

FROM RISK TO PREVENTION: THE CASE FOR PRECAUTIONARY FOOD REGULATION IN THE UNITED STATES

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ABSTRACT

Telling your financial planner how much risk you're willing to take with your investments, choosing your level of insurance coverage, and deciding whether to wear a seatbelt are all risks you consciously evaluate and control. But when it comes to the food you eat, you don't get to choose those risks—they're determined for you by a regulatory system that, at least in the United States, often puts industry interests ahead of consumer safety.

The United States' regulation of food is largely reactive, where a proven harm triggers action. Despite mounting health concerns, this regulatory framework permits the ongoing use of additives, chemicals, and foods that pose potential risks to public health. In contrast, the European Union grounds its approach in the Precautionary Principle, which requires proactive legal intervention in the face of scientific uncertainty. This Principle prioritizes consumer safety and mandates regulatory action, even without conclusive evidence of harm. This Note explores the differences between the regulatory frameworks of the United States and European Union, analyzing their impact on public health. It argues that the European Union's strict legal oversight has contributed to healthier populations and fewer food-related risks. By adhering to a safe until proven harmful regulatory model, the United States exposes its population to avoidable health risks and falls further behind international food safety standards. This Note asserts that adopting a precautionary framework in the United States is not just a regulatory change—it is a public health necessity.

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INTRODUCTION

Whether as a New Year's resolution or as a broader lifestyle goal, many Americans increasingly recognize the importance of maintaining a healthy lifestyle as they age.¹ What often goes unnoticed, however, is that the reactive regulatory framework governing food safety and standards constrains the level of health attainable within the United States. The United States' (US) reactive framework, mandates evidence of tangible harm from food before regulatory action can be taken, permitting the inclusion of potentially dangerous additives, colorants, supplements, and chemicals into the US food supply. In contrast, the European Union (EU), acting under a precautionary framework, regulated many of these dangerous inclusions in food much earlier. As its guiding framework, the Precautionary Principle drives earlier regulatory action in the EU by emphasizing action before potential harms arise.² This Principle has been applied to the governance of food within the EU, thereby leaving the food supply in the EU much safer than in the US.³

Food regulations are the backbone of public health. This proposition is highlighted by the stark contrast in health outcomes between US and EU. The EU's healthier citizens owe much to the Precautionary Principle, a proactive approach to food safety. The US should embrace this Principle without delay to boost its own public health.

This Note, in Part I, provides background concerning the adoption of the Precautionary Principle within the EU and, by contrast, the basis of the reactionary framework in the US and the reasons for its stronghold. Part I also details how the EU and US have applied their respective frameworks to the regulation of food.

Part II explores the various ways in which the Precautionary Principle has led to earlier and stricter regulation of potentially harmful elements in the EU's food supply, such as additives, colorants, supplements, and chemicals. It next details how the Precautionary Principle has enhanced transparency and understanding by consumers.

¹ Medifast, Inc., *Medifast Survey Finds 93% of U.S. Adults Set Health Goals*, PR NEWSWIRE (June 11, 2021, 8:30 AM), <https://www.prnewswire.com/news-releases/medifast-survey-finds-93-of-us-adults-set-health-goals-301310830.html> [https://perma.cc/R8WB-VFCF].

² Lucas Bergkamp & Jaap C. Hanekamp, *European Food Law and the Precautionary Principle: Paradoxical Effects of the EU's Precautionary Food Policies*, in 6 ECON. ANALYSIS L. EUR. LEGAL SCHOLARSHIP 217, 219 (Harry Bremmers & Kai Purnhagen eds., 2018); Didier Bourguignon, Eur. Parliamentary Rsch. Serv., *The Precautionary Principle: Definitions, Applications and Governance*, PE 573.876, 1 (2016).

³ See Bergkamp & Hanekamp, *supra* note 2, at 219.

Most importantly, Part II contends that the United States both can and should transition to a more precautionary framework.

Part III concludes by confronting and overcoming arguments against the Precautionary Principle. It highlights past situations in which regulatory delay in the US caused greater harm and reaffirms the need for a precautionary framework for food regulation.

I. BACKGROUND

Global food safety regulation reveals a striking divergence in the approaches taken by the EU and the US.⁴ Broadly speaking, the EU prioritizes prevention in the case of uncertainty, whereas, the US generally takes regulatory action once concrete evidence of harm has been proven.⁵ Since 1990, the US has been increasingly hesitant to adopt strict food safety regulations. In contrast the EU has surged ahead, quickly enacting firm regulatory regimes whenever human safety seems in jeopardy.⁶ This regulatory difference stems from the underlying guiding principles adopted in the European Union, specifically the Precautionary Principle.⁷ The EU's reliance on the Precautionary Principle has led to the proactive regulation of risks when it comes to food safety, while the US' seeming opposition to the Precautionary Principle has created a reactionary system around food regulation in which regulations are enacted only once harm is proven.⁸

A. THE PRECAUTIONARY PRINCIPLE IN THE EUROPEAN UNION

I. Origins and General Application

The European Union adopted the Precautionary Principle in 1992 through the Maastricht Treaty.⁹ The treaty emphasized taking action to protect the environment when potential threats of harm emerged.¹⁰ Since its adoption, the European Court of Justice—the judicial branch of the

⁴ Jonathan B. Wiener & Michael D. Rogers, *Comparing Precaution in the United States and Europe*, 5 J. RISK RSCH. 317, 317 (2002).

⁵ *Id.*

⁶ DAVID VOGEL, *THE POLITICS OF PRECAUTION* 4 (2012).

⁷ Bergkamp & Hanekamp, *supra* note 2, at 218.

⁸ Wiener & Rogers, *supra* note 4, at 317.

⁹ Bergkamp & Hanekamp, *supra* note 2, at 218.

¹⁰ *Id.*

EU—has expanded its scope beyond environmental concerns by ruling that the Precautionary Principle protects human health and safety.¹¹ Now included in Article 191 of the Treaty on the Functioning of the European Union, the Precautionary Principle directly prescribes that “a high level of human protection shall be ensured in the definition and implementation of all Union policies and activities.”¹² The Precautionary Principle becomes relevant when the EU pursues a high level of human protection, characterized by proactive policies that prioritize preventing harm and minimizing exposure to potential threats.¹³

A cornerstone of the Precautionary Principle is scientific uncertainty. In its broadest sense, precaution involves acting to mitigate possible risks or injuries before it is reasonably certain a threat will materialize.¹⁴ Accordingly, this Principle imposes regulation at an early stage, when scientific evidence, even without conclusive proof of harm, suggests a potential danger to human health or the environment.¹⁵ There are three core elements of the Precautionary Principle: (1) the existence of a risk perceived as a threat of harm to human health or the environment; (2) the presence of scientific uncertainty regarding the potential effects of that threat; and (3) corresponding action taken by a group or agency to bring attention to the threat and its potential risks.¹⁶ At its foundation, the Precautionary Principle aims to prevent harm before it occurs, rather than delaying action until harm has occurred and been substantiated.¹⁷

2. Application to Food Regulation

The European Union has fully embraced the Precautionary Principle in its regulation of food. The EU’s regulatory framework for food is Regulation 178/2002/EC, commonly known as the General Food Law.¹⁸ The General Food Law aims to provide a high level of protection

¹¹ Bergkamp & Hanekamp, *supra* note 2, at 218; Bourguignon, *supra* note 2, at 6, 10.

¹² Wieke Willemijn Huizing Edinger, *A Legal Perspective on EU Competence to Regulate the ‘Healthiness’ of Food*, 9 EUR. FOOD & FEED L. REV. 11, 13 (2014); Bourguignon, *supra* note 2, at 5.

¹³ Bourguignon, *supra* note 2, at 9.

¹⁴ Bergkamp & Hanekamp, *supra* note 2, at 219.

¹⁵ Bergkamp & Hanekamp, *supra* note 2, at 219; Bourguignon, *supra* note 2, at 4, 6.

¹⁶ Alessandra Guida, *The Precautionary Principle and Genetically Modified Organisms: A Bone of Contention Between European Institutions and Member States*, 8 J. L. & BIOSCIENCES, Jan.–June 2021, at 1, 8.

¹⁷ Bourguignon, *supra* note 2, at 6–7.

¹⁸ Bergkamp & Hanekamp, *supra* note 2, at 217.

to human life, health, and consumer interests.¹⁹ This objective clearly invokes the Precautionary Principle, and thus this Principle has become the fundamental guiding approach for the regulation of food.²⁰ This framework encourages strict regulation of food within the EU whenever potential dangers exist. Additionally, the framework emphasizes transparency and consumer education around food, viewing an informed consumer as essential to proactively protecting public health.²¹

The General Food Law also established the European Food Safety Authority (EFSA), which conducts scientific evaluations of food and provides advice on food related risks.²² The General Food Law is also enforced by the European Commission, which proposes and implements food safety regulations.²³ Together, the EFSA and the European Commission collaborate to determine and implement appropriate risk management measures under the General Food Law, guided by the Precautionary Principle.²⁴

The Court of Justice of the European Union (CJEU), analogous to the United States Supreme Court, plays a significant role in interpreting and applying the Precautionary Principle through the cases it resolves.²⁵ In 1983, the CJEU recognized the idea underlying the Precautionary Principle for the first time,²⁶ but it wasn't until 2000 in *Greenpeace France* that the court expressly referenced the Precautionary Principle in its reasoning.²⁷ Since 2000, the CJEU has frequently referred to the principle to uphold regulations that preventively protects human health and safety.²⁸

¹⁹ *Id.* at 218.

²⁰ *Id.* at 217.

²¹ EUROPEAN FOOD SAFETY AUTHORITY, ABOUT US, <https://www.efsa.europa.eu/en/about/about-efsa> [<https://perma.cc/8GKS-9UAD>] (last visited Nov. 3, 2025).

²² Bergkamp & Hanekamp, *supra* note 2, at 218; *European Food Safety Authority*, EUROPEAN UNION, <https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-food-safety-authority-efsa> [<https://perma.cc/766U-SUHF>] (last visited Oct. 18, 2024).

²³ *European Commission*, EUROPEAN UNION, <https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-commission> [<https://perma.cc/795H-B5UJ>] (last visited Oct. 18, 2024).

²⁴ See *European Food Safety Authority*, *supra* note 22.

²⁵ *Court of Justice of the European Union (CJEU)*, EUROPEAN UNION, <https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/court-justice-european-union-cjeu> [<https://perma.cc/5CS6-HUJC>] (last visited Nov 12, 2024); Bourguignon, *supra* note 2, at 10; Guida, *supra* note 16, at 6.

²⁶ Guida, *supra* note 16, at 6.

²⁷ *Id.*

²⁸ Guida, *supra* note 16, at 6; Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union*, 2002 E.C.R. II-3318.

Thus, many of the CJEU's decisions upholding food and consumer safety regulations reference the Precautionary Principle as a guiding pillar of EU law.²⁹

For example, the CJEU relied on the Precautionary Principle in *Case C-157/96, Queen v. National Farmers Union*, which came in front of the CJEU in 1988.³⁰ The EU had adopted an emergency measure designed to protect against bovine spongiform encephalopathy, an often-fatal neurological disease in cattle with links to human illness.³¹ The emergency measure enacted by the European Commission imposed a temporary, but total, ban on imports of bovine meat and bovine derived products by the Member States of the European Union.³² Importers of such products challenged the EU's ban.³³ The CJEU ultimately upheld the ban, declaring that the Commission was justified in enacting it.³⁴ The court reasoned that "where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent."³⁵ With that statement, the CJEU plainly embraced the Precautionary Principle to proactively protect against the potential dangers associated with bovine spongiform encephalopathy.

Another milestone case for the CJEU's embrace of the Precautionary Principle occurred in 2002 in *Case T-13/99, Animal Health SA v. Council of the European Union*.³⁶ Here, the CJEU upheld a ban on antibiotics in animal feed, explicitly citing the Precautionary Principle in its reasoning and highlighting the different regulatory approaches taken by the US and the EU.³⁷ Pfizer, an American pharmaceutical company, challenged the EU's ban on the use of antibiotics as growth promoters in animal feed.³⁸ As a reoccurring theme, American companies are deterred

²⁹ See *Case C-157/96, The Queen v. Nat'l Farmers' Union*, 1998 E.C.R. I-02211; *Case T-13/99, Pfizer Animal Health SA v. Council of the European Union*, 2002 E.C.R. II-3318; Guida, *supra* note 16, at 6.

³⁰ *Case C-157/96, The Queen v. National Farmers' Union*, 1998 E.C.R. I-02211.

³¹ *Id.* ¶ 1.

³² *Id.* ¶ 10.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.* ¶ 63.

³⁶ *Case T-13/99, Pfizer Animal Health SA v. Council of the European Union*, ECLI:EU:T:2002:209, (Sept. 11).

³⁷ *Id.*

³⁸ *Id.*

from adopting the Precautionary Principle because of restrictions on exports and trade.

The EU based its ban on acknowledged, yet uncertain, risks that consuming animals raised on feed containing growth promoters could lead to antibiotic resistance in humans.³⁹ Despite the absence of definitive risk, the CJEU ruled that the potential danger sufficiently justified the EU's ban.⁴⁰ The court reasoned that "where there is scientific uncertainty as to the existence or extent of risks to human health, the Community institutions may, *by reason of the Precautionary Principle*, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent."⁴¹ In addition, the court outlined the list of relevant factors in determining the level of risk deemed unacceptable: (1) the severity of the impact on human health, were the risk to occur; (2) the extent of possible adverse effects; (3) the persistency or reversibility of those effects; and (4) the possibility of delayed effects, as well as the more or less concrete perception of the risk based on available scientific knowledge.⁴² The court clearly relies on the Precautionary Principle as a cornerstone of EU food regulation.

B. THE REACTIONARY APPROACH IN THE UNITED STATES

1. *Overview of Reactionary Food Regulation*

In stark contrast with the European Union's embrace of the Precautionary Principle, the United States' approach to food regulation follows a reactive regulatory framework that waits for concrete evidence of harm before taking action.⁴³ Many notable differences exist between the two approaches.⁴⁴ The US does not outwardly and obviously embrace a guiding principle analogous to the Precautionary Principle in the EU.⁴⁵ Instead, analyzing existing caselaw, including the Supreme Court's handling of US regulations, reveals the US' reactionary nature. The US' response to certain EU regulations based on the Precautionary Principle

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.* (emphasis added).

⁴² *Id.* ¶ 153.

⁴³ *Id.* ¶ 139; see also *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452 (2012).

⁴⁴ See generally Wiener & Rodgers, *supra* note 4 at 317.

⁴⁵ *Id.* at 318.

further illustrates its reactionary nature, particularly when those regulations create trade conflicts.⁴⁶

To fully grasp the US' reactionary approach, it is important to understand the agencies tasked with food regulation in the US. The Food and Drug Administration (FDA) is the primary agency that regulates food in the US.⁴⁷ The FDA is tasked with protecting public health by ensuring the safety, efficacy, and security of the food supply and other products.⁴⁸ Within the FDA, the Food Safety and Inspection Service regulates meat, poultry, and processed egg products.⁴⁹ Additionally, the United States Department of Agriculture plays a significant role by conducting domestic reports and risk assessments.⁵⁰

The US' tendency to regulate reactively extends beyond food safety to broader regulatory policies, as exemplified in *Industrial Union Dept., AFL-CIO v. API*, commonly known as the Benzene Case.⁵¹ Although this case does not specifically pertain to food regulation, it highlights the overarching reactionary approach the US takes toward protective regulations.⁵² In this case, the US' Occupational Safety and Health Administration tasked the Secretary of Labor with creating standards to ensure safe and healthy working conditions.⁵³ The Secretary found that no safe exposure level could be determined for benzene, a colorless flammable liquid commonly found in oil and gasoline, and therefore set exposure limits at the lowest feasible level.⁵⁴ The fact that exposure to even low levels of benzene can impair cell functioning and

⁴⁶ Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 525 (1998); see, e.g., *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607 (1980); *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996); *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452 (2012).

⁴⁷ *Food Safety Agencies & Partners*, U.S. DEP'T OF AGRIC. (Mar. 07, 2019), <https://www.fsis.usda.gov/about-fsis/food-safety-agency-partners> [<https://perma.cc/YM7Y-7DW3>].

⁴⁸ *Food and Drug Administration (FDA)*, USA GOV, <https://www.usa.gov/agencies/food-and-drug-administration> [<https://perma.cc/NE8L-XNWK>] (last visited Oct. 18, 2024).

⁴⁹ *About FSIS*, U.S. DEP'T OF AGRIC., <https://www.fsis.usda.gov/about-fsis> [<https://perma.cc/R2UV-BFJY>] (last visited Oct. 18, 2024).

⁵⁰ *Health and Safety*, U.S. DEP'T OF AGRIC., <https://www.usda.gov/topics/health-and-safety> [<https://perma.cc/3TZR-FA5H>] (last visited Oct. 18, 2024).

⁵¹ See *Indus. Union Dept., AFL-CIO v. API*, 448 U.S. 607 (1980).

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.* at 613.

significantly increase the risk of developing leukemia led to this decision.⁵⁵

When assessing the regulation, the Supreme Court found that, because the Secretary of Labor did not have concrete findings that exposure to benzene presents a significant health risk, exposure levels cannot be set at the lowest possible level.⁵⁶ Here, the Supreme Court expressly stated that the Occupational Safety and Health Administration cannot regulate on the basis of mere conjecture about uncertain risk. This holding is in direct contrast with the Precautionary Principle employed in the EU.⁵⁷

The US also embraced a reactionary approach in the 2012 case *National Meat Association v. Harris*.⁵⁸ This case concerned a California law which, citing food safety and animal welfare concerns, prohibited the sale of non-ambulatory animals.⁵⁹ California lawmakers argued that outright banning the sale of such animals would prevent potentially diseased or contaminated meat from entering the food supply.⁶⁰ However, the Supreme Court struck down the California law, reasoning that it was preempted by the Federal Meat Inspection Act. This Act permits the sale of non-ambulatory animals, provided certain basic federal safety and inspection requirements are satisfied—thereby superseding any state laws that impose more restrictive standards.⁶¹ The Court's decision highlighted the tension between state efforts to adopt stricter, proactive safety measures and the dominance of federal law in regulating food safety. Ultimately, the reactive nature of the US regulatory framework is illustrated by this ruling, where interventions often occur only after the emergence of contamination risks or food safety concerns, rather than through preventative measures.

⁵⁵ *Id.*; *Chemical Emergencies, Benzene*, CTR. FOR DISEASE CONTROL (Sept. 6, 2024), <https://www.cdc.gov/chemical-emergencies/chemical-fact-sheets/benzene.html> [<https://perma.cc/5CS6-HUJC>].

⁵⁶ *Indus. Union Dept., AFL-CIO*, 448 U.S. at 640.

⁵⁷ *Wiener & Rodgers*, *supra* note 4 at 318.

⁵⁸ See *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452 (2012).

⁵⁹ *Id.* at 464. Non-ambulatory animals are those unable to walk.

⁶⁰ *Id.* at 455.

⁶¹ *Id.* at 459-460.

2. Reasons for a Reactive Framework

Several explanations have been suggested for why the United States has taken a more reactionary approach to food regulation. In the 1980s, risk management decisions in the US were shaped by formal risk assessments.⁶² These assessments led to an increased threshold of scientific evidence required to justify new regulations.⁶³ The US' focus on individualism and desire for minimal government intervention constitutes another reason for its embracing of a reactionary framework.⁶⁴ These preferences have shaped a regulatory framework that allows individuals to act on their own accord, unless interference is absolutely necessary.⁶⁵ Additionally, as seen through the US' reaction to many EU bans affecting trade, the US' interest in maximizing free trade and minimizing trade barriers likely motivates its more reactionary approach to food regulation.⁶⁶

For example, the 1989 Beef Hormone Dispute arose out of the EU's ban on importing meat from animals treated with any one of six types of growth hormones commonly used in the US.⁶⁷ The US challenged the ban, arguing that it lacked the scientific evidence to justify the restriction.⁶⁸ Eventually, the World Trade Organization ruled against the EU ban, aligning with the US' emphasis on scientific certainty, economic interests, and trade relations. A combination of these factors have likely contributed to the reactive regulatory approach practiced in the US. When regulating food, it is important to consider the outcomes of waiting for harm to occur before acting, compared to the EU's approach of preventing harm before it occurs.

II. ARGUMENT

Aligned with the aim of preventing harm proactively, it is no surprise that a comparison of the EU' and US' approaches to additives and chemicals in food reveals a more stringent regulatory framework in the EU. The following Part outlines how the Precautionary Principle functions

⁶² VOGEL, *supra* note 6, at 119.

⁶³ *Id.*

⁶⁴ *Id.* at 30.

⁶⁵ *Id.* at 3.

⁶⁶ *Id.* at 4.

⁶⁷ RENÉE JOHNSON, *The U.S.-EU Beef Hormone Dispute* (CONG. RSCH. SERV. R40449, 2017).

⁶⁸ *Id.*

within EU food regulations and how it contrasts with analogous US regulations. Overall, this argument posits that the US should adopt a precautionary approach to food regulation, proactively safeguarding its citizens from potential risks before the food reaches their table.

A. THE PRECAUTIONARY PRINCIPLE'S IMPACT ON FOOD ADDITIVE REGULATION IN THE EU

1. *Food Additives*

The rigorous food regulation in the EU, resulting from the Precautionary Principle, becomes apparent when comparing the number of food additives approved for use in the EU and the US.⁶⁹ As of 2024, the EU had approved fewer than five hundred food additives, in stark contrast to the estimated ten thousand additives approved for use in the US.⁷⁰ The substantial number of approved food additives in the US is a direct result of the reactive framework and regulatory loopholes created by the hands-off approach.

The US food industry distinguishes between “food additives” and “generally recognized as safe” (GRAS) ingredients.⁷¹ While food additives must be reviewed by the FDA, substances classified as GRAS ingredients are exempt thereby creating a significant regulatory loophole for US food manufacturers.⁷² In 1958, the Food Additive Amendment to the Federal Food, Drug, and Cosmetic Act first created the GRAS loophole.⁷³ The amendment was initially designed for well-known food ingredients such as vinegar, flour, and baking soda. It allows food manufacturers to bypass FDA safety review and take their products directly to market if experts generally recognize the ingredients as safe.⁷⁴

⁶⁹ Leigh Ann Winick, Adam Yamaguchi and Taylor Mooney, *The Federal Loophole that Allows Food Companies to Decide What's Safe for You to Eat*, CTR. FOR HEALTH L. AND POL'Y INNOVATION (Sept. 9, 2024), <https://chlp.org/news-and-events/news-and-commentary/food-law-and-policy/the-federal-loophole-that-allows-food-companies-to-decide-whats-safe-for-you-to-eat/> [https://perma.cc/3JBM-NSPZ].

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ Thomas Galligan, Jensen N. Jose & Adrienne Crezo, *How Food Companies Sneak New Ingredients Past the FDA*, CTR. FOR SCI. IN THE PUB. INT. (Mar. 4, 2024), <https://www.cspi.org/cspi-news/how-food-companies-sneak-new-ingredients-past-fda> [https://perma.cc/22JN-WCB9].

⁷⁴ *Id.*

This loophole expanded in 1997 when the FDA introduced a “voluntary notification” process for GRAS.⁷⁵ Under the voluntary notification process, food manufacturers are permitted to self-certify new additives as safe, circumventing FDA oversight.⁷⁶ By allowing the food industry to determine which substances qualify as GRAS ingredients, the FDA has enabled the classification to expand significantly beyond its original scope—common food ingredients.⁷⁷

Three different routes exist by which new food additives enter the US food supply.⁷⁸ Two of these three routes are through the GRAS loophole: one is secretive—where the manufacturer determines that the substance is generally recognized as safe with no FDA oversight.⁷⁹ The other involves discretionary notice, where the manufacturer informs the FDA through a voluntary notice that the substance is GRAS.⁸⁰ The third route is through FDA pre-market approval.⁸¹ Despite three available avenues, almost half of the food additives in the US fall under GRAS.⁸² Thus, the FDA requires no premarket approval for nearly half of all food additives before manufacturers place them on the market.⁸³ In 2021, the voluntary notification GRAS loophole was challenged in court. Ultimately the loophole was upheld and justified by a classic reactionary approach: the FDA will take action if research emerges suggesting harm from a new food ingredient.⁸⁴ Such hands-off regulation of food additives in the US has placed the FDA in the role of a referee, acting only when it sees a bad call, rather than taking its appropriate role as the coach, ensuring food safety from the outset.⁸⁵

In contrast, the EU has embraced its role as coach, actively guiding the game to prevent harmful additives from ever entering play. Driven by the Precautionary Principle, the EU’s stricter approach requires food additives’ safety be proven *before* entering the market. EU authorities

⁷⁵ Winick et al., *supra* note 69.

⁷⁶ *Id.*

⁷⁷ Rachel Harrison, *How a Legal Loophole Allows Unsafe Ingredients in U.S. Foods*, NEW YORK UNIV. NEWS (Aug. 8, 2024), <https://www.nyu.edu/about/news-publications/news/2024/august/legal-loophole-unsafe-ingredients.html> [<https://perma.cc/XPR4-GW7C>].

⁷⁸ Galligan et al., *supra* note 73.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *See id.*

⁸² Winick et al., *supra* note 69.

⁸³ *See id.*

⁸⁴ *See id.*

⁸⁵ *See id.*

must approve food additives before they can be used.⁸⁶ Unlike the US, the EU has no GRAS loophole; instead, it requires a multi-step approval process for food additives.⁸⁷ First, the applicant must submit an application containing both general and specific data needed for the risk assessments conducted by the European Food Safety Authority.⁸⁸ The EFSA then conducts risk assessments and evaluates an additive's safety by considering all available data on its chemical and biological properties, potential toxicity, and estimated dietary exposure.⁸⁹ In addition to this stringent process, the EFSA also conducts retroactive safety assessments of food additives approved before 2009—when the agency was established—to ensure they comply with current safety standards and reflect the latest scientific knowledge.⁹⁰

Although at first glance the differences in food additive regulations may not seem alarming, they can have profound effects for our health. Consumers cannot make informed decisions without actually knowing what is in the food they are consuming. Moreover, a thorough examination of the entities responsible for overseeing public health is essential. The US loopholes, as they currently exist, allow food manufacturers to be the deciding entity for roughly half of the new food additives entering the US food supply.⁹¹ The parties responsible for determining the safety of food in the US have the greatest financial incentive to make food addictive and profitable, rather than safe. The risks inherent in the US' approach to food additives, compared with the EU, demonstrates one of many reasons the US should adopt the precautionary approach to food regulation.

⁸⁶ *EU Rules – Food Additives*, EUR. COMM'N, https://food.ec.europa.eu/food-safety/food-improvement-agents/additives/eu-rules_en [<https://perma.cc/7RTE-UAB6>] (last visited Nov. 12, 2024).

⁸⁷ *Id.*

⁸⁸ *Common Authorization Procedure*, EUR. COMM'N, https://food.ec.europa.eu/food-safety/food-improvement-agents/common-authorisation-procedure_en [<https://perma.cc/SZQ8-BQU6>] (last visited Nov. 12, 2024).

⁸⁹ *Food Additives*, EUR. FOOD SAFETY AUTH., <https://www.efsa.europa.eu/en/topics/topic/food-additives> [<https://perma.cc/8Z56-C8CN>] (last visited Sept. 24, 2025).

⁹⁰ *Id.*

⁹¹ See Winick et al., *supra* note 69; Melanie Benesh & Bennet Rosenberg, *EWG Analysis: Almost All New Food Chemicals Greenlighted by Industry, Not the FDA*, ENV'T WORKING GRP. (July 22, 2025), <https://www.ewg.org/news-insights/news/2025/07/ewg-analysis-almost-all-new-food-chemicals-greenlighted-industry-not-fda> [<https://perma.cc/7MMN-PRZG>].

2. Color Additives

The European Union's application of the Precautionary Principle has led to more stringent regulations, and, in many cases, outright bans of color additives.⁹² To gain approval for a food color within the EU, the applicant submits an application to the European Commission, and the EFSA carries out a full-blown risk assessment, as it does for other food additives.⁹³ This process includes evaluating potential harms arising from the additive's use, in particular, long-term health effects and risks to vulnerable populations.⁹⁴ As part of the color additive application, the applicant must (1) justify the need for the additive, (2) demonstrate its effectiveness, (3) present the consumer benefits, and (4) explain how its use will not mislead consumers.⁹⁵ No such application requirements exist in the US.⁹⁶ Additionally, if the EU approves a color additive, the EU then requires a warning label be affixed to the food indicating that it contains potentially harmful color additives.⁹⁷

On the other hand, the US government has taken no formal nationwide action due to its prevailing focus on managing proven risks rather than potential ones.⁹⁸ Currently, the US permits the use of several synthetic color additives in food, whereas the EU has regulated certain dyes due to concerns about their potential link to attentional and behavioral problems in children.⁹⁹ The banned dyes is a major factor contributing to this discrepancy.¹⁰⁰ The US evaluates color additives based solely on safety assessments and approves them only if convincing evidence shows no harm will result from their intended use.¹⁰¹ But, this approach does not proactively consider potential risks in the way the EU's framework does.¹⁰² The EU's commitment to preventing risks before they emerge

⁹² Sari Lehto et al., *Comparison of Food Colour Regulations in the EU and the US: a review of current provisions*, 34 *Food Additives & Contaminants: Part A* 335, 340 (2017).

⁹³ *Id.* at 340.

⁹⁴ *See id.* at 340.

⁹⁵ *See id.* at 340.

⁹⁶ *Id.* at 341.

⁹⁷ *The Risks of Red 40: Crucial Facts Uncovered*, PEDERSON'S NATURAL FARMS, <https://pedersonsfarms.com/blogs/blog/the-risks-of-red-40-crucial-facts-uncovered> [<https://perma.cc/F5LU-5AC2>] (last visited Nov. 12, 2024) [hereinafter *The Risks of Red 40*].

⁹⁸ Lehto, *supra* note 92 at 338.

⁹⁹ *Id.* at 338.

¹⁰⁰ *See id.* at 338-340.

¹⁰¹ *Id.* at 341.

¹⁰² *See id.* at 341.

creates a significantly higher barrier to entry for color additives than exists in the US.

The US and EU also diverge in their approach to post-approval regulatory oversight and removal of color additives from their food supplies. In recent years, extensive research has highlighted the negative effects food colors and dyes can have on attention in children.¹⁰³ Data from multiple evidence streams support the conclusion that synthetic food dyes lead to hyperactivity and other neurobehavior problems in some children, especially children with a propensity for attention disorders.¹⁰⁴ Several studies have also reported early findings indicating that initial acceptable daily intake values may not provide adequate protection against neurobehavioral impacts in children caused by synthetic food dyes.¹⁰⁵ Children's lower tolerance to chemical exposure makes them more vulnerable than adults to the harmful effects of these synthetic colors.¹⁰⁶ In response to these concerns and with a desire to prevent harm before it occurs, the EU has banned many of these dyes and extensively regulated the rest.¹⁰⁷ For example, the EU imposes strict labeling requirements on the few dyes it does approve, mandating that every product containing these dyes includes a warning that it "may have an adverse effect on activity and attention in children."¹⁰⁸ The EU has relied on the Precautionary Principle for such post-approval regulation, pointing to the health consequences of hyperactivity and ADHD in children, migraine symptoms, as well as the risk of cancer as the grounding behind the regulation.¹⁰⁹

At the other end of the spectrum, the US has followed a reactionary approach and has hesitated to act, citing the inconclusive nature of such studies. Finally, after years of outcry from concerned

¹⁰³ MARIANNIE AKINTUNDE ET AL., HEALTH EFFECTS ASSESSMENT: POTENTIAL NEUROBEHAVIORAL EFFECTS OF SYNTHETIC FOOD DYES IN CHILDREN 20 (Off. Env't. Health Hazard Assessment, 2021).

¹⁰⁴ *Id.* at 20-21; *The Risks of Red 40*, *supra* note 97.

¹⁰⁵ Akintunde, *supra* note 104 at 23.

¹⁰⁶ Elizabeth Chuck, *California Governor Signs Landmark Legislation Prohibiting Six Artificial Dyes from the Food Served at Public Schools*, NBC NEWS (Sept. 30, 2024, 2:35 PM), <https://www.nbcnews.com/news/us-news/california-governor-signs-legislation-prohibiting-six-artificial-dyes-rcna173232> [<https://perma.cc/VQC5-DEV5>].

¹⁰⁷ *The Risks of Red 40*, *supra* note 98; Lisa Rapaport, *Why Are Some Food Additives That Are Banned in Europe Still Used in the U.S.?*, EVERYDAY HEALTH (Oct. 9, 2023), <https://www.everydayhealth.com/diet-nutrition/why-are-some-food-additives-that-are-banned-in-europe-still-used-in-the-us/> [<https://perma.cc/Y73E-FPMA>].

¹⁰⁸ Lehto et al., *supra* note 93, at 350-351.

¹⁰⁹ *The Risks of Red 40*, *supra* note 97; Rapaport, *supra* note 107.

parents and health organizations and following the EU's lead, individual states responded by enacting bans on synthetic dyes.¹¹⁰ In September 2024, California Governor Gavin Newsom signed the California Food Safety Act into law, being the first US law to ban food dyes from being served in public schools.¹¹¹ The law bans six harmful dyes: Red 40, Yellow 5, Yellow 6, Blue 1, Blue 2, and Green 3. The law cites neurobehavior problems in children as well as studies suggesting a potential link to cancer as reasons behind the ban.¹¹² California manufacturers are required to eliminate synthetic dyes from their recipes and substitute them with natural alternatives such as beet juice, carrot juice, pumpkin extract, or paprika extract.¹¹³ Many companies in the EU have already adopted these natural alternatives in place of synthetic dyes.¹¹⁴ To allow food manufacturers time to adjust their formulations, the California law is scheduled to take full effect on December 27, 2027.¹¹⁵

A precautionary approach promotes healthier outcomes in the EU, therefore, the US should adopt a framework for food regulation that aims to be more preventative in nature. Food dye regulation exemplifies how divergent regulatory frameworks in the US and EU are affecting public health outcomes.

Critics frequently argue the Precautionary Principle stifles innovation.¹¹⁶ Yet, in the case of regulating harmful food dyes, it has driven the development of healthier alternatives.¹¹⁷ Numerous alternatives to harmful dyes already exist, and the Precautionary Principle has pushed the EU to find those alternatives.¹¹⁸ While states such as California are allowed to implement stringent regulations, individual states alone cannot build a robust, nationwide food system.¹¹⁹ The FDA must take the lead in setting food safety standards to ensure the entire nation is protected.¹²⁰

¹¹⁰ See, e.g. Brian Ronholm, *California Leads the Nation with First Ban on Six Harmful Food Dyes in School Food*, CONSUMER REPS. (Sept. 28, 2024), https://advocacy.consumerreports.org/press_release/california-leads-the-nation-with-first-ban-on-six-harmful-food-dyes-in-school-food [https://perma.cc/HQ8W-UQCQ].

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ Chuck, *supra* note 106.

¹¹⁴ *Id.*

¹¹⁵ Ronholm, *supra* note 110.

¹¹⁶ Bourguignon, *supra* note 2, at 22.

¹¹⁷ *Id.*

¹¹⁸ See *id.*

¹¹⁹ Chuck, *supra* note 106.

¹²⁰ *Id.*

3. Supplements

The contrast in regulatory approaches extends beyond color additives. The regulation of dietary supplements also highlights the divergence between the EU's precautionary stance and the US' reactionary framework.¹²¹ The Precautionary Principle in the EU requires pre-market assurance that supplements are safe before reaching consumers. Meanwhile, the US has chosen to limit its regulation of dietary supplements to post-market enforcement.¹²² In the US, the Dietary Supplement Health and Education Act governs dietary supplements.¹²³ Under the Dietary Supplement Health and Education Act, the FDA does not have the authority to implement a pre-market approval process for supplements.¹²⁴ The FDA can only intervene after a supplement reaches the market and evidence demonstrates that it is unfit for consumption due to tangible harm to a consumer.¹²⁵ This leaves the FDA with only remedial, post-market enforcement as an option.¹²⁶ The reactionary approach places the responsibility for supplement safety squarely on the manufacturers and distributors, making them accountable for the safety of the supplements in US stores.¹²⁷

In contrast, the EU actively ensures supplement safety before allowing products to reach consumers. Within the EU, regulators treat supplements as food and require the EFSA to conduct a comprehensive safety assessment before any product can be sold.¹²⁸ This means the EU requires notification and registration for each supplement marketed to consumers, ensuring every supplement entering the market has undergone a safety assessment.¹²⁹

In addition, the EU's supplement regulation operates under positive lists—compilations of safe and approved vitamins, minerals, and

¹²¹ See *Questions and Answers on Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Feb. 21, 2024), <https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements#:~:text=In%20general%2C%20FDA%20is%20limited,before%20they%20reach%20the%20consumer> [https://perma.cc/AK4P-UJBN].

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ Valeriya Zayets, *Comparing Dietary Supplement Regulations in the U.S. and Abroad*, 74 U.S. FOOD & DRUG L.J. 613, 619 (2020).

¹²⁶ *Questions and Answers on Dietary Supplements*, *supra* note 121.

¹²⁷ Ouarda Djaoudene et al., *A Global Overview of Dietary Supplements: Regulation, Market Trends, Usage during the COVID-19 Pandemic, and Health Effects*, NUTRIENTS 1, 6-7 (2023).

¹²⁸ *EU Rules – food additives*, *supra* note 86.

¹²⁹ Djaoudene et al., *supra* note 128, at 7.

other substances regulators have explicitly approved for use.¹³⁰ Regulators prohibit the use of any substance not on one of the positive lists unless specifically approved.¹³¹ These positive lists serve as a primary check on the safety of supplements entering the food supply.¹³²

By adopting the Precautionary Principle as its framework for food regulation, the EU promptly prevents the use of potentially harmful additives, dyes, and supplements—prioritizing safety before any risk materializes. The US should adopt a similar precautionary approach to prioritize long-term health and safety of its citizens. Precautionary measures not only protect consumers from potential harm they also encourage the innovation of safer and healthier food production standards in the future.

B. THE PRECAUTIONARY PRINCIPLE'S INFLUENCE ON CHEMICAL REGULATION AFFECTING FOOD

1. BPA

Due to the strong influence of the Precautionary Principle within the EU, it is unsurprising that the EU imposes stricter regulations on Bisphenol A (BPA) compared to those imposed in the US.¹³³ The safety of BPA, a chemical used in the production of certain plastics, has become increasingly controversial within the US.¹³⁴ Because BPA is soluble, heat

¹³⁰ Shradha Thakkar et al., *Regulatory Landscape of Dietary Supplements and Herbal Medicines from a Global Perspective*, REGUL. TOXICOLOGY & PHARMACOLOGY, July 2020, at 1, 7; Zayets, *supra* note 126, at 626-27.

¹³¹ See Djaoudene et al., *supra* note 128, at 8-9.

¹³² See *id.* at 9.

¹³³ *EU-Wide Ban of Bisphenol A in Food Contact Materials Finally in Sight*, FOODWATCH (Dec. 7, 2024), <https://www.foodwatch.org/en/eu-wide-ban-of-bisphenol-a-in-food-contact-materials-finally-in-sight#:~:text=On%20June%2012%2C%202024%2C%20EU,can%20officially%20become%20EU%20law> [https://perma.cc/3QPM-FB6M] [hereinafter EU-Wide Ban of Bisphenol A]; BPA Laws and Regulations, BREAST CANCER PREVENTION PARTNERS, <https://www.bcpp.org/resource/bpa-laws-and-regulations/#:~:text=In%20response%20to%20a%20food,claimed%20market%20abandonment%2C%20not%20safety> [https://perma.cc/4G5S-LBJE] (last visited Oct. 3, 2024).

¹³⁴ See Cynthia Marie Metz, *Bisphenol A: Understanding the Controversy*, 64 WORKPLACE HEALTH & SAFETY 28 (2016); Bisphenol A (BPA), NAT'L INST. OF ENV'T HEALTH SCI., [https://www.niehs.nih.gov/health/topics/agents/sya-bpa#:~:text=Introduction-,Bisphenol%20A%20\(BPA\)%20is%20a%20chemical%20produced%20in%20large%20quantities,be%20found%20in%20breast%20milk](https://www.niehs.nih.gov/health/topics/agents/sya-bpa#:~:text=Introduction-,Bisphenol%20A%20(BPA)%20is%20a%20chemical%20produced%20in%20large%20quantities,be%20found%20in%20breast%20milk) [https://perma.cc/9W26-ATYL] (Sept. 17, 2024).

is able to break its bonds.¹³⁵ This allows for BPA in containers or water bottles to leach into food or beverages, thereby entering the human body when consumed.¹³⁶ Scientists and health agencies have differing views on BPA's safety; some argue low-level exposure is harmless, while others raise concerns about its hormone-mimicking effects and potential health risks.¹³⁷ The effect BPA has on human hormone levels is one of the most widely voiced concerns by both researchers and individual experts.¹³⁸ Many believe BPA mimics a hormone in the body—by disrupting normal levels it thereby significantly effects fertility and child development.¹³⁹ The effects on fertility have become more concerning through time.¹⁴⁰ One study found that men with higher BPA levels were three-to-four times more likely to have a low sperm concentration and count than men with BPA levels in the normal range.¹⁴¹ A different study of women undergoing fertility treatments found that women with higher levels of BPA were up to two times less likely to successfully become pregnant, in comparison to women with BPA levels in the normal range.¹⁴²

Despite studies demonstrating significant health concerns for both men and women, the US has enacted few regulations around BPA.¹⁴³ The lack of regulation is largely due to a regulatory preference for requiring definitive evidence of harm before taking action, and the FDA's lack of regulatory concern regarding the topic.¹⁴⁴ Regulation has focused specifically on products intended for infants and young children, but has been limited to baby bottles, sippy cups, and infant formula.¹⁴⁵ Notably, widespread public concern over the chemical's potential effects on hormone levels did not prompt this regulatory action.¹⁴⁶ Instead, the industry's voluntary decision to phase out the substance was a primary

¹³⁵ *Americans Exposed to BPA at Levels 5,000 Times Higher than EU*, TOMORROW'S WORLD TODAY (Mar. 7, 2022), <https://www.tomorrowworldtoday.com/health/americans-exposed-to-bpa-at-levels-5000-times-higher-than-eu/> [<https://perma.cc/P5C7-BRSJ>] [hereinafter *Americans Exposed*].

¹³⁶ *Americans Exposed*, *supra* note 136.

¹³⁷ Metz, *supra* note 135.

¹³⁸ See Metz, *supra* note 135.

¹³⁹ *Id.*

¹⁴⁰ See *id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ See BPA Laws and Regulations, *supra* note 134.

¹⁴⁴ See *id.*

¹⁴⁵ See *id.*

¹⁴⁶ *Id.*

catalyst.¹⁴⁷ The industry decision was cited by a marked decline in consumer demand for products containing BPA—a decline that may have reflected widespread public concern.¹⁴⁸ The US reinforces its stance on this decision through the FDA’s website, which emphasizes that current scientific literature suggests BPA is safe.¹⁴⁹ But, the agency is committed to monitoring ongoing research and taking action, if and when concrete evidence of harm from BPA exposure emerges—a textbook reactionary approach.¹⁵⁰

Meanwhile, on December 19, 2024, the European Commission agreed to the proposal of a total ban of BPA in all materials coming into contact with food—thereby eliminating the primary source of exposure to BPA.¹⁵¹ The 2024 ban follows increasing concerns surrounding BPA’s potential harm to fertility and the reproductive system.¹⁵² Prior to this total ban, the EU had only banned BPA in infant bottles, food packaging for children under age three, and thermal paper receipts.¹⁵³

The regulation of BPA is yet another example of the Precautionary Principle leading to safer and healthier outcomes within the EU. The heightened restrictions within the EU have shown to have a staggering effect on BPA, even prior to the 2024 total ban.¹⁵⁴ A 2022 study found Americans experienced BPA exposure levels five thousand times higher than individuals living in the EU.¹⁵⁵ It is eye-opening to imagine how that number will look once the EU’s 2024 ban is implemented. Adopting the Precautionary Principle and imposing a broader ban on BPA, as the EU

¹⁴⁷ *Id.*

¹⁴⁸ *See id.*

¹⁴⁹ *Questions & Answers on Bisphenol A (BPA) Use in Food Contact Applications*, U.S. FOOD AND DRUG ADMIN., (Feb. 21, 2018), <https://www.fda.gov/food/food-packaging-other-substances-come-contact-food-information-consumers/questions-answers-bisphenol-bpa-use-food-contact-applications> [hereinafter *Questions & Answers on BPA Use*].

¹⁵⁰ *Id.*

¹⁵¹ *Bisphenol A, European Food Safety Auth.*, <https://www.efsa.europa.eu/en/topics/topic/bisphenol#:~:text=EU%20framework,characterisation%20advice%20in%20particular%20cases> [<https://perma.cc/YC6H-RCPV>] (July 9, 2025).

¹⁵² Marta Iraola Iribarren, *EU Bans Harmful Chemical from Materials in Contact with Food*, EURO NEWS, <https://www.euronews.com/health/2024/12/20/eu-bans-harmful-chemical-from-materials-in-contact-with-food> (Dec. 21, 2024) [<https://perma.cc/MTH6-TWCA>].

¹⁵³ *Questions & Answers on BPA Use*, *supra* note 149.

¹⁵⁴ *See generally Americans Exposed to BPA at Levels 5,000 Times Higher than EU*, TOMORROW’S WORLD TODAY (Mar. 7, 2022), <https://www.tomorrowstoday.com/health/americans-exposed-to-bpa-at-levels-5000-times-higher-than-eu/> [<https://perma.cc/E5G6-LGS6>]. (observing that even before the 2024 total ban, BPA exposure levels in the European Union were significantly lower than in the United States)

¹⁵⁵ *Id.*

has done, is a necessary step for the US to proactively protect public health and mitigate the significant risks posed by this harmful chemical.

2. rBGH

The regulation of recombinant bovine growth hormone (rBGH or rBST) further illustrates the contrast between the EU's precautionary approach and the US' reactive stance. Like BPA, rBGH raises health concerns—particularly regarding potential cancer risks—highlighting the implications of divergent regulatory philosophies.¹⁵⁶

Recombinant bovine growth hormone (rBGH), also known as rBST, is a synthetic hormone commonly used in the dairy industry to boost milk production in cows.¹⁵⁷ Its use has sparked controversy, resulting in contrasting regulatory approaches in the US and the EU.¹⁵⁸ Most of the concerns with rBGH relate to its ties to cancer in humans.¹⁵⁹ Research has found that increased consumption of dairy from cows treated with rBGH can elevate blood levels of insulin-like growth factor 1, a hormone linked to cell growth and proliferation.¹⁶⁰ Although effects are inconclusive, in some studies, elevated levels of insulin-like growth factor 1 have also been associated with an increased risk of certain cancers, including premenopausal breast cancer.¹⁶¹ One notable study found that women with higher concentrations of rBGH had an increased chance of developing breast cancer compared with those who had lower concentrations of rBGH.¹⁶² This correlation persisted even after adjusting for various factors that could influence the results—such as age, physical activity, and body

¹⁵⁶ *Recombinant Bovine Growth Hormone (rBGH)*, AM. CANCER SOC'Y, <https://www.cancer.org/cancer/risk-prevention/chemicals/recombinant-bovine-growth-hormone.html#:~:text=It%20was%20first%20approved%20for,Canada%2C%20and%20some%20other%20countries> [https://perma.cc/KR9H-KGPP] (last visited Oct. 3, 2024) [hereinafter *Recombinant Bovine Growth*].

¹⁵⁷ *Bovine Growth Hormone (rBGH) or Recombinant Bovine Somatotropin (rBST)*, BREAST CANCER PREVENTION PARTNERS, <https://www.bcpp.org/resource/rbgh-rbst/#:~:text=The%20use%20of%20rBST%20in%20dairy%20cows%20has%20been%20shown,for%20pre%20menopausal%20breast%20cancer> [https://perma.cc/4TM4-S98R] (last visited Oct. 3, 2024) [hereinafter *Bovine Growth Hormone*].

¹⁵⁸ *See id.*

¹⁵⁹ *Recombinant Bovine Growth*, *supra* note 156.

¹⁶⁰ *Bovine Growth Hormone*, *supra* note 157; *Recombinant Bovine Growth*, *supra* note 156.

¹⁶¹ *Recombinant Bovine Growth*, *supra* note 156.

¹⁶² *Higher Concentrations of IGF-1 Are a Probable Cause of Breast Cancer*, EUR. SOC'Y FOR MED. ONCOLOGY (Mar. 11, 2020), <https://www.esmo.org/press-releases/concentrations-igf-1-probable-cause-breast-cancer> [https://perma.cc/J3FH-8L3H].

mass index.¹⁶³ Citing its potential health risks—particularly its link to cancer—the EU banned rBGH outright.¹⁶⁴ In adherence with the Precautionary Principle, this ban has been in place since January 1, 2000.¹⁶⁵

The US has consistently declined to ban—or even mildly regulate—rBGH in the dairy industry.¹⁶⁶ Despite numerous petitions and opportunities for regulation, the US has remained true to its reactionary regulatory framework. In 1996, the Supreme Court had an opportunity to regulate rBGH.¹⁶⁷ Reasoning that the potential harm from rBGH was not yet real or cognizable, the Supreme Court declined the proposed mandatory labeling of products containing rBGH.¹⁶⁸ The US has since adhered to this position, justifying its continued inaction by repeatedly emphasizing the absence of conclusive evidence regarding rBGH's effects.¹⁶⁹

The EU's precautionary approach to chemicals in the food supply evidently contributes to healthier outcomes. Furthermore, the absence of a precautionary framework in the US stifles any incentive for food manufacturers to develop safer alternatives. Rather than promoting innovation, the US remains complacent with ongoing exposure of potentially harmful chemicals in the food supply.

C. THE PRECAUTIONARY PRINCIPLE'S ROLE IN LABELING AND CONSUMER TRANSPARENCY

1. *Emphasis on Transparency and Education*

The desire for transparency and consumer education surrounding food and how its supplied is another major component of the precautionary

¹⁶³ *Id.*

¹⁶⁴ Joseph Holstead, *Recombinant Bovine Growth Hormone*, CONN. GEN. ASSEMBLY (Feb. 7, 2007), <https://www.cga.ct.gov/2007/rpt/2007-R-0159.htm#:~:text=Shortly%20thereafter%2C%20the%20European%20Union,%20v3n23a15%2Dbrinckman.htm> [https://perma.cc/FJG6-ZGZY] (a Connecticut Office of Legislative Research report).

¹⁶⁵ *See id.*; Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996).

¹⁶⁶ Holstad, *supra* note 14.

¹⁶⁷ Int'l Dairy Foods Ass'n, 92 F.3d 67.

¹⁶⁸ *Id.*

¹⁶⁹ *Recombinant Bovine Growth*, *supra* note 156.

framework within the EU.¹⁷⁰ The EU believes that proactively protecting public health begins with providing consumers straightforward information about what they ingest and the effects of their food choices. These choices contribute to a healthier and more informed society from the bottom up. The EU has worked to prioritize transparency through a variety of avenues, including the labeling of food.¹⁷¹ A push for front of package nutrition labels has been a topic recently.¹⁷² Placing nutrition labels prominently on the front of products makes them more noticeable and influences consumer's decision-making process at the grocery store. Although front-of-package labels have not yet been approved in the EU, the idea is fostering a conversation that has yet to gain traction in the US.¹⁷³

The Precautionary Principle has also prioritized clear and truthful food labeling.¹⁷⁴ Food labeling requirements in the EU are more exacting than those in the US.¹⁷⁵ EU regulations adjust their margins of error based on the nutrient in question.¹⁷⁶ There is a lower margin of error, near 10 percent, for the "big offenders" of many food-related illnesses such as fats, carbohydrates, salt, and sugar.¹⁷⁷ For the "healthier" macronutrients such as protein, fiber, and unsaturated fats, there is a wider margin of error, closer to 20 percent.¹⁷⁸ In contrast, the FDA permits food labels to be off by as much as 20 percent, which can mislead consumers.¹⁷⁹ By regulating

¹⁷⁰ See Bergkamp & Hanekamp, *supra* note 2; EUROPEAN COMMISSION, Food Law: General Principles, https://food.ec.europa.eu/horizontal-topics/general-food-law/food-law-general-principles_en [https://perma.cc/QB4M-QULR] (last visited Oct. 28, 2025).

¹⁷¹ See Nikhil Gokani & Amandine Garede, *Front-of-Pack Nutrition Labelling: Time for the EU to Adopt a Harmonized Scheme*, 33 EUR. J. PUB. HEALTH, 751 (2023).

¹⁷² See *id.* at 751.

¹⁷³ See *id.*

¹⁷⁴ Reiner Jumpertz et al., *Food Label Accuracy of Common Snack Foods*, 21 OBESITY J., 164 (2013).

¹⁷⁵ *Id.*

¹⁷⁶ Raqiyah Pippins, Howard Sklamberg & Elizabeth Trentacost, *Federal District Court Upholds FDA's GRAS Self-Determination Process*, ARNOLD & PORTER (Oct. 27, 2021), <https://www.arnoldporter.com/en/perspectives/advisories/2021/10/federal-district-court-upholds-fda-gras#:~:text=Federal%20District%20Court%20Upholds%20FDA%27s%20GRAS%20Self%20Determination%20Process,-Advisory&text=On%20September%2030%2C%202021%2C%20the,lawsuit%27s%20dismissal%20for%20food%20manufacturers> [https://perma.cc/NQH3-7J46].

¹⁷⁷ *Health and Consumers Directorate-General*, EUROPEAN COMM'N, (June, 2012), <https://assets.publishing.service.gov.uk/media/5a7cc3eced915d63cc65cb79/EU-Guidance-on-Tolerance.pdf> [https://perma.cc/DZ7F-LCQZ].

¹⁷⁸ See *Draft Guidance Document for Competent Authorities for the Control of Compliance with EU Legislation on*, EUR. COMM'N 1, 8 (2012), <https://assets.publishing.service.gov.uk/media/5a7cc3eced915d63cc65cb79/EU-Guidance-on-Tolerance.pdf> [https://perma.cc/AU8B-JVSG].

¹⁷⁹ Jumpertz et al., *supra* note 174, at 167.

the accuracy of food labels, the EU helps its citizens gain a clearer understanding of what they are consuming.

Moreover, the CJEU has reprimanded manufacturers who produce misleading food labels or packaging.¹⁸⁰ In 2015, the CJEU held that tea packaging depicting images of raspberries and vanilla was misleading because it did not contain either ingredient.¹⁸¹ This ruling reinforced the EU's commitment to ensuring consumers make informed decisions about their food choices.¹⁸²

The EU bases calorie content on portion sizes rather than grams (as the US does). This makes it easier for consumers to quickly estimate the amount they are consuming. The Precautionary Principle in the EU aims to protect consumers from the harmful effects of poor food choices.¹⁸³ The Precautionary Principle ensures EU citizens are well-informed and empowered to make educated decisions from the moment they enter the grocery store.¹⁸⁴ By prioritizing consumer education, enforcing transparent labeling, and implementing proactive measures, individuals are equipped to make educated dietary decisions.

2. Labeling of Potentially Harmful Foods

The Precautionary Principle in the EU has also emphasized the importance of labeling potentially harmful foods, ensuring consumers are fully informed before purchasing or consuming a product. In recent years, two products have been the primary target in the EU: food dyes and genetically modified organisms. Although the EU has not banned these products, a strong emphasis is placed on educating consumers about potential risks.¹⁸⁵

The EU has enacted regulation requiring food that contains potentially harmful food dyes to be accompanied by a warning regarding the adverse effects on activity and attention in children.¹⁸⁶ Since 2003, the

¹⁸⁰ See Case C-195/14, *Verbraucherzentralen v. Teekanne GmbH & Co. KG*, ECLI:EU:C:2015:361 (June 4, 2015).

¹⁸¹ See *id.*

¹⁸² See generally *id.*

¹⁸³ Laura Entis, *Differences Between EU and US Nutrition Labels go far Beyond Ounces and Grams*, THE GUARDIAN (Sept. 8, 2015), <https://www.theguardian.com/lifeandstyle/2015/sep/08/food-labeling-us-fda-eu-health-food-safety> [<https://perma.cc/CEH7-J6FP>]; Bergkamp & Hanekamp, *supra* note 2.

¹⁸⁴ *Id.*; Bergkamp & Hanekamp, *supra* note 2.

¹⁸⁵ See Lehto et al., *supra* note 92, at 351; see Harrison, *supra* note 77.

¹⁸⁶ Lehto et al., *supra* note 92, at 351.

EU has required foods containing 0.09 percent genetically modified ingredients to be labeled as such.¹⁸⁷ The US eventually implemented labeling requirements in 2022 as the controversy surrounding genetically modified organisms grew.¹⁸⁸ However, unlike the EU's clear labeling, US regulations allow the use of QR codes, phone numbers, or website links to convey information otherwise found on labels.¹⁸⁹

The EU's adoption of the Precautionary Principle leads to earlier and more stringent regulation of potentially harmful foods. In addition, the Precautionary Principle seeks to equip consumers with the information necessary to make well-informed decisions about controversial foods they consume. The US should adopt the Precautionary Principle to more effectively safeguard public health. Requiring clear labeling of potentially harmful products enables consumers to make informed decisions about their food.

III. COUNTERARGUMENTS & FINAL EMPHASIS ON PRECAUTION

A. WHY THE UNITED STATES SHOULD MOVE TOWARD THE PRECAUTIONARY PRINCIPLE

1. *Overcoming Counterarguments*

The US' decision to adopt a reactionary approach to food regulation, rather than one resembling the EU's Precautionary Principle, is unlikely to stem from a single cause. Rather, it is more plausible that a combination of factors has influenced this regulatory stance. Several academic works have suggested two reasons behind the reactionary approach of the US.¹⁹⁰ First, the Precautionary Principle stifles innovation and second, it imposes incidental trade barriers.¹⁹¹

Those who oppose the Precautionary Principle claim that regulation concentrated solely on avoiding risk and removing scientific

¹⁸⁷ Regulation (EC) No. 1830/2003 of the European Parliament and of the Council, 2003 O.J. (L 268) 24.

¹⁸⁸ U.S. FOOD AND DRUG ADMIN., HOW GMOs ARE REGULATED IN THE UNITED STATES (2024).

¹⁸⁹ Katie Peikes, *GMO food labeling has been required in the U.S. for a year. Have consumers noticed?*, NEB. PUB. MEDIA (Feb. 6, 2023, 5:00am), <https://nebraskapublicmedia.org/en/news/news-articles/gmo-food-labeling-has-been-required-in-the-us-for-a-year-have-consumers-noticed/#:~:text=Initially%2C%20the%20disclosure%20statement%20that,Louis%20Public%20Radio> [https://perma.cc/G9AA-B76K].

¹⁹⁰ Bourguignon, *supra* note 2; VOGEL, *supra* note 6.

¹⁹¹ Bourguignon, *supra* note 2; VOGEL, *supra* note 6.

uncertainty, inherently stifles technological innovation.¹⁹² This argument is overcome by illustrating how the Precautionary Principle has encouraged innovation. Take, for example, the use of food dyes. Instead of relying on many of the common food dyes with clear side effects in children, the EU is turning to natural alternatives, such as beet or carrot juice, or paprika extract.¹⁹³ US food manufacturers need to realize that safer and more sustainable alternatives are within their reach.

Opponents of the Precautionary Principle argue that implementing a strict regulatory framework surrounding food can cause trade disruptions and challenges.¹⁹⁴ Despite this argument receiving more traction, it is important to realize that the Precautionary Principle fosters higher safety standards, which can enhance consumer trust and increase demand for safer, high-quality products in the market.¹⁹⁵ Once consumers recognize the health benefits associated with a regulatory framework grounded in the Precautionary Principle, support for such an approach is likely to become widespread.

2. Proven Protection in Prior Contexts

Advocating for a principle that prioritizes preventing harms before they occur can be challenging, as the harms aimed to be prevented may never materialize. Examining instances where the EU has proactively applied the Precautionary Principle can be particularly enlightening. One example is phthalates—a group of chemicals used to make plastic more flexible and resilient.¹⁹⁶ Alarmed by studies linking phthalate exposure to liver, kidney, and testicular disorders, the EU implemented a total ban in 1999.¹⁹⁷ The US waited, however, until additional evidence emerged confirming the EU's concerns.¹⁹⁸ Eventually, the US banned phthalates

¹⁹² Bourguignon, *supra* note 2, at 22.

¹⁹³ Chuck, *supra* note 106; *The European Market Potential for Natural Food Colours*, CTR. FOR THE PROMOTION OF IMP. FROM DEV. COUNTRIES (CBI), (Oct. 17, 2022), <https://www.cbi.eu/market-information/natural-food-additives/natural-food-colours/market-potential#:~:text=The%20EU%27s%20regulatory%20framework%20favours,additive%20will%20not%20mislead%20consumers> [<https://perma.cc/67M4-YY9U>].

¹⁹⁴ VOGEL, *supra* note 6, at 27.

¹⁹⁵ *Id.* at 4.

¹⁹⁶ Chuck, *supra* note 106; CENTRE FOR THE PROMOTION OF IMPORTS FROM DEVELOPING COUNTRIES (CBI), *The European Market Potential for Natural Food Colours*, *supra* note 193.

¹⁹⁷ Xavier Bosch, *EU Bans Phthalates in Children's Toys*, 354 THE LANCET 2060 (1999).

¹⁹⁸ *Congress Moves to Ban Phthalates from Toys*, L.A. TIMES (July 29, 2008), <https://www.latimes.com/archives/la-xpm-2008-jul-29-na-toxin29-story.html> [<https://perma.cc/KKN4-4B3H>].

through the Consumer Product Safety Improvement Act in 2008.¹⁹⁹ It's crucial to consider the countless individuals in the US who were exposed to phthalates between 1999 and 2008 for the sake of facilitating easier trade. Was it worth the risk?

3. *A Safer and Healthier Framework*

The United States should adopt the Precautionary Principle as the guiding framework for food regulation. Although the US asserts many controversial areas regulated by the EU are “safe until proven otherwise,” a review of historical precedents challenges this stance. Medical procedures such as lobotomies, and substances such as lead paint, asbestos, DDT, and tobacco were once widely accepted as safe but are now recognized as severely harmful to human health. These examples underscore the risk that US food practices currently deemed safe may in the future be revealed to be dangerous. This reality demands that the US embrace the Precautionary Principle and implement cautious, proactive regulation to safeguard public health.

IV. CONCLUSION

While the current state of food safety in the United States may seem concerning, there is no need to pack your bags for Europe just yet. In January 2025, the FDA revoked authorization for Red Dye No. 3—the first meaningful federal review of highly disputed color additives.²⁰⁰ While this is just one step in the vast landscape of food regulation, it is encouraging to see the US acting. The US taking action also raises a question: has the US waited too long to regulate the food industry, potentially allowing irreversible harm to occur?

The health of American citizens is directly influenced by the regulatory frameworks governing the nation's food supply. While the EU has embraced the Precautionary Principle and proactively safeguarding

¹⁹⁹ U.S. Consumer Product Safety Comm'n, *CPSC Prohibits Certain Phthalates in Children's Toys and Child Care Products*, Release No. 18-014 (Oct. 20, 2017), <https://www.cpsc.gov/Newsroom/News-Releases/2018/CPSC-Prohibits-Certain-Phthalates-in-Childrens-Toys-and-Child-Care-Products> [<https://perma.cc/VB42-4Y9Z>] (last visited Oct. 28, 2025).

²⁰⁰ *FDA to Revoke Authorization for the Use of Red No. 3 in Food and Ingested Drugs*, U.S. FOOD & DRUG ADMIN. (Jan. 15, 2025), <https://www.fda.gov/food/hfp-constituent-updates/fda-revoke-authorization-use-red-no-3-food-and-ingested-drugs> [<https://perma.cc/C2RZ-R2JW>].

public health, the US continues to embrace a reactive approach, waiting for definitive proof of harm before acting.²⁰¹ The US' outdated model has allowed harmful additives, chemicals, and food to remain on the market. As a result, the US has continued to have worsening health outcomes as compared to the EU. To close this gap, the US must reform its food regulations by prioritizing prevention over industry convenience, and ensuring consumer safety. Policymakers, public health advocates, and consumers must demand stronger, science-driven food regulations aimed at preventing harm before it occurs. Change cannot wait for further damage to be done.

²⁰¹ Wiener & Rodgers, *supra* note 4, at 317.