

Review

Food Safety Standards, Regulatory Paradigms, and International Trade Between the European Union, the United States, and Other Major Commercial Blocs

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Abstract

Global food trade exposes sharp differences in food safety regulation, especially between the EU and the US. The EU follows a precautionary, hazard-based model, allowing intervention under scientific uncertainty to protect consumers, maintain public trust, and avoid long-term risks. The US applies a science-based, proof-of-harm approach, requiring clearer evidence of risk before limiting market access, supporting innovation and regulatory efficiency. These contrasting philosophies create trade tensions and non-tariff barriers, as seen in disputes over hormone-treated beef, genetically modified organisms, and chlorine-washed poultry. Beyond the transatlantic context, countries adopt precautionary, science-based, or hybrid systems depending on domestic priorities, institutional capacity, and trade commitments. Hybrid models in India, China, and parts of Africa combine precautionary safeguards with evidence-based risk assessment to balance consumer protection and market access. International bodies such as Codex Alimentarius, the WHO, and the WTO help manage regulatory divergence through standards, guidance, and dispute resolution, while recognising precaution under uncertainty. Recent EU agreements with Mercosur and India show pragmatic cooperation through transparency, safeguards, and sanitary and phytosanitary commitments. Overall, effective global food governance depends on hybrid, coordinated, and adaptive approaches that reconcile health protection, trade facilitation, and innovation.

Keywords: global food trade; codex alimentarius; precautionary principle; proof-of-harm model



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1. Introduction

The Global food trade has expanded significantly over recent decades, driven by technological innovation, supply chain integration, and the liberalisation of international markets. As food products increasingly cross national and regional borders, regulatory differences in food safety governance have become a major source of economic, legal, and political tension. Among these differences, one of the most prominent and enduring divides exists between the European Union (EU) and the United States (US), whose regulatory systems reflect fundamentally different approaches to managing scientific uncertainty and public health risk in the food sector [1–3]. However, a global foundation policy in each of these jurisdictions is based on the Codex Alimentarius (Codex) [4].

However, a global foundation for food safety policy in both jurisdictions is provided by the Codex Alimentarius. Codex standards, guidelines, and codes of practice are developed multilaterally by the Codex Alimentarius Commission, established by FAO and WHO, whose membership currently includes 188 member countries and one member organisation, the European Union [4]. These standards provide a common international reference for food safety, including food additives, contaminants, pesticide residues, veterinary drug residues, hygiene, labelling, and risk-analysis principles. Although Codex texts are not directly binding as national law, they form the scientific and technical foundation used by many countries to develop regulatory frameworks and to justify food safety policy, particularly under the WTO Sanitary and Phytosanitary Agreement, where Codex standards are recognised as international benchmarks for food safety measures [5,6].

Food safety regulation in the EU is strongly shaped by the precautionary principle, which permits policymakers to adopt protective measures where scientific evidence concerning potential harm remains uncertain or incomplete. Embedded within the EU's legal framework and codified in the General Food Law Regulation (GFLR) [7]. The precautionary principle reflects a governance philosophy that prioritises consumer protection and public confidence, even where this may result in restrictions on certain products or technologies pending further scientific assessment [7,8]. This approach has led the EU to impose strict regulatory controls on products such as hormone-treated beef, genetically modified organisms (GMOs), and certain pesticides and food additives [1,8].

By contrast, the United States generally follows a science-based, risk assessment model in which regulatory restrictions typically require demonstrable evidence that a product is harmful under conditions of normal consumption [9]. Under this model, agencies such as the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) place considerable emphasis on quantifiable risk evaluation, cost-benefit analysis, and post-market monitoring [9,10]. The American regulatory philosophy, therefore, tends to permit market access for new food technologies and additives unless a clear and scientifically verifiable risk has been identified [9,11].

High-pressure processing (HPP) provides a useful example of how innovative food-processing technologies may be treated differently across regulatory systems. HPP is a non-thermal process, usually applying 400–600 MPa, that can reduce vegetative microorganisms while preserving sensory and nutritional quality [12,13]. In the EU, foods produced by new technologies may fall under the novel-food framework when the process significantly changes composition, structure, nutritional value, metabolism, or levels of undesirable substances, requiring pre-market safety assessment before authorisation [14,15]. This can delay the uptake of technological innovations compared with North America, where HPP has been more readily adopted as a pathogen-reduction and shelf-life extension intervention when risk assessment supports safe use [13]. This example reinforces the broader contrast between the EU's precautionary, pre-market authorisation model and the more implementation-oriented North American approach.

These divergent regulatory frameworks have tangible implications for international trade. High-profile cases such as hormone-treated beef, GMOs, and chlorine-washed poultry illustrate how differences in precautionary thresholds and evidentiary standards create non-tariff barriers, trigger World Trade Organization (WTO) disputes, and affect market access for exporters [16,17]. Beyond the transatlantic context, countries worldwide adopt a spectrum of regulatory approaches, from precautionary to proof-of-harm models, influenced by economic priorities, institutional capacity, consumer perceptions, and international trade obligations [17].

Beyond the transatlantic relationship, the tension between precautionary and proof-of-harm regulatory approaches influences global food governance more broadly. Many

countries adopt hybrid regulatory systems that reflect domestic political priorities, consumer preferences, institutional capacity, and economic dependencies on major trading partners [18]. Meanwhile, international organisations, particularly the United Nations through bodies such as the Codex Alimentarius Commission (CAC) and the World Health Organization (WHO), seek to harmonise food safety standards whilst navigating competing regulatory philosophies. Although Codex standards are not mandatory in the same way as national legislation, they provide a near-global reference framework, as the CAC currently includes 189 members: 188 Member Countries and one Member Organisation, the EU [19].

Despite extensive literature on the precautionary principle, risk assessment, and food safety trade disputes, existing discussions often treat these issues separately: legal studies focus on WTO compatibility, regulatory analyses describe institutional procedures, and trade-oriented studies emphasise market access and non-tariff barriers. Less attention has been given to integrating these perspectives into a comparative narrative that explains how EU and US food safety paradigms developed, how they define regulatory effectiveness, and why scientific evidence alone is insufficient to explain persistent divergence. This represents an important knowledge gap because food safety regulation is not only a technical process of risk assessment, but also a governance system shaped by scientific uncertainty, public trust, political economy, consumer values, and international trade obligations. This addition makes clear that protectionism is not presented as the only or primary driver of food safety regulation, but as a further policy consideration that may interact with legitimate public-health, animal-health, and plant-health objectives.

This article examines how these contrasting regulatory models influence international food trade and global food governance. It first analyses the conceptual and legal foundations of the precautionary principle and the science-based risk assessment approach. It then explores how these paradigms operate within the EU and US regulatory systems and evaluates their trade implications through key case studies. The article further assesses how other regions and countries position themselves within this regulatory spectrum and considers the role of international institutions in mediating regulatory divergence. In doing so, the article seeks to contribute to ongoing debates concerning the relationship between science, regulation, trade liberalisation, and public health protection in an increasingly interconnected global food system.

Rather than treating the EU and US systems as static legal models, this review also considers how their regulatory approaches have developed in response to historical food safety crises, public trust, institutional traditions, trade priorities, and political pressures. Particular attention is given to regulatory effectiveness, recognising that food safety performance cannot be assessed only through legal structure, but must also consider prevention, responsiveness, consumer confidence, innovation, enforceability, and trade consequences. The review therefore examines not only regulatory divergence but also the economic, political, and societal barriers that limit deeper integration between precautionary and risk-based food safety systems.

2. Conceptual and Legal Foundations

2.1. The Precautionary Principle

The precautionary principle constitutes one of the central normative foundations of contemporary European food safety governance, being enshrined in the EU Treaty through Article 191 [20]. Broadly defined, the principle allows regulatory authorities to adopt protective measures where scientific evidence regarding potential risks to human health or the environment remains uncertain, incomplete, or inconclusive. Rather than requiring definitive proof of harm, the precautionary principle shifts regulatory attention towards the prevention of potential risks before they fully materialise [21].

The origins of the precautionary principle are commonly traced to German environmental law in the 1970s, particularly the concept of *Vorsorgeprinzip*, which emphasised anticipatory environmental protection [22]. The principle subsequently gained international recognition through its incorporation into multilateral environmental agreements and was formally articulated in Principle 15 of the 1992 Rio Declaration on Environment and Development [23]. The Rio Declaration states that the lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation [23]. Although originally framed within environmental governance, the principle gradually expanded into public health and food safety regulation [1].

Importantly, the precautionary principle does not eliminate scientific risk assessment but rather supplements it [24]. The EU regulatory framework distinguishes between risk assessment, which is primarily conducted through scientific evaluation, and risk management, which incorporates broader policy considerations such as societal values, consumer protection, and proportionality [7]. The European Food Safety Authority (EFSA) plays a central role in providing independent scientific advice, whilst political institutions, including the European Commission and Member States, retain decision-making authority regarding the adoption of precautionary measures [25].

Critics of the precautionary principle have argued that it may lead to regulatory overreach, inhibit technological innovation, and function as a disguised trade barrier [26]. Conversely, proponents contend that it reflects legitimate societal risk preferences and enhances public confidence in regulatory systems [21]. The principle, therefore, represents not merely a technical regulatory instrument but a broader governance philosophy reflecting differing attitudes towards uncertainty, risk tolerance, and the role of public authorities in protecting consumers [26].

2.2. The United States' Science-Based Risk Assessment Approach

In contrast to the EU model, food safety regulation in the US is generally grounded in a science-based risk assessment paradigm that emphasises demonstrable evidence of harm as a prerequisite for regulatory intervention [27]. This approach reflects broader traditions within American administrative law that prioritise empirical evidence, quantitative analysis, and cost–benefit evaluation in regulatory decision-making [9].

The US regulatory framework for food safety is characterised by a multi-agency structure, with primary responsibility shared among the FDA, the USDA, and the Environmental Protection Agency (EPA). The FDA oversees the safety of most food products, including additives and biotechnology-derived foods, whilst the USDA regulates meat, poultry, and egg products through the Food Safety and Inspection Service (FSIS). The EPA plays a significant role in establishing permissible levels of pesticide residues and environmental contaminants [28].

A defining feature of the American system is the concept of substances that are “Generally Recognised As Safe” (GRAS). Under this doctrine, food ingredients and additives may be marketed without extensive pre-market authorisation if qualified scientific experts consider them safe under intended conditions of use [29]. While this system facilitates regulatory efficiency and technological innovation, it places considerable reliance on scientific consensus and post-market surveillance mechanisms [30]. Risk assessment within the US model typically involves hazard identification, dose–response analysis, exposure assessment, and risk characterisation [31]. Regulatory decisions often incorporate cost–benefit analysis, reflecting the economic implications of regulatory action alongside public health objectives. Consequently, US regulators may tolerate certain levels of risk where these are deemed scientifically negligible or economically justified [32].

Supporters of the US approach argue that it promotes innovation, reduces unnecessary regulatory burdens, and ensures that policy decisions are grounded in measurable scientific evidence [33]. Critics, however, suggest that the requirement for demonstrable harm may delay regulatory intervention and underestimate long-term or cumulative risks, particularly where scientific knowledge remains incomplete [34].

2.3. Comparative Treatment of Scientific Uncertainty

The divergence between the European precautionary principle and the American risk-based model reflects fundamentally different approaches to the governance of scientific uncertainty [35]. At its core, the distinction concerns the allocation of the burden of proof. Within the EU framework, regulatory authorities may restrict or prohibit products where credible scientific uncertainty exists regarding potential harm [36,37]. In contrast, the US model generally requires evidence demonstrating that a product poses a measurable risk before regulatory restrictions are imposed [37].

These contrasting approaches are also reflected in the institutional distribution of authority. The EU system explicitly separates scientific evaluation from political decision-making, allowing policymakers to incorporate societal values and public perception into risk management decisions [38]. By comparison, the US system tends to place greater emphasis on technical scientific evaluation as the primary basis for regulatory action, although political and economic considerations remain influential in practice [39].

Furthermore, differences in public trust, consumer culture, and historical regulatory experiences contribute to the persistence of divergent regulatory philosophies [40]. The EU food policy has been profoundly shaped by food safety crises, including bovine spongiform encephalopathy (BSE), which reinforced public demand for precautionary regulatory safeguards [41]. In the US, regulatory development has historically been more closely linked to promoting technological advancement and market efficiency, reflecting distinct socio-political priorities [42].

These conceptual differences create significant challenges for international regulatory harmonisation and contribute directly to trade tensions between jurisdictions. Divergent evidentiary standards and regulatory thresholds frequently result in disagreements regarding product safety, complicating efforts to establish mutual recognition agreements or equivalence arrangements.

3. Regulatory Applications and Case Examples

3.1. Hormone-Treated Beef

In beef production systems where they are authorised, growth-promoting hormones are used to improve average daily gain, feed efficiency, carcass weight, and lean tissue deposition, thereby reducing the time and feed required to reach slaughter weight [43,44]. Their effects are mainly mediated through anabolic stimulation of protein accretion and changes in nutrient partitioning, which increase muscle growth relative to fat deposition [44]. In commercial beef systems, these products are commonly administered as slow-release implants, usually placed in the ear, and their use is managed through product-specific protocols that define the active compound, dose, timing, production stage, and reimplantation strategy [44,45]. Management is therefore based on matching implant potency and timing to animal age, sex, nutritional status, and production objectives, while residue-control systems and withdrawal requirements are used to ensure that edible tissues remain within accepted safety limits [45,46].

In the US, certain growth hormones are permitted in cattle production under USDA and FDA oversight, provided residues in meat remain within established safety limits based on scientific risk assessment of exposure and health outcomes [47]. The US regulatory

model evaluates hormone use through rigorous risk assessment, emphasising quantitative evidence of potential effects on human health rather than precautionary avoidance of all uncertain risks [47]. This regulatory stance has been central to trade disputes with the EU, which maintains a precaution-driven ban on hormone-treated beef despite contested scientific evidence of harm [48].

The hormone-treated beef dispute also illustrates that regulatory effectiveness is not assessed in the same way by the EU and the US. From the EU perspective, effectiveness is linked to maintaining a high level of consumer protection, preserving public confidence, and preventing exposure to risks considered uncertain or socially unacceptable [49]. From the US perspective, effectiveness is more closely associated with proportionality, scientific risk assessment, market access, and avoiding restrictions where clear evidence of harm has not been demonstrated. The dispute therefore shows that food safety regulation is not shaped by science alone, but also by public trust, domestic political expectations, agricultural interests, and differing views of what constitutes an acceptable level of risk.

The dispute over hormone-treated beef remains the most prominent example of EU–US regulatory conflict. Since the late 1980s, the EU has prohibited the import and marketing of beef from cattle treated with specific growth hormones, citing potential risks to human health and invoking the precautionary principle [50]. Scientific evidence regarding the health impacts of these hormones has been contested; nonetheless, the EU maintained its ban on the grounds of consumer protection and regulatory caution [48].

The US and Canada, major exporters of hormone-treated beef, challenged the EU measures before the WTO under the Sanitary and Phytosanitary (SPS) Agreement. In the 1998 WTO panel and subsequent appellate decisions, the EU's measures were found to be inconsistent with SPS requirements, primarily because they lacked a sufficient scientific risk assessment linking hormone use to concrete health hazards [51]. The WTO rulings highlighted the tension between the EU's precautionary approach and the SPS Agreement's emphasis on science-based justification.

Despite the WTO rulings, the EU largely maintained its regulatory position, implementing modifications in labelling and monitoring to address procedural concerns while preserving the substance of the ban [52]. The dispute illustrates the broader challenge of reconciling precautionary regulation with international trade obligations and highlights the political and societal importance that the EU attaches to risk avoidance in food safety.

Consequently, the hormone-treated beef case demonstrates the limits of regulatory harmonisation where scientific assessment, consumer legitimacy, and trade liberalisation are evaluated according to different policy priorities.

3.2. Genetically Modified Organisms (GMOs)

The US regulatory framework for GMOs is substantially more permissive than that of the EU. Under the Coordinated Framework for Regulation of Biotechnology, oversight responsibilities are shared between the FDA, USDA, and EPA [53]. GMOs are subject to risk assessment, but the threshold for market approval is evidence of harm rather than potential or uncertain risks. Mandatory labelling is generally not required unless the GMO differs materially in composition or nutritional value from its conventional counterparts. Consequently, GMOs such as soy, maize, and canola are widely cultivated and exported from the US, including to markets where EU regulatory restrictions limit access [54].

The EU regulatory framework governing genetically modified organisms represents another significant example of precautionary governance. EU legislation requires extensive risk assessments, authorisation procedures, and mandatory labelling for GMO products [55]. Approval processes involve scientific evaluation by EFSA, followed by decision-making at the EU and Member State levels [56].

Compared with the US, the EU has authorised relatively few GMO products for cultivation, although imports for animal feed are more common. Public scepticism towards GMOs within many EU Member States has reinforced cautious regulatory policies. The EU framework also allows Member States to restrict or prohibit GMO cultivation within their territories under certain conditions, further illustrating the integration of societal preferences into regulatory decision-making [56].

The regulatory divergence has led to trade barriers and complex supply chain issues. US exporters often face delayed market access, additional documentation requirements, and consumer resistance when exporting to the EU. At the same time, EU measures have prompted the US to raise concerns under WTO mechanisms, arguing that overly cautious or politically driven restrictions function as disguised trade barriers [56].

The GMO case also illustrates the influence of domestic public opinion on regulatory outcomes. Within the EU, consumer scepticism and political sensitivity regarding GMOs have reinforced the precautionary approach, whereas in the US, public perception and political debate have been more supportive of biotechnology and innovation [57,58].

3.3. Chlorine-Washed Poultry and Other Contested Products

Chlorine-washed poultry is another product that has become emblematic of transatlantic regulatory differences. The EU has traditionally prohibited the import of poultry washed with antimicrobial treatments such as chlorine, citing food safety and hygiene concerns [59,60]. The US, however, permits such treatments to reduce microbial contamination, relying on quantitative risk assessment and evidence that the practice does not pose significant health hazards [61].

This poultry case is particularly useful because it reveals a different balance of risk priorities within the two regulatory systems. In the North American model, antimicrobial rinses and other pathogen-reduction treatments are primarily justified as interventions to control biological hazards, especially *Salmonella* and *Campylobacter*, which remain major microbiological risks in poultry meat [62,63]. Reviews of poultry processing indicate that antimicrobial interventions can reduce carcass contamination during processing, although their effectiveness depends on the compound used, concentration, contact time, organic load, and integration with other hygiene measures [62]. By contrast, the EU position places greater emphasis on chemical hazard prevention and on the possibility that chlorine-based treatments may generate residues or disinfection by-products that could be carried over into poultry meat. This concern is not limited to toxicology alone, but also reflects a regulatory preference for controlling contamination throughout the supply chain rather than relying on end-point decontamination at the processing stage [12,63]. The dispute therefore illustrates how the US system prioritises measurable reduction in biological hazards, whereas the EU system places greater weight on chemical uncertainty, process hygiene, and consumer confidence.

The case also highlights the significance of supply-chain management. From the EU perspective, food safety is expected to be achieved through integrated controls from farm to fork, including flock health, biosecurity, transport hygiene, slaughterhouse sanitation, and traceability, rather than through a single terminal intervention [12]. In contrast, the North American approach gives greater regulatory acceptance to processing-stage interventions when these can demonstrably reduce pathogen loads [62]. This difference is important because it shows that the dispute is not simply about whether chlorine treatments are safe, but about where responsibility for food safety should be located within the supply chain: upstream prevention and process control, or downstream risk reduction at processing.

Similar disputes have arisen over other food additives [8], pesticide residues [64], and novel food technologies [60]. These cases collectively reveal the persistent gap be-

tween precautionary and science-based regulatory regimes and the resultant challenges for harmonising standards in international trade.

Pesticides and food additives are regulated primarily through the EPA and FDA frameworks. The US system establishes tolerances or “safe levels” based on comprehensive scientific data. Regulatory approval is contingent upon a risk assessment demonstrating that anticipated exposures do not exceed safety thresholds. Post-market surveillance and monitoring of residue levels further support regulatory enforcement, allowing risk management to remain evidence-based rather than anticipatory [21].

The precautionary principle also significantly influences EU regulation of pesticides and chemical residues in food production, making it possible to take protective action under uncertainty [21]. EU legislation imposes strict maximum residue limits and requires comprehensive pre-market safety assessments for active substances. The EU has adopted hazard-based regulatory criteria for certain chemicals, allowing substances to be restricted or prohibited based on intrinsic hazardous properties, even where exposure risks remain uncertain. This regulatory strategy differs from the risk-based approaches that focus primarily on acceptable exposure levels. The EU’s hazard-based model has contributed to regulatory divergence with major trading partners and has been criticised by some stakeholders as overly restrictive [65]. However, proponents argue that it enhances long-term environmental and public health protection by addressing cumulative and systemic risks.

The practical consequences of divergent food safety regulatory approaches are particularly evident in a series of high-profile international trade disputes. Table 1 presents selected examples involving hormone-treated beef, genetically modified organisms, chlorine-washed poultry, and pesticide residues, illustrating how differences in precautionary thresholds, evidentiary standards, and SPS measures have generated market access conflicts and WTO challenges between major trading partners.

Table 1. Major international food safety trade disputes and regulatory drivers.

Product/Issue	EU Position	US Position	Regulatory Basis	Trade Outcome
Hormone-treated beef	Ban maintained	Permitted under risk assessment	Precautionary principle vs. SPS science requirements	WTO dispute
GMOs	Strict approval and labelling	Broad approval and cultivation	Precaution vs. innovation-oriented regulation	Market access tensions
Chlorine-washed poultry	Import prohibition	Approved antimicrobial treatment	Hazard prevention vs. exposure assessment	Persistent trade disagreement
Pesticide residues	Hazard-based restrictions	Tolerance thresholds	Hazard vs. risk-based regulation	Export compliance barriers
Gene editing technologies	Restrictive/cautious	Product-based assessment	Precaution vs. case-by-case science	Emerging divergence

4. The EU and US Regulatory Models Strengths and Critiques: Economic and Trade Implications, Political and Societal Dimensions

4.1. Economic and Trade Implications

Regulatory divergence between the EU and the US has measurable trade and economic impacts, particularly when differing approaches to risk and hazard shape food and agricultural policy. The EU's more precautionary, hazard-based food safety and sanitary and phytosanitary (SPS) measures are associated with non-tariff barriers that increase compliance costs for exporters and restrict market access. For example, detailed supply-chain modelling shows that the EU ban on hormone-treated beef imposes substantial costs on US producers attempting to export into the EU market, as compliance with stringent EU standards can exceed those required elsewhere and alter welfare implications for trade negotiations [48].

Empirical analyses of SPS and technical barriers indicate that such measures significantly reduce US agricultural exports, equivalent to ad valorem tariff effects, highlighting how regulatory divergence can distort trade flows without traditional tariffs. Furthermore, research on dairy trade demonstrates that regulatory convergence toward common SPS measures reduces but does not eliminate trade costs, underscoring how enduring differences in sanitary requirements continue to impede bilateral commerce [66].

Scholars also emphasise that the EU's regulatory regime, grounded in extensive precaution and lower maximum residue limits compared with US norms, inherently diverges from risk-based frameworks, contributing to asymmetric regulatory environments that affect competitiveness and agricultural supply chains [35]. Critics, including producers and trade economists, have argued that this divergence functions as a de facto trade barrier, even where legitimate public-health aims underpin policy choices [67].

4.2. Political and Societal Dimensions

From a public health perspective, both the EU and US frameworks aim to protect consumers, but they diverge sharply in risk management philosophy. The EU's precautionary approach permits regulatory action in situations of scientific uncertainty to minimise potential health risks and reinforce consumer confidence, a stance that is deeply rooted in its food safety governance and legal tradition. Under the EU General Food Law and risk regulation paradigms, policymakers may act on plausible hazards even when definitive risk characterisation is lacking, thereby reflecting broader societal priorities about health protection and uncertainty [68].

In contrast, the US science-based approach, exemplified through formal risk assessment and evidence-driven standards, focuses regulatory action on quantified risks, directing limited resources towards well-characterised hazards and permitting broader access for innovative foods and technologies. This framework tends to emphasise empirical justification over hypothetical harm, potentially delaying preventive measures where data gaps persist. Comparative regulatory analyses underline how these differing paradigms shape outcomes in areas such as biotechnologies and chemical food safety, with EU systems typically adopting more conservative thresholds and procedural requirements [8,35].

Public perception and trust play pivotal roles: in precaution-oriented societies, transparency and robust safeguards are valued, whereas in risk-tolerant contexts, there is greater emphasis on innovation and market access. The EU's extensive pre-market authorisation procedures, including traceability and labelling requirements, are shown to increase compliance costs and slow adoption of novel foods, relative to US frameworks that facilitate faster technology uptake but may attract scrutiny post-market [68]. Finally, global regulatory divergence carries equity and trade implications. Precautionary regimes can impose disproportionate compliance costs on developing-country exporters seeking ac-

cess to high-standard markets, while science-based systems may challenge countries with limited monitoring capacity to manage emerging risks equitably. Hybrid models seek a balance, but their effectiveness depends on institutional capacity and scientific expertise, highlighting the interplay between regulatory philosophy, public health equity and global food system dynamics [69].

5. Global Regulatory Models

The divergence between precautionary and science-based approaches to food safety is not confined to the EU and the US. Around the world, countries adopt varying regulatory frameworks influenced by domestic political priorities, scientific capacity, trade relationships, and societal risk perceptions. Understanding these global models is essential for analysing international trade dynamics, regulatory convergence, and the influence of international organisations.

5.1. Countries Embracing the Precautionary Principle

Several jurisdictions have formally integrated precautionary principles into food safety and biotechnology governance, often resembling the European Union's model of anticipatory risk management. The EU's General Food Law embeds precaution as a guiding risk-management tool, enabling regulators to take protective measures where scientific uncertainty persists about potential harm to health or the environment. This approach underpins EU frameworks for GMOs, pesticides, contaminants and novel foods, where authorisation often requires stringent evidence of safety before market entry [1,7].

All 27 EU Member States operate under this shared legal regime, albeit with some variation in national implementation and opt-out provisions on GMO cultivation, reflecting broader societal and political commitments to precaution [1].

In Japan, food safety policy emphasises conservative regulatory assessments for novel foods and genetically modified products, with risk evaluations conducted by the Food Safety Commission that tend towards cautious approval in the face of uncertainty. Recent literature recognises Japan's multi-layered system incorporating risk and benefit considerations in regulatory design, illustrating how precaution inflects food governance beyond pure risk quantification [70].

In Canada, the regulatory frameworks for novel foods and biotechnology combine mandatory pre-market safety assessment with a science-based approach to risk evaluation and evolving policy efforts to reduce innovation barriers. Yet, scholars have documented that regulatory burden persists and affects the pace at which new products are commercialised, reflecting a hybrid system that influences both oversight and market dynamics [71]. Although Canada retains its own food safety legislation and regulatory institutions, many aspects of its system align more closely with the US than with the EU, partly because the US is Canada's main agri-food trading partner and because North American food supply chains are highly integrated. This alignment is reflected in efforts to harmonise food safety legislation and regulatory practice around science-based principles in order to protect public health while avoiding unnecessary barriers to bilateral food trade [72]. Canada may therefore be better described as a science-based or hybrid regulatory system, rather than as a strictly precautionary model.

In Norway, GMO regulation under the Gene Technology Act incorporates societal and environmental considerations and mandates rigorous risk assessment, traceability and labelling for all genome-modified organisms, maintaining a precautionary stance even amid proposals to modernise frameworks [73].

Switzerland similarly classifies gene-edited organisms alongside GMOs, requiring regulatory oversight and continuing to prioritise precaution in biotech governance. Recent

analyses note that this aligns Swiss policy with broader European precautionary norms, although prospective regulatory adjustments are under discussion [74]. South Africa also follows the EU [74]. Across these countries and regions, precautionary regulatory frameworks are characterised by pre-market authorisation, detailed risk assessment requirements, traceability and labelling, and a willingness to intervene in the absence of complete scientific certainty to protect public health and the environment.

5.2. Countries Following Science-Based, Proof-of-Harm Approaches

Several countries primarily adopt science-based regulatory frameworks in which food safety and biotechnology decisions are grounded in quantitative evidence and risk assessment rather than precautionary restriction without clear harm. In the United States, risk management by agencies such as the FDA and EPA emphasises measured risk, dose-response assessment and post-market surveillance of food substances and agricultural inputs, with decisions contingent upon demonstrable health risks before imposing restrictions. This approach has roots in extensive risk analysis norms and international standards such as the Codex risk assessment model, which many science-based systems use to evaluate hazard and exposure data [75].

Australia and New Zealand apply a similar risk-based assessment for novel foods through Food Standards Australia and New Zealand (FSANZ), where products that lack a history of safe human consumption undergo a statutory pre-market safety assessment before market entry, focusing on scientifically established hazards and exposure outcomes rather than hypothetical risks. Their joint food code reflects a structured, evidence-driven safety evaluation for foods, including genetically modified ingredients, before authorisation [76].

In major agricultural exporters such as Brazil, regulatory frameworks for genetically engineered and biotechnology-derived products have evolved to emphasise scientific risk assessment criteria tailored to product characteristics, aiming to facilitate innovation and access to global markets while maintaining safety review processes proportionate to risk. Recent regulatory updates in Brazil streamline assessments for gene-edited organisms to reflect empirical hazard evaluation and case-by-case review [77].

Many developing countries with limited regulatory capacity or strong export linkages to science-oriented markets also lean on internationally recognised risk assessment standards, adopting proof-of-harm criteria aligned with Codex or Organisation for Economic Co-operation and Development (OECD) consensus documents to avoid unnecessary market barriers. Across these jurisdictions, the presumption of safety is upheld until empirical evidence indicates a measurable risk, reflecting a core principle of science-based regulation.

5.3. Hybrid and Regional Approaches

Many countries implement hybrid regulatory frameworks that blend elements of precautionary regulation with science-based, risk-focused assessment in food safety governance. In China, food safety governance has evolved toward a comprehensive system that integrates risk management with multi-agency coordination and increasing alignment with international norms. National food safety policy reform in China now emphasises prevention, risk monitoring, and collaborative governance, indicating a shift from reactive incident response to more structured risk reduction and evidence-informed standards, while consumer concerns about food safety incidents continue to influence policy priorities [78,79].

In India, the Food Safety and Standards Authority of India (FSSAI) is mandated by the Food Safety and Standards Act to establish and enforce science-based food safety standards while also undertaking pre-market review of novel foods and food additives. FSSAI operates within a risk analysis framework that includes formal risk assessment, risk

management and risk communication, and state-level authorities enforce standards across diverse food categories, resulting in variable implementation of precautionary measures depending on product type and risk profile [80].

In Africa, food safety regulatory philosophies differ significantly across countries and regions. National food control systems vary in capacity, enforcement and harmonisation, with some states operationalising precautionary controls for high-risk imports and others pursuing alignment with international science-based standards to support trade and public health goals. Continental efforts such as the planned Africa Food Safety Agency aim to harmonise risk assessment capacity and regulatory approaches across members of the African Union, highlighting a hybrid model shaped by institutional capacity constraints, trade considerations, and public health needs [81,82].

These hybrid models reflect attempts to balance precautionary governance, empirical risk analysis and trade facilitation, influenced by resource constraints, institutional capacity and international normative frameworks such as the Codex risk analysis paradigm. To facilitate comparison between the dominant regulatory paradigms governing international food safety systems, Table 2 summarises the principal characteristics of precautionary, science-based or proof-of-harm, and hybrid regulatory models.

Table 2. Comparative characteristics of precautionary and science-based food safety regulatory systems.

Dimension	Precautionary Model (EU-Type)	Science-Based/Proof-of-Harm Model (US-Type)	Hybrid Models
Regulatory trigger	Potential risk under scientific uncertainty	Demonstrated measurable harm	Combination of precaution and risk assessment
Burden of proof	Often on producer to demonstrate safety	Often on regulator to demonstrate harm	Shared/adaptive
Governance philosophy	Prevention and consumer protection	Innovation and market efficiency	Risk balancing
Risk management style	Hazard-based	Exposure/risk-based	Context dependent
Treatment of uncertainty	Regulatory action allowed despite incomplete evidence	Greater evidentiary threshold before intervention	Variable
Examples of countries	EU, Norway, Switzerland	US, Australia, Brazil	China, India, African states
Typical SPS impact	Higher compliance burdens	Faster market approval	Mixed outcomes
Public perception influence	Strong	Moderate	Increasing
Trade implications	Potential non-tariff barriers	Facilitates exports and innovation	Regulatory flexibility

6. The United Nations and International Standards

International institutions play a central role in mediating regulatory divergence between precautionary and science-based approaches to food safety. Through standard-setting, guidance, and dispute resolution mechanisms, the UN and affiliated bodies seek to harmonise food safety practices, facilitate trade, and protect public health.

6.1. Codex Alimentarius Commission

The Codex [83] is a comprehensive collection of international food standards, guidelines, and codes of practice developed and adopted by the Codex Alimentarius Commission (CAC). Established in 1963 by FAO and WHO, its main goals are to protect consumer health and promote fair practices in the global food trade [84]. Codex texts are based on the most up-to-date scientific evidence and serve as benchmarks in the WTO agreements on food safety and technical trade standards. Although not legally binding, many governments use them as the basis for national food legislation. The CAC includes 188 member countries, the EU as a member organisation, and numerous observers. Codex standards define permitted levels of additives, contaminants, and chemical residues to ensure food safety worldwide [4].

CAC serves several key functions in global food safety governance. By establishing internationally recognised benchmarks, CAC facilitates trade and helps to reduce technical barriers, as countries that adopt Codex standards can signal compliance with global norms, thereby enhancing the credibility of their exports. The standards are developed based on scientific risk assessment and evidence, reflecting a predominantly science-based approach. Committees such as the Joint FAO/WHO Expert Committee on Food Additives, provide scientific evaluations of hazards and exposure, ensuring that regulatory decisions are grounded in robust evidence. Codex standards also play an important role in international trade disputes, serving as reference points under the WTO SPS Agreement. When national regulations diverge from Codex benchmarks, countries are required to justify their measures based on scientific risk assessment or other accepted criteria, reinforcing the influence of Codex on both regulation and trade [4].

While Codex primarily reflects science-based principles, it acknowledges the need for precaution where scientific uncertainty exists, allowing countries to adopt more protective measures provided they are justified, proportionate, and communicated transparently [85].

6.2. World Health Organization, World Trade Organization, and the Sanitary and Phytosanitary Agreement

The institutional relationship between Codex, FAO, WHO, and WTO is important for understanding how international food safety standards operate. The CAC is the central body of the Joint FAO/WHO Food Standards Programme and was established by FAO and WHO to develop international food standards that protect consumer health and ensure fair practices in food trade [84]. Within this structure, FAO contributes expertise related to agriculture, food production, food systems, and trade, while WHO contributes its public-health mandate, including the prevention of foodborne disease and the promotion of evidence-based health protection. The WTO is not part of Codex, but Codex standards have a specific role within the WTO Sanitary and Phytosanitary Agreement, where they are recognised as international reference standards for food safety. Therefore, Codex can be understood as the scientific and technical standard-setting body, FAO and WHO as the parent organisations that provide institutional and expert support, and WTO as the trade-law framework that gives Codex standards practical relevance in resolving food safety-related trade disputes [86,87].

Although WHO is one of the parent organisations of Codex, it also has its own independent mandate to promote and protect public health. In food safety, this mandate includes supporting Member States in strengthening national food control systems, improving foodborne disease surveillance, developing risk assessment capacity, and using scientific evidence in food safety decision-making. The WHO complements the CAC by providing scientific guidance on public health risks associated with food and by promoting evidence-based food safety systems. WHO's Global Strategy for Food Safety 2022–2030 guides

Member States to strengthen national food safety systems, generate and use scientific evidence, and improve risk assessment and communication in decision-making processes [88].

In addition, WHO supports countries to develop regulatory frameworks, conduct foodborne disease surveillance, and implement international standards through coordinated governance and technical cooperation under the same strategy, which highlights evidence-driven food safety systems. Through these activities, WHO reinforces evidence-based policymaking while also recognising the legitimacy of precautionary measures in situations of uncertainty, particularly when public health risks are potentially severe or irreversible [88].

The WTO provides the primary legal framework for resolving disputes arising from divergent food safety regulations. The SPS Agreement requires SPS measures to be based on scientific risk assessments “as appropriate to the circumstances” and encourages harmonisation with international standards such as Codex texts. Under this agreement, measures must be grounded in scientific principles, and countries are generally required to conduct risk assessments where appropriate [17].

Precautionary measures are permitted, but they must be provisional and subject to review as additional scientific evidence becomes available. The SPS Agreement also mandates non-discrimination and equivalence, requiring countries to treat “like products” from different trading partners equitably and to accept equivalent sanitary or phytosanitary measures where the exporting Member objectively demonstrates they achieve the importing Member’s appropriate level of protection (Article 4), a principle that has been the subject of recent academic analysis highlighting the conditional nature of equivalence rights and obligations under the SPS legal framework [89]. Finally, the agreement recognises Codex standards as benchmarks for permissible regulatory measures; divergence from these standards requires scientific justification or demonstration that equivalent protection is provided [90].

High-profile disputes, such as the EU–US hormone-treated beef case and GMO trade conflicts, illustrate the practical tension between precautionary regulation and the WTO’s emphasis on scientific evidence. WTO jurisprudence requires that precautionary measures be proportionate, transparent, and defensible based on available data, but does not fully resolve the philosophical divergence between regulatory paradigms [91].

7. The New EU Trade Agreements with Mercosur and India: Implications for Food Safety Regulation

The EU’s recent (signed in January 2026; provisionally implemented in May 2026) trade agreements with the Mercosur bloc and the Republic of India highlight how divergent regulatory philosophies on food safety, particularly the EU’s precautionary approach and the science-based, evidence-centred framework favoured by many trade partners, shape trade policy outcomes. These agreements illustrate both the strategic importance of food safety norms in trade negotiations and the regulatory challenges that arise when harmonising disparate approaches to risk governance.

7.1. EU–Mercosur Partnership Agreement and Food Safety

The EU–Mercosur Partnership Agreement, finally concluded after decades of negotiation, includes explicit reaffirmation of the EU’s stringent SPS standards and the right of the EU to uphold high levels of protection for human, animal and plant health. The agreement’s operative framework maintains that any product imported into the EU must comply with existing EU food safety, animal and plant health rules, which are grounded in robust risk assessment and rooted in the precautionary principle. This reflects the EU’s

insistence that precautionary measures, including provisional SPS actions taken where scientific evidence is inconclusive, remain fully operative under the trade deal [92].

Nonetheless, the relation between trade liberalisation and regulatory autonomy has proven politically contentious. Some critics have argued that provisions in the SPS chapter of the pandemic-era draft deal did not explicitly enshrine the precautionary principle within the core SPS text, potentially limiting the EU's ability to use precaution proactively in preventing imports of potentially unsafe goods, an interpretation that has fuelled controversy over how food safety checks and inspections will be conducted in practice [93,94]. In response, EU institutions have emphasised that the agreement upholds the EU's non-negotiable standards on maximum pesticide residues, bans on hormone-treated meat, and other conditions essential to consumer protection [92,95].

To manage sensitivities associated with greater market access for agricultural products, the EU has strengthened safeguard mechanisms that allow temporary suspension of tariff preferences should imports harm domestic production, including products such as beef and poultry, which are often at the centre of food safety debates. These safeguards dovetail with the EU's precautionary philosophy by emphasising early response options where there is credible evidence of risk or market disruption, even if longer-term scientific consensus is pending [94].

7.2. EU–India Free Trade Agreement: Balancing Standards and Market Access

The EU–India Free Trade Agreement (FTA), signed in January 2026 after nearly two decades of talks, similarly emphasises the EU's commitment to uphold strict food safety and animal and plant health standards in trade. According to official EU summaries, all imports from India will continue to be subject to the EU's comprehensive SPS regime, with no exceptions, and the agreement preserves the EU's ability to adopt provisional SPS measures when scientific evidence is insufficient, a clear reflection of the precautionary approach embedded in EU policy [96].

At the same time, the FTA includes structured procedures for transparency, predictability and cooperation on SPS matters, such as clear timelines for import conditions, certification procedures, regionalisation criteria, and exchanges of information, elements intended to help Indian exporters align with EU requirements and address barriers linked to regulatory divergence [96]. India has historically faced trade limitations with the EU due to stringent SPS norms, including differences in pesticide residue limits and other food safety standards that exceed global benchmarks such as Codex guidelines [97]. The agreement's SPS chapter thus reflects a negotiated balance: India gains market access for many products within calibrated tariff frameworks, but both sides retain the right to enforce their respective regulatory criteria.

This balance is emblematic of how trade agreements attempt to manage regulatory duality: the EU insists on upholding its precautionary food safety regime, while partners like India navigate how to meet science-based SPS requirements that may be more demanding than domestic thresholds. The inclusion of mechanisms for information exchange, cooperative controls, and bilateral consultation is intended to reduce friction arising from these divergent regulatory philosophies and ensure that trade expansion does not compromise consumer protection or animal and plant health in either market [96].

7.3. Food Safety, Precaution, and Regulatory Convergence

Both the Mercosur and India FTA demonstrate the enduring influence of food safety regulatory philosophies in shaping trade outcomes. Under WTO rules such as the SPS Agreement, WTO members are free to adopt levels of protection they consider appropriate, including precautionary measures where scientific evidence is lacking, provided these

measures are not applied arbitrarily or as a disguised restriction on trade [53]. In practice, the EU's precautionary framework imposes higher regulatory thresholds, particularly for products with uncertain or potential long-term risks, whereas many trading partners emphasise science-based assessments consistent with global standards like Codex.

Trade agreements like those with Mercosur and India thus incorporate hybrid governance mechanisms that preserve domestic regulatory autonomy while facilitating market access. The inclusion of cooperation modalities, transparency rules, and safeguard provisions, alongside binding commitments that maintain stringent food safety standards, reflects a pragmatic response to regulatory divergence. By embedding these elements into trade frameworks, the EU upholds high levels of consumer and environmental protection, consistent with the precautionary principle, while mitigating barriers to international trade arising from different risk assessment philosophies.

Recent trade agreements negotiated by the European Union provide important examples of how contemporary trade frameworks attempt to reconcile market liberalisation with stringent food safety and SPS requirements. Table 3 compares the principal food safety and regulatory cooperation provisions contained in the EU–Mercosur Partnership Agreement and the EU–India Free Trade Agreement, highlighting the mechanisms used to balance precautionary governance, trade facilitation, and regulatory autonomy.

Table 3. Comparative overview of the EU–Mercosur and EU–India trade agreements in relation to food safety regulation, sanitary and phytosanitary measures, and regulatory cooperation.

Agreement	SPS Approach	Precautionary Safeguards	Trade Facilitation Mechanisms
EU–Mercosur	Maintains EU SPS standards	Explicit preservation of EU protections	Safeguards and cooperation
EU–India FTA	Regulatory cooperation	Provisional SPS measures retained	Transparency and certification procedures

8. Policy Discussion

The regulatory divergence between the European Union's precautionary approach and the United States' science-based system has long generated trade tensions and policy uncertainty. Reconciling these differences requires strategies that balance public health protection, technological innovation, and market access. This section examines key policy options, focusing on mechanisms for regulatory alignment and the role of science diplomacy in facilitating cooperative solutions.

8.1. Comparative Regulatory Effectiveness and Hazard Control

The structural divergence between the EU and US regulatory philosophies directly translates to measurable differences in public health outcomes. When evaluating which system is more effective at controlling hazards, the data reveals a nuanced trade-off between biological and chemical risk management.

Reported foodborne illness data should be interpreted with caution because apparent differences between jurisdictions may reflect surveillance intensity as well as true differences in disease burden. In the United States, the higher reported incidence of infections such as salmonellosis and campylobacteriosis may partly reflect extensive state and federal surveillance systems, including the Foodborne Diseases Active Surveillance Network, which actively monitors laboratory-diagnosed infections and supports outbreak detection and trend analysis [98]. Similarly, recent EU One Health Zoonoses Reports show that campylobacteriosis and salmonellosis remain the first and second most reported zoonoses

in the EUT, with increases in reported cases in 2023 compared with 2022, and a further increase in campylobacteriosis notification rates in 2024 [99,100]. These trends may reflect changes in exposure, food-chain risks, diagnostic capacity, reporting completeness, and surveillance coverage. Therefore, reported incidence should not be used alone to judge whether the EU or US system is more effective. Instead, comparisons should consider surveillance design, case definitions, laboratory testing, outbreak attribution, compliance monitoring, and prevention measures across the food chain [101,102]. Chemical Hazards (Pesticide Residues): Regarding chemical control, the EU's precautionary framework is structurally more restrictive, resulting in significantly lower Maximum Residue Limits (MRLs) and the outright prohibition of numerous active ingredients widely permitted in the US. However, evaluating strictly by domestic legal compliance, both regulatory enforcement frameworks are exceptionally effective. Annual monitoring data from the European Food Safety Authority indicates that 96% to 98% of sampled commercial produce complies with domestic EU MRL boundaries [103,104]. Parallel enforcement data published by the US Food and Drug Administration demonstrates a highly comparable compliance baseline, with over 95% of tested domestic and imported commodities falling securely within US Environmental Protection Agency tolerances [105].

These outcomes demonstrate that regulatory “effectiveness” cannot be defined by a single metric. The discussion must acknowledge that the EU framework excels at mitigating upstream chemical and biological hazards through strict preventative entry barriers. Conversely, the US system accepts higher baseline chemical tolerances and upstream biological risks, relying on highly efficient, technologically driven post-harvest interventions to protect consumer health while prioritising volume and market access.

8.2. Mutual Recognition, Equivalence, and Regulatory Cooperation

One prominent strategy to mitigate trade tensions is the adoption of mutual recognition or equivalence agreements. Under mutual recognition agreements (MRAs), countries acknowledge that each other's regulatory standards achieve comparable levels of protection, allowing products approved in one jurisdiction to enter the other without duplicating regulatory procedures. MRAs have been applied in specific sectors, such as meat inspection and certain food additives, although political and public acceptance can limit their scope [106]. Equivalence agreements, by contrast, emphasise achieving similar public health outcomes rather than identical procedures. For instance, the EU and US could recognise that differing inspection regimes or production methods deliver comparable levels of safety, thereby reducing non-tariff barriers. Successful implementation requires robust risk assessment frameworks, transparency, and ongoing monitoring to ensure continued compliance. However, differences in risk perception and societal expectations can constrain these mechanisms. EU consumers, for example, may demand stricter precaution than equivalence alone can provide, highlighting the political sensitivity of regulatory harmonisation.

Bilateral and plurilateral regulatory cooperation further facilitates understanding and alignment of food safety standards. Transatlantic dialogues, such as the EU–US Food and Agriculture Working Group, aim to share scientific expertise, harmonise testing methodologies, and improve transparency. Agencies can collaborate to standardise risk assessment protocols, reducing disputes over scientific evidence and ensuring more consistent application of regulatory principles. Joint scientific committees to evaluate emerging technologies, including gene-edited crops, can build trust and provide a shared basis for decision-making. Regulatory cooperation emphasises transparency and mutual learning rather than imposing uniform standards, recognising the legitimacy of differing precautionary thresholds while facilitating trade.

8.3. Science Diplomacy, Trade Instruments, and Policy Constraints

Science diplomacy plays a critical role in bridging divergent regulatory philosophies. Evidence-based negotiation, using independent scientific evidence, can reconcile differences over contentious products, while public consultation and stakeholder engagement, particularly in precaution-oriented jurisdictions, enhance the legitimacy and acceptance of regulatory compromises. Capacity-building initiatives, including technical assistance and training for developing countries, help ensure that nations with limited institutional resources can participate effectively in international trade and implement standards aligned with global norms.

Trade agreements can incorporate mechanisms to manage regulatory divergence. Provisions under the SPS Agreement may permit precautionary measures in situations of uncertainty, provided these are proportionate, temporary, and transparent. Early warning systems, joint committees, and consultations can prevent disputes from escalating to formal WTO proceedings, which are often politically sensitive and protracted. Harmonised labelling, traceability, and certification schemes further facilitate trade while maintaining consumer confidence in both precautionary and science-based markets.

Despite these mechanisms, several challenges persist. Cultural and societal differences, including divergent consumer expectations regarding risk and precaution, can limit mutual recognition and harmonisation. Scientific uncertainty and emerging risks, such as novel technologies or long-term exposure effects, may perpetuate regulatory disagreement. Domestic political economy factors, including industry lobbying, historical food safety crises, and public opinion, can also influence regulatory choices, sometimes outweighing economic efficiency considerations. These factors underline the complexity of achieving substantive convergence between precautionary and science-based regulatory systems, highlighting the need for flexible, adaptive, and cooperative policy frameworks.

8.4. Barriers to Regulatory Integration and Comparative Effectiveness

A central difficulty in comparing the EU and US food safety systems is that regulatory effectiveness depends on the criterion being assessed. If effectiveness is defined as early prevention under uncertainty, the EU precautionary model has clear strengths because it allows regulators to act before scientific evidence of harm is complete. This can strengthen consumer protection, maintain public confidence, and reduce exposure to uncertain or long-term hazards. However, this same model can also delay innovation, increase compliance costs, and create non-tariff barriers when trading partners consider EU measures to be more restrictive than necessary.

By contrast, the US risk-based model may be considered effective when the criteria are regulatory efficiency, technological innovation, and market access. Its reliance on measurable risk assessment can avoid unnecessary restrictions and support rapid adoption of new food technologies. Nevertheless, this model may be less effective where scientific uncertainty is high, where long-term or cumulative risks are difficult to quantify, or where public trust depends on visible pre-market safeguards rather than post-market control. Therefore, the two systems are not simply more or less protective; they prioritise different dimensions of effectiveness.

Regulatory integration is also limited by factors that extend beyond food safety science. Economic interests shape the negotiating positions of producers, exporters, retailers, and agricultural sectors that either benefit from regulatory flexibility or seek protection from competing imports. Political pressures also influence food safety decisions, particularly where high-profile products such as hormone-treated beef, genetically modified crops, or chlorine-washed poultry become symbols of national regulatory identity. In this sense, food

safety policy may reflect not only scientific evidence, but also domestic electoral incentives, lobbying, public perception, and the desire to protect national production models.

Nationalism and regulatory sovereignty further complicate convergence. Food safety standards are often perceived by governments and consumers as expressions of national or regional values, not merely technical rules. The EU's precautionary approach is closely linked to its post-crisis emphasis on consumer protection, traceability, and institutional accountability, whereas the US system reflects a stronger tradition of technological acceptance, cost-benefit reasoning, and market-oriented regulation. These differences make full harmonisation unlikely, even where both systems pursue legitimate food safety goals.

Consequently, future integration is more likely to occur through partial and procedural mechanisms rather than through complete regulatory convergence. Equivalence agreements, shared risk assessment protocols, transparent SPS procedures, joint scientific panels, digital traceability, and targeted mutual recognition may reduce trade friction while allowing each jurisdiction to preserve its preferred level of protection. This suggests that the most realistic policy objective is not the replacement of one model by the other, but the development of flexible governance mechanisms capable of comparing outcomes, improving trust, and managing disagreement when scientific uncertainty, economic interests, and political values intersect.

8.5. Regulatory Requirements Beyond Food Safety: Protectionism, Market Access and Supply Management

Although food safety regulations are formally justified by the protection of public health, their practical effects often extend beyond food safety alone. Under the WTO Sanitary and Phytosanitary Agreement, members retain the right to set food safety, animal health and plant health measures, but these measures must be science-based, non-discriminatory, and not more trade-restrictive than necessary [17,107]. This legal framework reflects the dual nature of food safety regulation: it protects consumers and animal or plant health, but it can also affect market access, production costs, competitiveness, supply-chain organisation, and the ability of domestic producers to compete with imports.

The distinction between legitimate food safety protection and regulatory protectionism is therefore difficult to define in practice. Food standards may be shaped not only by scientific risk assessment, but also by political economy, interest-group pressure, consumer preferences, and trade exposure [108]. Measures such as restrictions on hormone-treated beef, genetically modified crops, antimicrobial poultry treatments, or pesticide residues may reflect genuine concerns about uncertainty, long-term exposure, consumer trust, or production standards. However, they may also have protective economic effects by limiting imports produced under lower-cost or different regulatory conditions. This dual function explains why food safety disputes frequently move beyond scientific risk assessment and become embedded in wider debates about agricultural competitiveness, rural livelihoods, national food standards, and the perceived fairness of international trade.

Market access is also shaped by the administrative and technical capacity required to comply with importing-country standards. Even when regulations are not intentionally protectionist, strict certification, traceability, labelling, residue testing, inspection, and documentation requirements can increase compliance costs for exporters. These burdens may be manageable for large multinational firms but more difficult for small producers, developing-country exporters, or supply chains that are not organised around the importing market's regulatory model. Previous analyses of agri-food standards show that food safety and quality requirements can act both as barriers to entry and as mechanisms for upgrading, depending on exporter capacity and institutional support [109,110].

Supply management provides another important dimension of this debate. Food safety controls are embedded in broader systems of production planning, inspection,

logistics, and market organisation. The EU model tends to place greater emphasis on upstream control, traceability, and prevention across the supply chain, consistent with the farm-to-fork approach and wider objectives of food-system governance [111]. The North American model is more accepting of validated downstream interventions when these demonstrably reduce risk. These differences affect how responsibility for food safety is distributed among farmers, processors, regulators, importers, and retailers. They also influence production costs and market organisation, particularly in sectors such as poultry, beef, and fresh produce, where standards applied at farm, slaughter, processing, or import level can determine access to high-value markets.

Therefore, the EU–US regulatory divide should not be interpreted solely as a technical disagreement about scientific evidence. It also reflects different political economies of food production and trade. Food safety requirements can protect consumers, but they can also protect domestic regulatory preferences, production systems, and market structures. Recognising this wider context does not mean that food safety measures are illegitimate. Rather, it shows that regulatory evaluation should consider both public-health justification and trade effects, including whether measures are proportionate, transparent, evidence-informed, non-discriminatory, and open to equivalence where different systems can achieve comparable levels of protection.

9. Future Directions

Future research on food safety governance and international trade should focus on the growing complexity of global food systems, particularly in relation to emerging technologies, evolving trade architectures, climate-related risks, and increasing societal expectations regarding transparency and sustainability. Although this review highlights the persistent divergence between precautionary and science-based regulatory paradigms, the rapid transformation of agri-food systems suggests that regulatory frameworks will require greater adaptability, coordination, and scientific integration in the coming decades. Recent analyses of EU food safety governance have similarly emphasised the need for more integrated and adaptive regulatory systems capable of responding to emerging chemical, environmental, and technological risks [8].

One important avenue for future research concerns the regulation of novel food technologies, including gene editing, synthetic biology, cultured meat, precision fermentation, nanotechnology, and artificial intelligence applications in food production and monitoring. Existing regulatory systems were largely designed for conventional food safety challenges and may not adequately address the uncertainties associated with these innovations. Comparative studies examining how precautionary and proof-of-harm systems evaluate emerging technologies could provide valuable insights into balancing innovation with consumer protection. Recent scholarship has highlighted the increasing regulatory complexity surrounding genetically modified crops and cellular agriculture in the European Union, particularly regarding the tension between innovation, sustainability, and precautionary governance [55,112].

Emerging genomic technologies require greater attention in future food safety governance, particularly gene editing and CRISPR-based new genomic techniques. These methods can introduce targeted genetic changes without necessarily inserting foreign DNA, creating regulatory uncertainty over whether they should be treated as conventional breeding, genetically modified organisms, or a separate regulatory category [54,56]. Recent reviews show that global regulatory approaches remain fragmented, with the EU historically applying a more process-based and precautionary approach, while countries such as the US, Canada, Brazil and Australia have moved towards more product- or risk-based assessments [54,56]. This divergence is scientifically significant because CRISPR-derived

crops and foods may raise questions about off-target effects, unintended compositional changes, traceability, labelling, consumer acceptance and trade disruption, even where the final genetic change could also occur through conventional breeding [113,114]. Future research should therefore examine whether gene-edited foods require distinct risk assessment procedures and how international standards can reduce regulatory conflict while preserving consumer protection and innovation.

Another critical area for future investigation is the interaction between food safety regulation and sustainability objectives. Increasingly, food governance is being linked to broader environmental concerns, including climate change mitigation, biodiversity protection, antimicrobial resistance, pesticide reduction, and sustainable agricultural practices. The EU's Farm to Fork strategy and related reforms demonstrate how food safety regulation is progressively integrating sustainability and environmental protection objectives alongside traditional public health concerns [68]. Future research should therefore examine whether precautionary approaches are better suited to managing long-term systemic environmental risks, or whether science-based adaptive regulatory systems can provide equivalent protection while minimising unnecessary trade barriers.

Future scholarship should also explore the implications of climate change for international food safety governance. Rising temperatures, changing pest distributions, water scarcity, and extreme weather events are likely to alter patterns of foodborne disease, contaminant exposure, and agricultural production. These developments may intensify regulatory divergence as countries adopt different responses to emerging risks and supply chain disruptions. Greater attention should therefore be given to the resilience of international SPS systems and the capacity of global institutions such as Codex, WHO, FAO, and the WTO to respond to dynamic and transboundary food safety threats. Recent data-driven approaches, including large-scale EFSA monitoring databases and AI-assisted food safety surveillance systems, may provide valuable tools for strengthening early-warning capabilities and regulatory responsiveness [115].

The role of consumer perception, misinformation, and public trust in shaping regulatory policy also warrants deeper interdisciplinary investigation. As demonstrated throughout this review, food safety regulation is not determined solely by scientific evidence but is also influenced by cultural values, political pressures, historical experiences, and societal attitudes towards uncertainty and technology. Future research integrating legal analysis, behavioural science, political economy, and risk communication could improve understanding of how regulatory legitimacy is constructed across different jurisdictions and how public trust influences trade outcomes and policy acceptance. Recent work on biotechnology governance and the precautionary principle in the EU illustrates how societal trust and institutional legitimacy continue to shape regulatory responses to innovation [35,116].

Further comparative analysis of hybrid regulatory systems in emerging economies, particularly in China, India, Africa, and Latin America, would also contribute significantly to the literature. Many of these countries are developing flexible governance models that combine precautionary safeguards with evidence-based risk assessment while simultaneously navigating institutional constraints and trade obligations. Evaluating the effectiveness of these hybrid systems in practice may provide valuable lessons for future international regulatory cooperation and convergence.

Finally, future policy-oriented research should investigate innovative governance mechanisms capable of reducing regulatory conflict while preserving domestic regulatory autonomy. Areas deserving particular attention include dynamic equivalence agreements, joint scientific review panels, digital traceability systems, blockchain-enabled food certification, and enhanced science diplomacy initiatives. Advances in digital food-chain monitoring, AI-supported risk assessment, and cybersecurity resilience within agri-food

systems are likely to become increasingly important components of future food safety governance [117].

The rapid evolution of global food systems, technological innovation, and environmental pressures is creating new regulatory challenges for food safety governance. Table 4 summarises the principal emerging issues likely to shape future regulatory debates, together with their implications for international trade and priority areas for future research. These challenges highlight the need for adaptive, cooperative, and scientifically robust governance frameworks capable of balancing innovation, sustainability, and consumer protection.

Table 4. Emerging challenges and future research priorities in global food safety governance.

Future Challenge	Regulatory Implications	Research Needs
Gene editing and synthetic biology	Uncertain classification and approval pathways	Comparative regulatory analysis
Cultured meat and precision fermentation	Novel food safety assessment	Harmonised international standards
Climate change and foodborne risks	Dynamic SPS adaptation	Resilient surveillance systems
AI and digital food monitoring	Data governance and traceability	Regulatory oversight frameworks
Consumer trust and misinformation	Legitimacy of regulatory decisions	Behavioural and communication studies
Sustainability integration	Balancing trade and environmental goals	Cross-sector policy evaluation
Blockchain and digital certification	Enhanced traceability and verification	International interoperability standards
Hybrid governance systems	Flexible precaution/risk balancing	Comparative institutional studies

10. Conclusions

The comparative analysis of food safety regulation highlights the enduring divergence between the EU's precautionary, hazard-based approach and the US' science-based, proof-of-harm framework. These contrasting regulatory philosophies reflect deeper societal, political, and historical factors, including differing attitudes toward scientific uncertainty, public trust, and consumer protection. The EU's precautionary model prioritises prevention in the face of incomplete evidence, leading to stricter pre-market controls, labelling requirements, and regulatory oversight, while the US framework emphasises empirical risk assessment, post-market monitoring, and regulatory efficiency.

This regulatory divergence has tangible consequences for international trade. High-profile disputes over hormone-treated beef, GMOs, and chlorine-washed poultry illustrate how differing evidentiary standards and precautionary thresholds create non-tariff barriers, complicate market access, and trigger WTO challenges. Beyond the transatlantic context, countries worldwide adopt a spectrum of regulatory models, ranging from precautionary to science-based, with hybrid frameworks emerging in regions such as China, India, and Africa. These hybrid systems seek to balance domestic protection, empirical risk assessment, and trade facilitation, reflecting the interplay between institutional capacity, market integration, and public health priorities.

International institutions, including the CAC, WHO, and WTO, play a central role in mediating regulatory divergence. Through standard-setting, guidance, and dispute resolution, these organisations provide benchmarks for scientific risk assessment while recognising the legitimacy of precautionary measures under uncertainty. Yet, the persis-

tence of philosophical and societal differences underscores the limits of harmonisation and the ongoing need for flexible, cooperative frameworks.

Recent EU trade agreements with Mercosur and India exemplify pragmatic strategies for managing regulatory duality. By embedding mechanisms for transparency, cooperation, and safeguards alongside binding commitments to maintain stringent SPS measures, these agreements uphold high levels of consumer and environmental protection while facilitating market access. Such hybrid governance arrangements demonstrate that regulatory convergence is less about uniformity and more about achieving shared objectives through structured coordination, procedural predictability, and respect for domestic autonomy.

Altogether, the comparison shows that neither the EU nor the US system is universally more effective in all dimensions of food safety governance. The EU model is stronger where the policy priority is early prevention, consumer reassurance, and the management of uncertain or long-term risks. The US model is stronger where effectiveness is judged by regulatory efficiency, innovation, proportionality, and market facilitation. The main policy challenge is therefore not to determine a single superior model, but to identify where each approach performs well, where each creates costs or uncertainties, and how international cooperation can reduce conflict without undermining legitimate domestic choices.

In an increasingly interconnected global food system, the coexistence of precautionary and science-based approaches, supplemented by hybrid mechanisms and international coordination, offers a path toward balancing public health protection, trade facilitation, and innovation. Future policy efforts should continue to emphasise dialogue, capacity-building, and adaptive frameworks to navigate emerging risks and evolving technological landscapes.

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Abbreviations

The following abbreviations are used in this manuscript:

BSE	Bovine Spongiform Encephalopathy
CAC	Codex Alimentarius Commission
Codex	Codex Alimentarius
EFSA	European Food safety Authority
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FAO	Food and Agriculture Organisation
FSIS	Food Safety and Inspection Service
FSANZ	Food Standards Australia New Zealand

FSSAI	Food Safety and Standards Authority of India
FTA	Free Trade Agreement
GRAS	Generally Recognised As Safe
GFLR	General Food Law Regulation
GMO	Genetically Modified Organism
HPP	High-Pressure Processing
MRLs	Maximum Residue Limit
MERCOSUR	Mercado Común del Sur
MRA	mutual recognition agreements
OECD	Organisation for Economic Co-operation and Development
SPS	Sanitary and Phytosanitary
US	United States
USDA	United States Department of Agriculture
WHO	World Health Organization
WTO	World trade Organization

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