatory reformulation ensures fairness in the market and encourages widespread public health improvements.[53] Moreover, products unable to meet these standards could be removed from shelves, ultimately enhancing the overall quality and safety of the food supply.[54]

Furthermore, businesses cannot turn a blind eye due to the urgency of the push for reform. In December 2023, the Environmental

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46. Dustin Chambers & Courtney A. Collins, *How Do Federal Regulations Affect Consumer Prices? An Analysis of the Regressive Effects of Regulation* (Feb. 23, 2016)(Mercatus working paper), https://www.mercatus.org/research/working-papers/how-do-federal-regulations-affect-consumer-prices-analysis-regressive.

47. *Id*.

48. Jessica Fanzo et al., *Challenges and Opportunities for Increasing the Effectiveness of Food Reformulation and Fortification to Improve Dietary and Nutrition Outcomes*, FOOD POL'Y, Aug. 2023, at 1,10.

49. *Id*. (reformulating food products can be a costly endeavor. According to the 2014 Reformulation Cost Model by the U.S. Food and Drug Administration, expenses for reformulation can range from $5,000 to $4 million per product. One study on reformulating children's food products found that costs per serving rose by three to 12 cents, making it challenging for food manufacturers to implement changes without raising prices and potentially losing customers.)

50. *Id*. at 9.

51. *FDA To Remove Trans Fat From Food By 2018*, UPMC HEALTHBEAT (June 19, 2015), https://share.upmc.com/2015/06/fda-to-remove-trans-fat-from-food-by-2018/.

52. Gabrielle Khalife, *Three Years After FDA Released Its Determination the U.S. Is Now Trans-Fat Free*, HUNTER COLL. N.Y.C. FOOD POL'Y CTR. (SEPT. 4, 2018), https://www.nycfoodpolicy.org/three-years-later-the-u-s-is-now-trans-fat-free/.

53. *Id*.

54. *Id*.

Defense Fund and its partners submitted two petitions to the FDA, calling for the revocation of approvals for four known carcinogens: benzene, trichloroethylene, methylene chloride, and ethylene dichloride. Despite being identified as cancer-causing agents since the 1970s and 1980s, these chemicals remain present in certain food products.[55] The FDA's inaction on these known health risks has amplified demands for reform, reflecting a broader push to eliminate harmful substances from the food supply and ensure consumer safety.[56]

Regulatory changes can impose additional burdens on businesses in the food industry, including the need to invest more in compliance efforts and address the pace at which new rules are introduced.[57] Companies will have to navigate stricter transparency and traceability requirements, especially in areas like ingredient sourcing and supply chain transparency, to meet consumer expectations and avoid reputational risks.[58]

IV. ECONOMIC RISKS AND BUSINESS IMPLICATIONS

Non-compliance with food safety regulations can expose U.S. food companies to considerable financial risks and reputational damage.[59] Once a company shows a lack of integrity, their reputation is threatened as the trust between them and their customers, investors, and other key stakeholders erode.[60] This erosion of trust can precipitate novel legal challenges, including government-led lawsuits seeking abatement costs and injunctive relief for public nuisance and unfair competition[61] Thus, companies must carefully comply with shifting food standard regulations, although the pace at which they are evolving presents challenges for compliance.[62]

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55. Liora Fiksel, *Why Are Four Notorious Carcinogens Approved by FDA for Food?*, EDF BLOGS (Feb. 1, 2024), https://blogs.edf.org /health/2024/02/01/why-are-four-notorious-carcinogens-approved-by-fda-for-food/.

56. *Id*.

57. *Managing Regulatory and Compliance Challenges in The Food Industry*, RISK & COMPLIANCE (Sept. 2018), https://riskandcomplianc emagazine.com/managing-regulatory-and-compliance-challenges-in-the-food-industry.

58. *Id*.

59. Soobin Seo et al., *The Impact of Food Safety Events on the Value of Food-Related Firms: An Event Study Approach*, 33 INT'L J. HOSP. MGMT. 153, 154-55, (2013); *see also* Ava C. McCann, *The Skittles Bill: A Legal Analysis of California's Ban on Disease-Linked Food Additives*, SYRACUSE L. REV. (Nov. 2, 2023), https://lawreview.syr. edu/the-skittles-bill-a-legal-analysis-of-californias-ban-on-disease-linked-food-additives/.

60. U.N. OFFICE ON DRUGS & CRIME, *Something's Off: Corruption Risks Related to Food Safety and its Public Health Threats*, at 54-55, (2023).

61. Scott Young, *The New Case Against Ultraprocessed Food,* HARV L. TODAY (Jan. 14, 2026), https://hlsl.harvard.edu/today/the-new-case-against-ultraprocessed-food/.

62. RISK & COMPLIANCE, *Managing Regulatory and Compliance Challenges in The Food Industry*, (Sept. 2018), https://riskandcompliancemagazine.com/managing-regulatory-and-compliance-challenges-in-the-food-industry.

A. Associated Costs with Compliance

However, before diving into the repercussions of non-compliance, it is essential to understand how costly compliance itself can be for food companies. For example, the FDA's economic analysis of the proposed nutrition labeling regulations (Federal Register, 1991), identified several substantial costs for firms.[63] Administrative expenses were estimated at $152 million for approximately 8,900 companies, covering the efforts to interpret the new rules and decide on compliance strategies.[64] For businesses not already providing voluntary nutrition labels, testing costs to determine nutrient content were projected at $112 million in the first year and $195 million over twenty years.[65]

The most significant financial burden came from printing costs.[66] Changing printing plates or other mechanisms to accommodate the new labels was estimated to cost around $756 million.[67] Additionally, inventory costs, representing the value of existing labels that could no longer be used, were estimated at $421 million. These expenses contributed to a total quantified cost of about $1.5 billion over twenty years for compliance with the new regulation.[68] This significant expenditure highlights that compliance with regulatory requirements imposes substantial financial burdens on food companies and has the potential to profoundly impact their profitability and strategic decision-making.

B. Associated Costs with Non-Compliance

Nevertheless, the costs associated with non-compliance can also be significant and far-reaching. Food companies who fail to meet FDA regulatory requirements for their products may face financial consequences, including regulatory penalties, product recall expenses, legal proceedings, and remediation costs, with the total cost varying based on the severity and circumstances of the violation.[69]

To exemplify, the number of food recalls in the U.S. is largely attributed to increasingly heightened regulatory scrutiny.[70] According to a joint industry study by the Food Marketing Institute and the Grocery Manufacturers Association, the average cost of a recall to a food

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63. Elise Golan, Fred Kuchler & Lorraine Mitchell, *Economics of Food Labeling*, U.S. Dep't of Agric., Econ. Research Serv., Agric. Econ. Rep. No. 793 (Dec. 2000).

64. *Id*.

65. *Id*.

66. *Id*.

67. *Id*.

68. *Id*.

69. Andy Pritchard, *The Costs of Non-Compliance for FDA Regulation Violations,* WEEVERAPPS (May 29, 2023), https://weeverapps.com/ compliance-management/non-compliance-costs/.

70. Tyco Integrated Security, *Recall: The Food Industry's Biggest Threat to Profitability*, FOOD SAFETY MAGAZINE (Oct. 11, 2012), https://www.food-safety.com/articles/2542-recall-the-food-industrys-biggest-threat-to-profitability.

company is $10 million in direct costs, not including brand damage and lost sales.[71] For larger brands, these costs can be significantly higher.[72] Direct expenses typically include notification to regulatory bodies, supply chain partners, and consumers; product retrieval and reverse logistics; storage and destruction of unsalable products; and additional labor costs associated with these activities, as well as investigating the root cause of the recall.[73]

However, companies do not only need to worry about potential product recalls as class action lawsuits pose an additional and significant economic threat. For example, the recent class action lawsuit filed against Food Lion regarding their Omazing orange soda alleges that the soda contains brominated vegetable oil (BVO), an additive banned by the FDA as of July 3, 2024, due to health concerns such as neurological problems and thyroid issues.[74] Consumers claim that Food Lion failed to adequately warn them about the presence of BVO and its potential risks.[75] As a result, the company faces significant legal challenges, including demands for refunds, medical monitoring costs, and other damages.[76] Therefore, the substantial risks and costs associated with non-compliance make strict adherence to regulatory requirements not just a legal necessity but a vital component of a food company's financial and reputational well-being.

C. Impacts of a Damaged Reputation

While the financial burdens of compliance and the significant costs associated with recalls are critical considerations for food companies, perhaps the most profound impact of non-compliance arises from potential damage to a company's reputation. When companies fail to comply with food safety regulations, the damage hits brand reputation hard because the risk to consumers is great as prolonged exposure to unsafe food additives may disrupt hormone function and increase the risk of cancer.[77] Thus, a single incident can erode public trust, leading to immediate drops in sales and customer loyalty, especially if social media

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71. *Id*.

72. *Id*.

73. *Id*.

74. Kelly Mehorter, *Class Action Lawsuit Says Food Lion Orange Soda Contains Toxic, FDA-Banned Brominated Vegetable Oil*, CLASSACTION.ORG (Oct. 24, 2024), https://www.classaction.org/news/class-action-lawsuit-says-food-lion-orange-soda-contains-toxic-fda-banned-brominated-vegetable-oil.

75. *Id*.

76. *Id*.

77. *Food Safety Regulations: The Risks of Non-Compliance with it*, DROPPE (Sept. 16, 2024), https://droppe.com/blog/article/risk-of-non-compliance-with-food-safety-regulations; *Lack of Key Considerations in FDA Food Chemical Safety Process Leaves Consumers at Risk of Chronic Diseases*, ENV'T DEFENSE FUND (Sept. 23, 2020), https://www.edf.org/media/lack-key-considerations-fda-food-chemical-safety-process-leaves-consumers-risk-chronic.

amplifies the issue.[78] Regulatory fines or shutdowns can compound these financial losses.[79]

For years, both U.S. federal and state governments, along with private industry stakeholders, have worked diligently to shield consumers from deceptive product messaging.[80] With the rise of lawsuits scrutinizing the misleading of consumers, food manufacturers often face not only the threat of legal penalties but also the potential reputational damage that comes with negative publicity.[81] Many companies opt to settle out of court to avoid the costly legal fees and public fallout that such lawsuits can generate, further impacting consumer trust and brand perception.[82] Non-compliance also affects stakeholders like suppliers and investors, making recovery even more challenging.[83] Thus, ensuring compliance with food safety regulations and norms is not just about avoiding penalties, it is about safeguarding a company's brand and maintaining long-lasting business viability.

Rebuilding a damaged reputation in the long-term requires costly marketing efforts and process improvements, yet past mistakes may continue to influence consumer choices.[84] For instance, in 2015, Kellogg's made an impactful fallacy when the company vowed to remove the artificial colors and ingredients in their products by the end of 2018.[85] They fueled consumer distrust by never discontinuing the use of the controversial additives.[86] In 2024, the consumers had enough and went on to hold a protest, creating a petition with over 400,000 signatures demanding the company stop injecting harmful additives

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78. DROPPE, *supra* note 77; *see also* Terry Slavin, *Why We Should All Be Crying Over Arla's Spilt Milk*, REUTERS (Dec. 9, 2024), https://www.reuters.com/ sustainability/climate-energy/comment-why-we-should-all-be-crying-over-arlas-spilt-milk-2024-12-09/ (In the United Kingdom, a new dairy feed additive used on farms was said to be filtering toxic chemicals into cows' milk which was then sold by a company called Arla. Social media sites like Facebook and TikTok amplified the alleged problem by quickly spreading the information before the company could debunk the claims. TikTokers posted videos of them pouring Arla's milk down the drain and warned that Arla products should be avoided "like the plague." Despite the claims being rooted in misinformation, the brand's reputation is now connected to "countless online conspiracy theories" because of an additive used in animal feed. Therefore, social media has the power to put companies' reputations at significant risk through the use of fear mongering that is grounded in the public's heightened concerns of toxic chemicals).

79. DROPPE, *supra* note 77.

80. Melanie Marie Glover, *The Marketing of Self-Care and Alternative Therapies in the U.S. in 2019: How Industry Stakeholders Appeal to Consumers' Perceptions of Novel Food Products and Additives*, 15 J. FOOD L. & POL'Y 48, 73 (2019).

81. Jane Caldwell, *Food Labels Are Constant Targets of Litigation*, AM. COUNCIL ON SCI. AND HEALTH (Apr. 4, 2022), https://www.acsh.org/news/2022/04/04/food-labels-are-constant-targets-litigation-16219.

82. *Id*.

83. *Id*.

84. DROPPE, *supra* note 77.

85. Nicholas McEntyre, *Protesters Demand Kellogg's Remove 'Harmful Additives' Injected into Froot Loops, Apple Jacks in US: 'Here for All the Mothers,'* N.Y. POST (Oct. 16, 2024), https://nypost.com/2024/10/16/us-news/kelloggs-protesters-demand-cereal-company-remove-artificial-dyes-and-preservatives-during-michigan-rally/.

86. *Id*.

into American Froot Loops and Apple Jacks.[87] Red 40 and Yellow 5 are used to make these products in the U.S. in "pursuit of short-term profits" but are not permitted in products sold in the U.K. While Kellogg contended that their products are safe and abide by federal regulations in the U.S., general compliance is not all that matters for a brand's reputation.[88] Consumer perception can make or break a brand's trajectory of success.

D. Global Compliance and Multinational Challenges

For American food companies, challenges do not end at controlling consumer perception. As previously mentioned, attempting to comply with different countries' food safety standards and import/export regulations is a noteworthy obstacle.[89] The acceptability of food additives is far from universal in the global markets.[90] Therefore, "businesses looking to expand internationally must navigate a web of regulations to gain access to new regions."[91]

For decades, the three prominent safety assessment systems, also known as the "Big Three," have guided these regulations.[92] The Big Three is comprised of the Joint FOA/WHO Expert Committee on Food Additives (JECFA), the European Food Safety Authority (EFSA), and the United States FDA.[93] Thus, for a company to expand or succeed globally, they must understand the nuances of each safety system's approach. For instance, the E.U.'s precautionary approach, in contrast to the U.S.'s risk-based approach, assumes a food product is unsafe until proven otherwise.[94] Under the E.U.'s system, food products face blanket bans or restrictions until their safety is clearly demonstrated to the EFSA, which then approves the use of the new additive before it enters the market.[95] As a result, additives such as titanium dioxide, Red 40, Yellow 5, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), and brominated vegetable oil (BVO) are illegal in the E.U. and remain legal in the U.S.[96]

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87. *Id*.

88. *Id*.

89. NVISION GLOBAL, *Navigating Global Trade Challenges in the Frozen Food Industry*, SUPPLY CHAIN (Jan. 22, 2025), https://corporate.nvisionglobal.com /navigating-global-trade-challenges-in-the-frozen-food-industry/.

90. Mitchell Cheeseman, GLOBAL REGULATION OF FOOD ACTIVITIES, *in* FOOD ADDITIVES AND PACKING 3-4 (2014).

91. *See* RDR GLOBAL PARTNERS, *supra* note 12.

92. *See* Cheeseman, *supra* note 90.

93. *Id*.

94. *See* RDR GLOBAL PARTNERS, *supra* note 12.

95. *Id*.

96. *Id*.

However, with the recent change in American administration, FDA regulations are tightening.[97] As of January 2025, Red Dye No. 3 is finally banned in the U.S., with studies showing it is linked to causing cancer.[98] Therefore, as a food company, it is increasingly burdensome to stay in compliance with changing and varying safety system standards because the standards persistently demand substantial financial investments in reformulating products, ensuring accurate labeling, and meeting regulatory inspections.[99]

Although difficult, compliance is not impossible. Costco Wholesale Corporation is a prime example of how businesses can thrive despite varying food safety standards. To ensure compliance with diverse regulations, Costco requires each of its suppliers to adhere to the highest food safety protocols in the industry.[100] This includes maintaining detailed documentation, implementing robust Hazard Analysis and Critical Control Points (HACCP) plans, and meeting each specific country's regulations.[101] In the U.S., suppliers must comply with the Food Safety Modernization Act's Foreign Supplier Verification Program (FSVP), which Costco enforces by requiring a compliance letter specific to the items and facilities involved.[102] Thus, with strategic planning and a proactive approach, Costco proves that complex global safety systems can be navigated successfully.

Overall, multinational regulatory compliance can pertain to several aspects of normal business operations, such as quality and safety, financial reporting and accounting, and material sourcing laws.[103] Thus, "food manufacturing compliance is an ongoing investment in business success," and many companies engage external experts to gain additional insights and guidance on the subject, ultimately resulting in added expenses.[104]

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97. Robert F. Kennedy Jr., *Enough Is Enough*, at 05:30 (YOUTUBE, Sept. 25, 2025), https://www.youtube.com/watch?v=0_OjKe4BuDE.

98. U.S. FOOD & DRUG ADMIN., *FDA to Revoke Authorization for the Use of Red No. 3 in Food and Ingested Drugs*, (Jan. 15, 2025), https://www.fda.gov/food/hfp-constituent-updates/fda-revoke-authorization-use-red-no-3-food-and-ingested-drugs; Carly Stern, *Health Watchdog Warns of 3 Other Food Additives Linked to Cancer Following Red Dye Ban*, N.Y. POST (Jan. 16, 2025), https://nypost.com/2025/01/16/health/watchdog-warns-of-3-food-additives-linked-to-cancer-after-red-dye-ban/ (Red dye No. 3 has been banned in cosmetics and topical drugs since the 1990s for health reasons, but was not banned from American food until 2025.)

99. *See* RDR GLOBAL PARTNERS, *supra* note 12.

100. COSTCO WHOLESALE CORP., *Food Safety & Quality Audit Expectations for Costco Suppliers* (Apr. 1, 2023), https://azzule.com/wp-content/uploads/2022/11/Food-Safety-Quality-Audit-Expectations-V2.0-Costco.pdf.

101. *Id*.

102. *Id*.

103. TILLEY DISTRIB., *The Costs of Regulatory Non-Compliance* (Oct. 1, 2024), https://www.tilleydistribution.com/insights/the-costs-of-regulatory-non-compliance/.

104. *Id*.

V. BALANCING PROFITABILITY AND COMPLIANCE

With increased compliance expenses, a critical question arises: how can businesses generate sufficient profit to remain competitive in a rapidly evolving market? To achieve a balance between profitability and compliance, companies must implement proactive strategies, such as strengthening corporate governance structures and leveraging compliance teams to research and navigate new regulatory complexities.[105]

A. Corporate Governance and Risk Mitigation

By incorporating stronger corporate governance practices, American companies can enhance their growth and mitigate additive-related risks.[106] Companies lacking corporate governance systems have pushed the public to become more skeptical of the food they are eating.[107] Therefore, transparency, accountability, and ethical behavior are central pillars of effective corporate governance, which can result in growing consumer trust and maintaining business profits.[108] However, a corporate governance framework is influenced by the legal, regulatory, institutional, and ethical context of the surrounding community.[109] Thus, the role of compliance teams and legal departments in mitigating risks varies for every company.[110]

Although there are elements of variability depending on the business, a multitude of "best practices for corporate governance apply to large companies, small companies, public companies, and private companies," and "they even apply to nonprofit organizations and other entities."[111] An important beginning step in developing effective corporate governance practices is recruiting a diverse board of directors that collectively aims to create a diverse, equitable, and

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105. PSICOSMART EDITORIAL TEAM, *How Do International Regulations Impact Corporate Governance Standards Globally?*, PSICO SMART (Aug. 28, 2024), https://psico-smart.com/en/blogs/blog-how-do-international-regulations-impact-corporate-governance-standards-globally-87832.

106. *Id*. ("According to a report by the Organization for Economic Co-operation and Development (OECD), countries that enforce robust corporate governance standards experience an average growth rate of 2-3% higher than their counterparts lagging in governance practices.")

107. Chun-Hsin Chou et al., *What is the Impact of Corporate Governance on the Food Industry at Different Thresholds of Internationalization? A Review*, 67 AGRIC. ECON. 21, 31 (2021).

108. PSICOSMART EDITORIAL TEAM, *supra* note 105.

109. Chun-Hsin Chou et. al., *supra* note 107.

110. AM. PRO. GUIDE, *How Compliance Officers Mitigate Legal Risks*, https://americanprofessionguide.com/how-compliance-officers-mitigate-legal-risks/ (last visited Jan. 25, 2025); KING LAWYER, *The Importance of Legal Teams for Companies: Ensuring Compliance and Mitigating Legal Risks*, https://reyabogado.com/us/why-do-companies-need-a-legal-team/ (last visited Jan. 25, 2025).

111. Kezia Farnham, *14 Effective Corporate Governance Best Practices to Implement Now*, DILIGENT CORP. (Jan. 2, 2025), https://www.diligent.com/resources/blog/best-practices-for-corporate-governance.

inclusive organization.[112] Ideal board members possess CEO or senior management experience with unique backgrounds and no conflicts of interest.[113] Having strong leadership within a company's board can help align incentives and further maintain profitability goals.[114]

B. Proactive Planning for Stricter Regulations

Ideal board leadership can also help companies confront tightening FDA regulations on food additives. American Froot Loops and Apple Jacks with Red 40 or Yellow 5 may become extinct one day under the new administration. The aforementioned recent ban on Red Dye No. 3 in foods and ingested drugs, due to its association with cancer in animal studies, exemplifies this reality. Companies using Red Dye No. 3 are required to reformulate products by January 2027.[115] This single change will affect thousands of food products sold in the U.S., such as Betty Crocker's loaded mashed potatoes and MorningStar Farms' plant-based bacon strips.[116]

Moreover, Robert F. Kennedy Jr., nominated by President-elect Donald Trump and confirmed in February 2025 to lead the Department of Health and Human Services, has made food dyes a key focus.[117] His stance suggests that the recent ban on Red Dye No. 3 marks the beginning of a broader initiative for the U.S. government to crack down on food additives in American food products.[118] Americans may eventually get the same products with the same food quality as many European countries.[119]

However, with this changing regulatory landscape, companies must be vigilant when it comes to compliance research, so they may proactively adapt.[120] Businesses that fail to anticipate and comply with stricter standards risk both legal and reputational risks.[121] Therefore, to ensure profitability and gain a strategic advantage, companies should consider the following four recommended actions:[122]

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112. *Id*.

113. *Id*.

114. *Id*.

115. Roshan Fernandez and Jesse Newman, *FDA Bans Artificial Dye Red 3 From Food*, WALL ST. J. (Jan. 15, 2025), https://www.wsj.com/ health/healthcare/fda-bans-artificial-dye-red-3-from-food-26c9c0e1.

116. *Id*.

117. *Id*.

118. *Id*.

119. Noni Weigand, *Taking A Closer Look at Food Standards: EU Versus U.S.*, RANGEME (July 6, 2021), https://www.rangeme.com/ blog/taking-a-closer-look-at-food-standards-eu-versus-u-s/.

120. FOODINDUSTRY.COM, *The GRAS System: A Critical Look at Food Safety Vulnerabilities* (July 2024), https://www.foodindustry.com/articles/gras-and-a-critical-look-at-food-safety-vulnerabilities/.

121. *Id*.

122. *Id*.

1. **Audit Ingredient Portfolios** – Regularly review and replace controversial additives, such as BHA or BHT, to ensure compliance with updated regulations and consumer expectations.[123]

2. **Develop Strong Internal Safety Protocols** – Conduct third-party safety assessments for all new additives and stay ahead of emerging research that might affect GRAS status.[124]

3. **Reformulate Products** – Shift toward clean label alternatives to align with consumer demand and avoid future bans.[125]

4. **Prepare for Regulatory Tightening** – Monitor policy updates from global regulatory bodies, engage in public comment sessions during FDA rule-making processes, and implement precautionary reformulations ahead of regulatory mandates.[126]

By integrating these strategies, businesses can successfully balance profitability with compliance, staying ahead of regulatory changes while appealing to evolving consumer preferences.[127] Instead of waiting for mandatory regulations, companies that take a proactive stance on food safety will not only reduce legal risks but also strengthen their market position, enhance brand reputation, and drive long-term profitability in a competitive industry.[128]

VI. CONCLUSION

The widespread use of food additives, once a cost-saving strategy, now presents significant legal and reputational risks for U.S. businesses that can lead to substantial expenses. Incorporating high-risk food additives into products for financial gain is no longer a profitable strategy for American food companies. The benefits the additives once brought to the table, such as longer shelf life and better taste and texture, are no longer worth the risks of litigation, mandated reformulation, and reputational harm. Now, businesses must rethink their business strategies around food additives to maintain profitability.

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123. *Id*.

124. *Id*. (companies can adhere to best practices set by the Global Food Safety Initiative (GFSI), which advocates for implementing more rigorous internal controls to ensure food additive safety).

125. *Id*. ("Major food brands, including Kraft, have reformulated products to eliminate artificial dyes in response to growing health concerns. . . . Kraft's decision to remove synthetic colors from its macaroni and cheese was driven largely by consumer pressure").

126. *Id*.

127. *Id*.

128. *Id*.

The rise of lawsuits and consumer protection cases highlights how the public and regulatory bodies are increasingly holding companies accountable for using additives under false or misleading claims. The potential payouts for such lawsuits, ranging from settlements to compliance costs, often outweigh the initial financial gains of using additives.

Additionally, with the FDA's banning and closing of loopholes, it is harder to justify the use of controversial additives. When faced with recalls and reformulation, the financial burdens of noncompliance can reach into the billions of dollars. Not to mention, consumers' growing demand for safer ingredients, if not met, can result in brand deterioration and a decline in sales.

Based on these reasons, businesses should prioritize getting ahead of reformulating products with safer, natural alternatives, enhancing transparency in labeling and ingredient disclosures, and aligning with stricter international food safety standards. To do this and ensure long-term success, it is important for companies to strengthen their corporate governance by implementing proactive compliance programs, investing in research and development, and fostering ethical business practices.

Companies that take preemptive steps will position themselves as industry leaders while avoiding costly regulatory setbacks. By being proactive rather than reacting to enforcement actions, they will gain a strategic advantage. Ultimately, the future of the food industry will be defined by companies that balance profitability with consumer safety, demonstrating that financial success and regulatory compliance can coexist in a responsible and ethical business model.