

Preventive Trade Compliance Strategies for Reducing FDA Import Refusals and Strengthening Supply Chain Resilience in U.S. Food Imports: A Critical Integrative Review and Documentary Analysis

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Abstract

International food supply chains face increasing regulatory complexity and operational risk, particularly in the United States, where FDA requirements can result in import refusals and supply chain disruptions. This article presents a critical integrative review supported by regulatory and documentary analysis examining how preventive trade compliance can reduce FDA import refusals while strengthening supply chain resilience. Based on scientific literature and official regulatory sources, the study proposes the Preventive Trade Compliance Framework (PTCF), an integrated managerial framework organized around five dimensions: Regulatory Intelligence, Supplier Governance, Documentation Integrity, Preventive Risk Assessment, and Continuous Improvement. The framework integrates fragmented compliance activities into a preventive supply chain perspective, supporting the identification and mitigation of compliance risks before shipment. By positioning regulatory preparedness as a strategic organizational capability, the PTCF provides a conceptual foundation for improving operational resilience and future empirical research on the relationship between preventive trade compliance and supply chain performance.

1. Introduction

Global food supply chains have become increasingly interconnected over the past three decades. Advances in transportation technologies, trade liberalization, digital logistics systems, and supplier globalization have substantially increased the volume and complexity of food

products entering the United States. While globalization has expanded market opportunities and improved consumer access to a wider variety of food products throughout the year, it has simultaneously increased regulatory complexity and exposed supply chains to a broader range of operational, sanitary, geopolitical, and compliance-related risks (Christopher & Peck, 2004; Tang, 2006; Sheffi & Rice, 2005; Ivanov & Dolgui, 2020).

The United States is one of the world's largest food import markets, relying on international suppliers to satisfy domestic demand for fruits, vegetables, seafood, dairy products, processed foods, beverages, spices, ingredients, and numerous other food categories. As import volumes continue to increase, regulatory agencies face the challenge of protecting public health while facilitating legitimate trade. Consequently, regulatory compliance has become an increasingly important component of modern supply chain management (Christopher, 2016).

Within this regulatory environment, the U.S. Food and Drug Administration (FDA) plays a central role in overseeing the safety of most imported food products. Under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and particularly following the enactment of the Food Safety Modernization Act (FSMA), the FDA has progressively shifted from a reactive inspection model toward a preventive, risk-based regulatory approach. Rather than relying primarily on end-product inspections, the current regulatory framework requires importers and foreign suppliers to demonstrate that preventive food safety controls have been effectively implemented throughout the supply chain before products enter U.S. commerce (Food Safety Modernization Act, 2011).

One of the FDA's principal enforcement mechanisms is the refusal of admission of imported products that fail to comply with applicable regulatory requirements. Import refusals may result from microbiological contamination, chemical hazards, labeling deficiencies, adulteration, misbranding, inadequate documentation, supplier non-compliance, or violations identified during import examinations (U.S. Food and Drug Administration, 2024f). These enforcement actions may generate significant financial losses, additional storage costs, product destruction, shipment re-exportation, contractual disputes, insurance claims, and reputational consequences that frequently extend beyond the individual shipment itself (Craighead et al., 2007).

From a logistics perspective, FDA import refusals may create operational disruptions affecting inventory availability, transportation scheduling, supplier relationships, customer service, and organizational resilience (Tang, 2006; Manuj & Mentzer, 2008; Kleindorfer & Saad, 2005). Recent literature has extensively examined food safety systems, supply chain resilience, international logistics, risk management, supplier relationships, and regulatory governance. However, these research streams have largely evolved independently. Studies focusing on logistics resilience often devote limited attention to detailed regulatory compliance processes, whereas regulatory publications primarily emphasize legal requirements without fully exploring their operational implications for supply chain performance. Likewise, research on food safety management generally concentrates on manufacturing controls rather than examining preventive trade compliance as an integrated logistics capability (Jüttner et al., 2003; Scholten et al., 2014; Wieland & Wallenburg, 2012).

This fragmentation creates an important opportunity to develop a more comprehensive understanding of how preventive regulatory compliance contributes to resilient international food supply chains. Specifically, there remains a need to conceptually integrate international trade compliance practices, regulatory requirements, logistics risk management, and supply chain resilience into a unified preventive management perspective (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009).

Accordingly, the purpose of this article is to critically integrate scientific literature with official regulatory documentation to examine how preventive trade compliance strategies can reduce FDA import refusals while strengthening supply chain resilience (Christopher, 2016; Ivanov, 2021).

To accomplish this objective, the article combines evidence derived from peer-reviewed academic publications with documentary analysis of major FDA regulatory instruments, including the Food Safety Modernization Act (FSMA), the Foreign Supplier Verification Program (FSVP), FDA Import Alerts, FDA Guidance Documents, Warning Letters, Prior Notice requirements, Food Facility Registration requirements, and other publicly available regulatory resources (Bowen, 2009; Whittemore & Knafl, 2005; Snyder, 2019).

Finally, based on the synthesis of scientific and regulatory evidence, this study proposes the Preventive Trade Compliance Framework (PTCF), which organizes preventive compliance

activities into five interconnected managerial dimensions: Regulatory Intelligence, Supplier Governance, Documentation Integrity, Preventive Risk Assessment, and Continuous Improvement.

2. Methodology

2.1 Research Design

This study adopts a qualitative conceptual research design based on a critical integrative literature review combined with regulatory and documentary analysis. The objective was not to quantify statistical relationships or evaluate the effectiveness of specific regulatory interventions through empirical testing. Instead, the study seeks to integrate fragmented knowledge from scientific literature and official regulatory documentation to develop a comprehensive conceptual framework capable of supporting preventive trade compliance in international food supply chains (Whittemore & Knafl, 2005; Snyder, 2019).

A critical integrative review was selected because the research question extends beyond summarizing existing evidence. Rather than simply identifying previous findings, the study aims to synthesize concepts originating from different fields—including supply chain resilience, international logistics, food safety regulation, trade compliance, enterprise risk management, and organizational learning—into a unified theoretical perspective. Integrative reviews are particularly appropriate when knowledge is dispersed across multiple disciplines and when conceptual development represents one of the primary objectives of the research (Torraco, 2005).

Unlike systematic reviews, which primarily aggregate empirical evidence using predefined inclusion protocols, the present study emphasizes conceptual integration. Scientific publications and official regulatory documents were analyzed jointly because both provide essential perspectives for understanding preventive trade compliance. While the academic literature explains theoretical constructs such as resilience, governance, and risk management, regulatory documents describe the practical mechanisms through which these concepts are implemented within international food import operations. Accordingly, the research design supports the conceptual integration of scientific and regulatory evidence into the proposed PTCF (Christopher & Peck, 2004; Sheffi, 2005; Ponomarov & Holcomb, 2009).

2.2 Sources of Evidence

Evidence used in this study was obtained from two complementary categories of sources: academic literature and official regulatory documentation.

Priority was given to peer-reviewed publications and established scholarly works directly relevant to the conceptual domains examined in this study. Seminal publications were retained when necessary to establish the theoretical foundations of supply chain resilience, risk management, and organizational learning, while more recent academic and institutional publications were incorporated to reflect contemporary regulatory and operational developments. Publications addressing food safety management, international logistics, global sourcing, and regulatory governance were also incorporated to provide a multidisciplinary understanding of preventive compliance within international food supply chains (World Health Organization, 2022; Food and Agriculture Organization of the United Nations, 2021; Codex Alimentarius Commission, 2022; World Trade Organization, 2023).

The documentary analysis focused primarily on publicly available regulatory documents issued by the U.S. Food and Drug Administration (FDA). These documents included the Food Safety Modernization Act (FSMA), the Foreign Supplier Verification Program (FSVP), FDA Guidance Documents, Import Alerts, Warning Letters, Prior Notice requirements, Food Facility Registration requirements, Detention Without Physical Examination (DWPE) procedures, the Regulatory Procedures Manual, and related FDA compliance resources (Bowen, 2009; U.S. Food and Drug Administration, 2024a, 2024b, 2024c, 2024d, 2024g, 2024h, 2024i).

Additional institutional publications issued by organizations such as the U.S. Government Publishing Office, the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), the World Trade Organization (WTO), and the U.S. Department of Agriculture (USDA) were consulted whenever they contributed to understanding the broader regulatory and operational context of international food trade (World Health Organization, 2022; World Trade Organization, 2023; United States Department of Agriculture, 2024).

2.3 Analytical Procedure

The analytical process was conducted in four sequential stages designed to progressively integrate scientific and regulatory knowledge.

In the first stage, the academic literature was reviewed to identify the principal concepts associated with supply chain resilience, trade compliance, food safety regulation, logistics risk management, supplier governance, enterprise risk management, and organizational learning (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009; Ivanov, 2021; International Organization for Standardization, 2018; Committee of Sponsoring Organizations of the Treadway Commission, 2017). Particular attention was given to recurring theoretical constructs explaining how organizations anticipate disruptions, manage uncertainty, and strengthen operational continuity.

The second stage consisted of documentary analysis of official FDA regulations and guidance documents. Rather than focusing exclusively on legal interpretation, the analysis examined the preventive philosophy underlying contemporary U.S. food regulation and identified the principal organizational activities required to achieve regulatory compliance. Particular emphasis was placed on supplier verification, preventive controls, documentation integrity, regulatory intelligence, traceability, and continuous monitoring (U.S. Food and Drug Administration, 2024c).

During the third stage, findings from the academic literature and regulatory documentation were compared to identify recurring themes and conceptual convergence. Similar organizational patterns appearing across different regulatory instruments—including FSMA, FSVP, Import Alerts, Warning Letters, Prior Notice, and Facility Registration—were examined alongside concepts developed within the supply chain resilience literature (Bowen, 2009).

The final stage consisted of conceptual synthesis. The recurring themes identified throughout the literature review and documentary analysis were reorganized into an integrated managerial framework, resulting in the development of the Preventive Trade Compliance Framework (PTCF). Rather than introducing new regulatory requirements, the framework reorganizes existing preventive compliance activities into interconnected organizational capabilities intended to strengthen regulatory preparedness and supply chain resilience (Torraco, 2005).

2.4 Research Scope and Limitations

This study is conceptual in nature and therefore does not include primary empirical data, surveys, interviews, or statistical analyses. The proposed framework was developed through the integration of academic literature and publicly available regulatory documentation. Consequently, the findings should be interpreted as a theoretical contribution intended to support future empirical investigation rather than as evidence of causal relationships.

In addition, the regulatory analysis focuses primarily on the U.S. Food and Drug Administration and the regulatory framework governing food imports into the United States. Although many of the managerial principles discussed may be applicable to other regulatory environments, the framework was developed specifically within the context of U.S. food import regulation.

Future research should evaluate the applicability of the Preventive Trade Compliance Framework (PTCF) across different industries, countries, and regulatory systems through case studies, surveys, longitudinal analyses, and quantitative assessments of operational performance.

3. Literature Review

3.1 Supply Chain Resilience in International Food Trade

Global food supply chains have undergone profound transformations over recent decades. The expansion of international trade, increasing consumer demand for year-round food availability, globalization of supplier networks, and advances in transportation and logistics technologies have substantially increased the complexity of international food distribution systems. While these developments have improved efficiency and market accessibility, they have simultaneously increased vulnerability to disruptions arising from operational failures, regulatory non-compliance, geopolitical instability, climate-related events, public health emergencies, and supplier-related risks (Christopher & Peck, 2004; Tang, 2006; Sheffi & Rice, 2005; Ivanov & Dolgui, 2020).

Supply chain resilience has therefore emerged as one of the most significant concepts in logistics and operations management. Rather than focusing exclusively on recovering from disruptions after they occur, contemporary resilience emphasizes organizations' ability to

anticipate risks, adapt to changing environments, absorb operational shocks, and maintain business continuity throughout the supply chain (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009; Ivanov, 2021).

Food supply chains present unique resilience challenges because product safety cannot be compromised. Unlike many industrial products, food products are directly associated with public health, requiring organizations to simultaneously manage logistics efficiency, regulatory compliance, traceability, quality assurance, supplier verification, and sanitary controls. Consequently, resilience in food supply chains extends beyond transportation continuity and inventory availability to include regulatory preparedness and preventive compliance (World Health Organization, 2022; Christopher & Peck, 2004).

Recent research suggests that resilient food supply chains depend upon integrated risk management practices involving collaboration among suppliers, manufacturers, logistics providers, regulatory agencies, and importers. Information sharing, documentation accuracy, digital traceability, preventive quality systems, and supplier qualification are consistently identified as critical resilience capabilities that reduce operational uncertainty while facilitating regulatory compliance (Scholten et al., 2014; Wieland & Wallenburg, 2012; Ambulkar et al., 2015).

Within international trade, compliance failures may generate consequences comparable to traditional supply chain disruptions, including interrupted supply continuity, increased logistics costs, damaged commercial relationships, and reputational effects (Sheffi, 2005; Tang, 2006).

3.2 Trade Compliance as a Strategic Capability

Historically, trade compliance has frequently been treated as a back-office administrative function primarily responsible for customs documentation and regulatory filings. However, contemporary international supply chains require a broader understanding of compliance as an integrated managerial capability influencing strategic decision-making throughout procurement, sourcing, logistics, quality management, and supplier governance (Manuj & Mentzer, 2008).

Trade compliance encompasses the systematic application of regulatory requirements governing product classification, customs procedures, documentation accuracy, product labeling, sanitary standards, country-of-origin declarations, import licensing, supplier verification,

transportation requirements, and recordkeeping obligations. Organizations that integrate compliance into operational planning generally experience fewer regulatory interruptions, greater operational visibility, and improved supply chain reliability (Manuj & Mentzer, 2008; Christopher, 2016).

The evolution of global regulatory frameworks has progressively shifted compliance responsibilities toward preventive management. Rather than relying exclusively on inspections at the point of entry, regulatory systems increasingly require organizations to demonstrate that compliance activities have been incorporated throughout production, supplier management, transportation, and distribution processes.

This transition reflects broader developments in supply chain governance. Organizations are now expected to maintain effective internal controls, supplier monitoring systems, documentation verification procedures, corrective action mechanisms, and continuous compliance improvement programs. Consequently, trade compliance contributes not only to regulatory conformity but also to operational efficiency, risk reduction, and competitive advantage (International Organization for Standardization, 2018; Committee of Sponsoring Organizations of the Treadway Commission, 2017).

From a logistics perspective, preventive compliance may reduce uncertainty by addressing documentation errors, labeling deficiencies, supplier failures, and regulatory non-conformities before shipment (Tang & Tomlin, 2008; Wagner & Bode, 2008).

3.3 Regulatory Compliance in U.S. Food Imports

The United States maintains one of the world's most comprehensive regulatory systems for food safety. The U.S. Food and Drug Administration (FDA) is responsible for regulating the majority of food products imported into the country under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act), with its regulatory responsibilities significantly expanded following the enactment of the Food Safety Modernization Act (FSMA) (Food Safety Modernization Act, 2011; U.S. Food and Drug Administration, 2024b).

The implementation of FSMA represented a fundamental shift in U.S. food regulation by emphasizing prevention rather than reaction. Instead of relying predominantly on post-market enforcement and border inspections, the legislation introduced preventive controls intended to

reduce food safety risks throughout the supply chain before products reach consumers (Food Safety Modernization Act, 2011; U.S. Food and Drug Administration, 2024b).

One of the most significant regulatory instruments established under FSMA is the Foreign Supplier Verification Program (FSVP). This program requires importers to verify that foreign suppliers produce food under safety standards that provide the same level of public health protection required of domestic producers. Consequently, importers assume greater responsibility for supplier evaluation, hazard analysis, documentation review, corrective actions, and continuous verification activities (U.S. Food and Drug Administration, 2024c).

This preventive philosophy substantially changes the traditional role of importers. Rather than acting merely as purchasers or customs declarants, importers become active participants in ensuring regulatory compliance throughout international supply chains. Successful compliance therefore increasingly depends upon effective supplier governance, continuous information exchange, standardized documentation, preventive risk assessment, and ongoing monitoring of supplier performance.

3.4 FDA Import Refusals as Supply Chain Disruptions

FDA import refusals represent one of the most significant regulatory risks affecting international food logistics. A shipment may be refused admission when it fails to comply with applicable statutory or regulatory requirements, including deficiencies related to food safety, labeling, adulteration, contamination, documentation, or other violations identified during import examinations (U.S. Food and Drug Administration, 2024f).

Although import refusals are frequently analyzed from a legal perspective, their operational consequences extend throughout the supply chain. Refused shipments often generate transportation delays, additional storage costs, demurrage charges, customs complications, contractual disputes, inventory shortages, product destruction or re-exportation, and reputational damage that may affect future commercial relationships (Craighead et al., 2007).

These consequences demonstrate that regulatory non-compliance functions as a supply chain disruption capable of affecting multiple stakeholders simultaneously. Suppliers, importers, logistics providers, customs brokers, retailers, and consumers may all experience operational impacts resulting from a single regulatory event (Tang, 2006; Kleindorfer & Saad, 2005).

Moreover, recurring compliance failures may trigger intensified regulatory scrutiny, increased inspection frequency, Import Alerts, and additional verification requirements, further increasing logistics complexity while reducing operational flexibility (U.S. Food and Drug Administration, 2024c).

3.5 Preventive Compliance and Risk Management

Contemporary supply chain risk management increasingly emphasizes prevention rather than reaction. Organizations are encouraged to identify vulnerabilities before disruptions occur through systematic risk assessment, continuous monitoring, supplier evaluation, and the proactive implementation of internal controls (ISO, 2018; COSO, 2017).

Within international food trade, preventive compliance aligns naturally with these principles. Many of the factors associated with FDA import refusals—including documentation errors, labeling deficiencies, inadequate supplier verification, missing records, and incorrect product classifications—can be identified and corrected before shipment.

Accordingly, organizations that establish structured compliance verification processes before export may reduce operational uncertainty. Preventive activities may include documentation validation, supplier qualification programs, regulatory intelligence, labeling verification, product specification review, shipment audits, and corrective action procedures (Manuj & Mentzer, 2008; U.S. Food and Drug Administration, 2024b, 2024c).

Together, these mechanisms illustrate the operational role of preventive compliance within international food trade.

3.6 Research Gap

Despite the growing body of literature addressing food safety, supply chain resilience, international logistics, and regulatory governance, relatively few studies integrate these research domains into a unified preventive trade compliance perspective.

Existing research frequently examines food safety management independently from logistics resilience or analyzes regulatory compliance without considering its broader operational implications for supply chain performance. Likewise, studies addressing resilience tend to emphasize disruption recovery, inventory management, transportation flexibility, or supplier

diversification while devoting comparatively limited attention to preventive regulatory compliance as an organizational capability (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009; Ivanov, 2021).

Furthermore, official FDA guidance documents provide extensive regulatory requirements but generally do not translate these requirements into integrated managerial frameworks capable of supporting strategic logistics decision-making. Conversely, the supply chain resilience literature rarely incorporates detailed regulatory mechanisms into its theoretical models.

This fragmentation highlights an opportunity for conceptual integration. Specifically, there remains a need for a managerial framework that systematically connects preventive regulatory compliance activities with established supply chain resilience principles applicable to international food imports (Torraco, 2005).

The present study seeks to address this gap by integrating scientific literature with regulatory documentation to develop the Preventive Trade Compliance Framework (PTCF), a conceptual model intended to support proactive compliance management while strengthening resilient international food supply chains.

4. Regulatory and Documentary Analysis

4.1 The U.S. Food Regulatory Architecture

Unlike many countries in which a single governmental authority is responsible for food safety, the United States operates under a multi-agency regulatory framework in which responsibilities are distributed among several federal entities. This institutional arrangement reflects the complexity of modern food supply chains and requires importers to understand not only customs procedures but also food safety legislation, public health requirements, and agency-specific regulatory obligations (U.S. Customs and Border Protection, 2024).

For the majority of imported food products, regulatory oversight is exercised by the U.S. Food and Drug Administration (FDA), while U.S. Customs and Border Protection (CBP) administers customs entry procedures and border enforcement. The U.S. Department of

Agriculture (USDA), through the Food Safety and Inspection Service (FSIS), regulates meat, poultry, and certain processed egg products, whereas the Animal and Plant Health Inspection Service (APHIS) oversees specific animal and plant health requirements. Consequently, a single international shipment may simultaneously involve customs, food safety, sanitary, and agricultural compliance obligations (U.S. Customs and Border Protection, 2024; United States Department of Agriculture, 2024).

This multi-layered regulatory environment significantly increases operational complexity for importers. Successful importation depends not only on transportation efficiency but also on accurate product classification, complete documentation, supplier qualification, facility registration, labeling compliance, Prior Notice requirements, and continuous conformity with evolving regulatory standards.

4.2 From Reactive Inspection to Preventive Regulation

Historically, U.S. food regulation relied heavily on the inspection of imported products at ports of entry. Regulatory intervention primarily occurred after shipments reached the United States, with enforcement actions focusing on identifying contaminated, adulterated, or otherwise non-compliant products during import examinations.

The enactment of the Food Safety Modernization Act (FSMA) fundamentally transformed this regulatory philosophy by shifting the emphasis from reaction to prevention. Rather than depending principally on border inspections, the FDA increasingly requires organizations to demonstrate that preventive food safety controls have been implemented throughout production, processing, storage, transportation, and supplier management before products enter U.S. commerce (U.S. Food and Drug Administration, 2024c).

This preventive approach recognizes that inspection alone cannot ensure food safety within increasingly globalized supply chains. Millions of food shipments enter the United States annually, making comprehensive physical inspection impractical. Consequently, regulatory effectiveness depends upon risk-based management systems capable of identifying hazards before products are exported.

The preventive philosophy introduced by FSMA extends responsibility beyond manufacturers and directly affects importers, who must actively verify that foreign suppliers

comply with U.S. food safety requirements. As a result, importers have evolved from passive purchasers to accountable participants within the food safety system (U.S. Food and Drug Administration, 2024c).

This transformation requires supplier qualification, hazard assessment, documentation review, and monitoring to occur before shipment departure.

4.3 Foreign Supplier Verification Program (FSVP)

Among the regulatory instruments established under FSMA, the Foreign Supplier Verification Program (FSVP) represents one of the most significant regulatory changes affecting international food trade. The regulation requires designated U.S. importers to develop, implement, maintain, and periodically reassess a documented verification program for each imported food product, unless a specific exemption applies (21 CFR Part 1, Subpart L; U.S. Food and Drug Administration, 2024c).

The objective of FSVP extends beyond administrative compliance. It requires systematic verification that imported food has been produced under standards providing the same level of public health protection required of domestic producers. Importers must therefore evaluate both product characteristics and supplier performance through a structured, risk-based process.

The regulation requires importers to perform several core activities, including:

- conducting or relying on hazard analyses that identify known or reasonably foreseeable biological, chemical, and physical hazards;
- evaluating supplier performance and food safety history;
- determining and implementing appropriate supplier verification activities;
- documenting compliance activities;
- implementing corrective actions whenever necessary; and
- periodically reassessing suppliers or whenever new risk information becomes available (U.S. Food and Drug Administration, 2024c).

Supplier verification may include on-site audits, laboratory testing, review of food safety records, or other risk-based verification activities depending on the hazards identified.

Importantly, the regulation recognizes that different foods present different risk profiles; therefore, verification activities should be proportionate to the identified hazards rather than applied uniformly across all products.

From a supply chain management perspective, FSVP substantially expands the traditional responsibilities of importers. Organizations are expected not only to purchase compliant products but also to establish governance mechanisms capable of continuously evaluating supplier reliability, documenting verification activities, and responding proactively to emerging compliance risks (Manuj & Mentzer, 2008).

4.4 Preventive Controls as a Supply Chain Strategy

One of the defining characteristics of the Food Safety Modernization Act (FSMA) is its emphasis on preventive controls rather than end-product inspection. This principle reflects a broader evolution in quality management and supply chain governance, where risk mitigation is increasingly achieved through process control rather than reliance on final inspections (Food Safety Modernization Act, 2011; U.S. Food and Drug Administration, 2024b).

Within international food supply chains, preventive controls require organizations to identify hazards before production, establish appropriate monitoring procedures, verify the effectiveness of preventive measures, maintain comprehensive documentation, and implement corrective actions whenever deviations are identified.

This preventive philosophy naturally extends beyond manufacturing facilities. Importers, logistics providers, customs brokers, suppliers, and manufacturers all contribute to maintaining product integrity throughout cross-border operations. Documentation accuracy, traceability systems, transportation controls, supplier communication, and record management therefore become essential components of preventive compliance (U.S. Food and Drug Administration, 2024b).

Preventive controls may also be incorporated into enterprise risk management systems to address regulatory vulnerabilities before they result in shipment disruption (ISO, 2018; COSO, 2017).

4.5 Prior Notice and FDA Facility Registration

One of the fundamental preventive mechanisms established within the U.S. food import system is the requirement that imported food shipments be electronically reported to the FDA before arriving in the United States. This requirement, known as Prior Notice, enables the agency to conduct risk assessments before products physically reach U.S. ports of entry (21 CFR Part 1, Subpart I; U.S. Food and Drug Administration, 2024g).

The Prior Notice requirement was originally introduced under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and remains an essential component of FDA import oversight. Importers must provide detailed shipment information, including product identification, manufacturer, shipper, consignee, anticipated port of entry, and estimated arrival time. This information enables the FDA to identify potential public health concerns, allocate inspection resources according to risk, and coordinate enforcement activities with U.S. Customs and Border Protection (CBP).

Failure to submit accurate Prior Notice information may result in shipment delays, refusal of admission, or administrative actions that increase logistics costs and disrupt supply chain continuity.

Similarly, many foreign food manufacturers, processors, packers, and storage facilities must register with the FDA before exporting products regulated by the agency into the United States. Facility Registration enables regulatory authorities to identify production sites, facilitate inspections when necessary, and maintain traceability throughout international food supply chains (21 CFR Part 1, Subpart H; U.S. Food and Drug Administration, 2024a).

Both Prior Notice and Facility Registration illustrate an important characteristic of modern regulatory governance: compliance increasingly depends on information quality rather than solely on physical inspections. Accurate, timely, and complete electronic information enables regulators to identify higher-risk shipments while facilitating legitimate trade for compliant operators.

4.6 FDA Import Refusals

Among the various enforcement mechanisms available to the FDA, Import Refusals represent one of the most visible indicators of regulatory non-compliance within international food supply chains (U.S. Food and Drug Administration, 2024f).

An Import Refusal occurs when the FDA determines that a product offered for import violates applicable provisions of the Federal Food, Drug, and Cosmetic Act. Once a refusal is issued, the shipment generally cannot enter U.S. commerce unless appropriate legal procedures permit corrective action. Depending on the circumstances, products may be exported, destroyed, or otherwise disposed of under regulatory supervision.

From a legal perspective, import refusals constitute enforcement actions designed to protect public health. From a logistics perspective, however, they represent significant supply chain disruptions capable of generating cascading operational consequences.

Unlike traditional transportation delays, regulatory refusals frequently produce simultaneous impacts across multiple operational dimensions. Organizations may experience:

- increased port storage costs;
- container detention and demurrage charges;
- transportation rescheduling;
- inventory shortages;
- contractual penalties;
- product disposal expenses;
- customer dissatisfaction;
- supplier disputes;
- insurance claims; and
- long-term reputational damage (Craighead et al., 2007).

These consequences demonstrate that regulatory compliance failures should be analyzed using the same risk management principles commonly applied to other supply chain disruptions (Tang, 2006; Kleindorfer & Saad, 2005).

Importantly, FDA Import Refusals may originate from preventable organizational deficiencies rather than unexpected contamination events. Documentation inconsistencies, inaccurate labeling, incomplete supplier verification, facility registration deficiencies, and

administrative errors may all contribute to enforcement actions that could have been avoided through stronger preventive compliance systems (U.S. Food and Drug Administration, 2024f).

4.7 FDA Import Alerts

FDA Import Alerts constitute another important preventive regulatory instrument within the U.S. food import system. Import Alerts identify products, manufacturers, countries, or specific compliance issues that have demonstrated recurring regulatory concerns, thereby enabling FDA field personnel to apply risk-based enforcement more efficiently (U.S. Food and Drug Administration, 2024d).

Many Import Alerts authorize Detention Without Physical Examination (DWPE), allowing FDA to detain certain imported products based on previous evidence of non-compliance without requiring physical examination of every shipment. This approach reflects the agency's preventive philosophy by allocating inspection resources according to identified regulatory risk.

Import Alerts frequently involve microbiological contamination, pesticide residues, undeclared allergens, insanitary manufacturing conditions, economically motivated adulteration, labeling deficiencies, and repeated failures to comply with FDA requirements. Importantly, the publication of an Import Alert generally reflects recurring organizational or supplier-related deficiencies rather than isolated incidents.

For importers and foreign manufacturers, Import Alerts represent significant operational risks. Products subject to DWPE may experience extended delays, increased storage costs, additional laboratory testing requirements, contractual disputes, shipment re-exportation, or product destruction. These consequences illustrate how regulatory actions may directly influence logistics performance, inventory availability, customer service, and supply chain continuity (Craighead et al., 2007).

Beyond their enforcement function, Import Alerts also provide valuable regulatory intelligence. Organizations that continuously monitor newly issued Import Alerts may identify emerging regulatory trends, reassess supplier performance, strengthen preventive controls, and proactively implement corrective measures before similar deficiencies affect their own supply chains. This anticipatory use of regulatory information is consistent with established principles of supply chain resilience (Christopher & Peck, 2004; Ivanov, 2021).

4.8 FDA Warning Letters

While Import Refusals and Import Alerts primarily address products entering the United States, FDA Warning Letters communicate observed regulatory violations directly to regulated firms. Unlike statutory provisions, which establish general legal requirements, Warning Letters illustrate how those requirements are interpreted and applied during actual inspections and enforcement activities, providing valuable insight into FDA regulatory expectations (U.S. Food and Drug Administration, 2024i).

A Warning Letter formally notifies an organization that significant regulatory deficiencies have been identified and requests prompt corrective action. Although Warning Letters do not themselves impose penalties, they indicate that the FDA considers voluntary correction necessary before stronger enforcement measures become appropriate.

Analysis of publicly available Warning Letters reveals recurring compliance deficiencies involving:

- inadequate preventive controls;
- deficient supplier verification;
- incomplete or inaccurate documentation;
- sanitation deficiencies;
- labeling violations;
- failure to maintain required records;
- insufficient hazard analyses; and
- ineffective corrective action procedures (U.S. Food and Drug Administration, 2024i).

These recurring observations suggest that regulatory deficiencies may reflect weaknesses in organizational systems. Warning Letters can therefore provide compliance professionals and

supply chain managers with evidence of recurring deficiencies that may inform internal preventive measures (Garvin, 1993; Senge, 1990).

4.9 Regulatory Intelligence as a Competitive Capability

The regulatory instruments discussed throughout this study—including Prior Notice, Facility Registration, FSVP, Import Refusals, Detention Without Physical Examination (DWPE), Import Alerts, and Warning Letters—share a common characteristic: they continuously generate information capable of supporting organizational decision-making.

Traditionally, many organizations respond to regulatory actions only after enforcement occurs. However, resilient organizations increasingly adopt a proactive approach by systematically monitoring regulatory developments, analyzing enforcement trends, and incorporating this information into operational decision-making. This capability may be described as regulatory intelligence: the continuous collection, interpretation, and application of regulatory information to support preventive compliance and strategic risk management.

Regulatory intelligence extends beyond legal interpretation. It encompasses the ability to identify emerging enforcement priorities, recognize recurring compliance deficiencies, evaluate supplier performance, anticipate regulatory changes, and incorporate this knowledge into procurement, logistics planning, supplier governance, documentation management, and quality assurance (ISO, 2018; COSO, 2017).

This capability may reduce uncertainty by enabling organizations to identify compliance risks before shipment (Christopher & Peck, 2004; Ivanov, 2021).

4.10 Cross-Analysis of FDA Enforcement Mechanisms and Their Implications for Supply Chain Risk

Although FDA regulatory instruments differ in their legal objectives and enforcement mechanisms, they collectively form an integrated, risk-based regulatory system designed to prevent unsafe food from entering the U.S. market. Rather than functioning as isolated enforcement actions, Prior Notice, Facility Registration, FSVP, Import Refusals, Import Alerts, Detention Without Physical Examination (DWPE), and Warning Letters constitute complementary components of a preventive regulatory architecture that encourages continuous

compliance throughout international food supply chains (U.S. Food and Drug Administration, 2024a, 2024c, 2024d, 2024f, 2024g, 2024h, 2024i).

From a supply chain management perspective, these instruments should not be interpreted solely as legal obligations imposed by regulatory authorities. Instead, they provide valuable indicators of operational risk capable of supporting proactive managerial decision-making. Each mechanism generates information regarding vulnerabilities within international supply chains, enabling organizations to identify weaknesses before they develop into significant operational disruptions.

For example, Prior Notice and Facility Registration emphasize information quality and traceability before shipment arrival. FSVP expands importer responsibility by requiring systematic supplier evaluation and documented verification activities. Import Refusals provide evidence of compliance failures occurring at the border, while Warning Letters identify recurring organizational deficiencies observed during inspections. Import Alerts and DWPE communicate patterns of elevated regulatory concern derived from previous enforcement experience.

Viewed collectively, these regulatory mechanisms provide information that organizations can use to identify recurring causes of non-compliance and inform preventive risk management. This use of regulatory information is consistent with principles of organizational learning and enterprise risk management (Garvin, 1993; Senge, 1990; COSO, 2017).

4.11 Emerging Themes from the Regulatory Analysis

The documentary analysis conducted in this study identified several recurring themes that consistently appear across FDA regulations, guidance documents, Import Alerts, Warning Letters, and enforcement procedures (U.S. Food and Drug Administration, 2024d, 2024h, 2024i).

First, preventive action consistently receives greater regulatory emphasis than corrective action. Rather than relying primarily on border inspections, current regulatory policy encourages organizations to identify hazards, evaluate suppliers, verify documentation, and implement preventive controls before products enter international commerce (Food Safety Modernization Act, 2011).

Second, importer accountability has increased substantially under the preventive regulatory model. Importers are expected not merely to receive compliant products but to actively participate in supplier governance, hazard assessment, documentation review, and ongoing compliance verification through structured, risk-based processes (U.S. Food and Drug Administration, 2024c).

Third, documentation quality emerged as a recurring determinant of regulatory performance. Incomplete records, inaccurate product information, labeling deficiencies, and insufficient verification documentation frequently contribute to enforcement actions even in situations where no actual food safety hazard is identified. This finding highlights the importance of documentation not only as an administrative requirement but also as evidence demonstrating that preventive activities have been properly implemented (U.S. Food and Drug Administration, 2024f, 2024i).

Fourth, regulatory compliance depends heavily on effective information management, including traceability, recordkeeping, supplier communication, corrective action documentation, and continuous monitoring (ISO, 2018; COSO, 2017).

Finally, the regulatory framework consistently reinforces the importance of continuous improvement. Organizations are expected to periodically reassess suppliers, update verification procedures, incorporate lessons learned from inspections and enforcement actions, and continuously adapt their compliance systems to evolving regulatory expectations (Garvin, 1993; Senge, 1990).

5. Discussion

These findings support the integration of preventive regulatory activities into strategic supply chain management (Christopher & Peck, 2004; Tang, 2006; Ponomarov & Holcomb, 2009).

The analysis further demonstrates that many FDA enforcement actions originate from deficiencies that are organizational rather than technical in nature. Documentation inconsistencies, ineffective supplier qualification, incomplete verification activities, deficient

recordkeeping, inadequate communication, and failures to implement preventive controls frequently precede regulatory intervention. Consequently, reducing import refusals depends not only on product safety but also on organizational governance, information quality, and systematic risk management (U.S. Food and Drug Administration, 2024f, 2024i).

This finding supports a broader interpretation of preventive trade compliance. Instead of viewing compliance exclusively as a legal obligation or administrative function, organizations should integrate regulatory activities into strategic supply chain management. Regulatory monitoring, supplier governance, documentation integrity, preventive risk assessment, and continuous improvement become complementary organizational capabilities that contribute simultaneously to compliance performance and operational resilience (ISO, 2018; COSO, 2017).

Regulatory intelligence represents one mechanism through which publicly available enforcement information can support informed managerial decision-making. Import Alerts, Warning Letters, guidance documents, and enforcement trends may provide organizations with evidence for anticipating emerging compliance risks. This use of regulatory information is consistent with principles of organizational learning (Garvin, 1993; Senge, 1990).

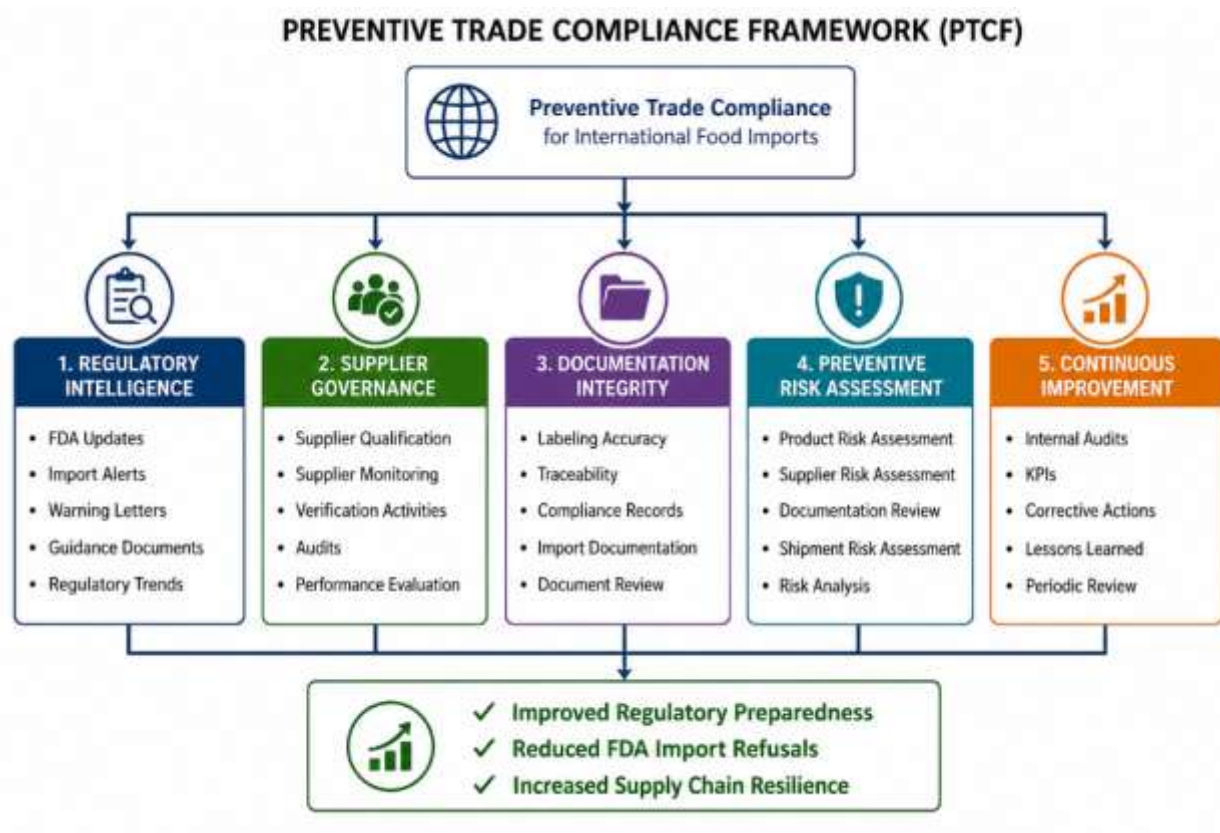
Supplier governance provides another connection between regulation and resilience. Under FSVP, hazard analysis, verification activities, corrective actions, and periodic reassessment extend importer responsibility throughout the supplier relationship (U.S. Food and Drug Administration, 2024c).

Collectively, these findings provide the conceptual basis for integrating preventive regulatory practices into a unified managerial framework. Based on this theoretical and documentary synthesis, the next section proposes the Preventive Trade Compliance Framework (PTCF), which organizes these preventive capabilities into an integrated managerial model intended to support proactive decision-making across international food supply chains.

6. Preventive Trade Compliance Framework (PTCF)

6.1 Framework Overview

Figure 1. Preventive Trade Compliance Framework (PTCF)



The framework integrates five complementary organizational capabilities that collectively strengthen preventive trade compliance, reduce regulatory risk, and improve supply chain resilience in international food imports. Source: Developed by the author.

Table 1. Core Components of the Preventive Trade Compliance Framework (PTCF)

Component	Primary Objective	Examples of Activities	Expected Outcomes
Regulatory Intelligence	Monitor regulatory developments	FDA Guidance, Import Alerts, Warning Letters, regulatory updates	Early identification of compliance risks
Supplier Governance	Strengthen supplier oversight	Qualification, audits, performance monitoring, supplier verification	Improved supplier reliability
Documentation Integrity	Ensure accurate regulatory documentation	Label verification, traceability, import records, document review	Reduced documentation deficiencies
Preventive Risk Assessment	Identify risks before shipment	Product assessment, supplier evaluation, shipment review, risk analysis	Fewer import refusals
Continuous Improvement	Promote organizational learning	Internal audits, KPIs, corrective actions, periodic reassessment	Long-term resilience and continuous compliance

Figure 1 illustrates the five interconnected dimensions of the proposed PTCF, while Table 1 summarizes their objectives, representative activities, and expected outcomes. Based on the literature review and documentary analysis, the framework organizes preventive compliance activities into an integrated managerial model designed to identify, evaluate, monitor, and mitigate regulatory risks throughout the import process.

6.2 Core Components of the Framework

The PTCF comprises five interconnected managerial dimensions:

1. Regulatory Intelligence

Organizations should continuously monitor regulatory developments, including FDA Guidance Documents, Import Alerts, Warning Letters, regulatory updates, enforcement trends, and emerging compliance risks. This capability enables organizations to anticipate regulatory changes and proactively adapt internal processes before enforcement actions become necessary (U.S. Food and Drug Administration, 2024d, 2024i).

2. Supplier Governance

Effective preventive compliance requires systematic supplier qualification, risk-based supplier evaluation, periodic performance reassessment, and verification that preventive food safety controls remain consistently implemented throughout the supply chain.

3. Documentation Integrity

Documentation serves as the primary evidence demonstrating regulatory compliance. Organizations should establish standardized procedures for preparing, verifying, maintaining, and periodically reviewing product specifications, labeling information, traceability records, supplier documentation, import records, and regulatory files. Accurate documentation improves transparency while reducing avoidable regulatory deficiencies (U.S. Food and Drug Administration, 2024c).

4. Preventive Risk Assessment

Organizations should systematically identify, evaluate, and mitigate compliance risks before shipment. Preventive risk assessment includes evaluating supplier reliability, product characteristics, applicable regulatory requirements, transportation conditions, documentation completeness, labeling accuracy, and previous regulatory history. This process enables organizations to address vulnerabilities proactively rather than responding after shipment interruption (ISO, 2018; COSO, 2017).

5. Continuous Improvement

Preventive compliance requires continuous organizational learning. Internal audits, corrective actions, supplier reassessments, regulatory monitoring, performance indicators, and lessons learned from inspections or enforcement activities should be incorporated into ongoing process improvement.

These five dimensions operate as an integrated organizational system in which information generated by one capability continuously supports decision-making across the others.

6.3 Practical Application

The proposed framework may be applied by importers, food manufacturers, foreign suppliers, logistics providers, customs brokers, regulatory consultants, and multinational organizations operating within regulated international food supply chains.

Organizations can integrate the PTCF into existing supply chain management processes. Examples include:

- supplier qualification before procurement decisions;
- regulatory review before shipment authorization;
- documentation verification before customs entry;
- continuous monitoring of FDA enforcement trends;
- periodic reassessment of supplier performance;
- implementation of preventive corrective actions before export.

The framework is intentionally flexible and may be adapted according to organizational size, product characteristics, supply chain complexity, and regulatory exposure.

6.4 Expected Organizational Benefits

Implementation of the PTCF may contribute to:

- improved regulatory preparedness;
- enhanced supply chain visibility;
- greater supplier reliability;
- improved documentation quality;
- fewer import disruptions;
- more effective risk management;
- stronger organizational learning;
- increased operational resilience.

Although empirical research will be necessary to validate these proposed relationships, the framework provides an initial conceptual model linking preventive trade compliance with supply chain resilience through interconnected managerial capabilities rather than isolated compliance activities.

7. Conclusion

International food supply chains operate within a complex regulatory environment in which compliance failures may generate operational disruptions extending beyond legal consequences (Christopher & Peck, 2004; Ivanov, 2021; Ivanov & Dolgui, 2020).

This study demonstrates that FDA regulatory requirements extend beyond statutory obligations and function as preventive governance mechanisms capable of influencing supplier

management, documentation quality, organizational decision-making, operational continuity, and supply chain resilience. The documentary analysis revealed that regulatory instruments such as the Food Safety Modernization Act (FSMA), the Foreign Supplier Verification Program (FSVP), Prior Notice, Facility Registration, Import Alerts, Warning Letters, and Import Refusals collectively encourage organizations to adopt preventive management practices throughout international food supply chains (Food Safety Modernization Act, 2011; U.S. Food and Drug Administration, 2024a, 2024c, 2024d, 2024f, 2024g, 2024i).

To address the fragmentation identified in the literature, this study proposed the Preventive Trade Compliance Framework (PTCF), integrating regulatory compliance, supply chain resilience, enterprise risk management, supplier governance, and organizational learning into a unified conceptual model.

The proposed framework contributes to the literature in three principal ways. First, it integrates previously fragmented research streams into a coherent theoretical perspective. Second, it positions preventive trade compliance as a strategic managerial capability supporting supply chain resilience rather than solely a regulatory obligation. Third, it provides an initial conceptual foundation capable of supporting future empirical research examining the relationship between preventive compliance practices, regulatory performance, operational resilience, and international supply chain performance (Torraco, 2005).

Although the framework has not yet been empirically validated, it offers practical guidance for importers, exporters, manufacturers, logistics providers, customs brokers, regulatory consultants, and multinational organizations seeking to strengthen preventive compliance systems within international food supply chains.

Future research should evaluate the applicability of the Preventive Trade Compliance Framework (PTCF) through empirical validation using case studies, surveys, longitudinal investigations, and quantitative analyses involving different industries, countries, and regulatory environments. Such research would contribute to validating the framework and further clarifying the relationship between preventive trade compliance, regulatory performance, and supply chain resilience.

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Data Availability Statement

No primary datasets were generated or analyzed during this study. All information used in this research was obtained from publicly available scientific literature and official regulatory documents.

Declaration of Competing Interest

The author declares no competing interests.

References

- Ambulkar, S., Blackhurst, J., & Grawe, S. J. (2015). Firm's resilience to supply chain disruptions: Scale development and empirical examination. *Journal of Operations Management*, 33–34, 111–122.
- Bowen, G. A. (2009). Document analysis as a qualitative research method. *Qualitative Research Journal*, 9(2), 27–40.
- Christopher, M. (2016). *Logistics & Supply Chain Management* (5th ed.). Pearson.
- Christopher, M., & Peck, H. (2004). Building the resilient supply chain. *International Journal of Logistics Management*, 15(2), 1–14.
- Codex Alimentarius Commission. (2022). *General Principles of Food Hygiene (CXC 1-1969)*. FAO/WHO.
- Committee of Sponsoring Organizations of the Treadway Commission (COSO). (2017). *Enterprise Risk Management—Integrating with Strategy and Performance*. COSO.

Craighead, C. W., Blackhurst, J., Rungtusanatham, M. J., & Handfield, R. B. (2007). The severity of supply chain disruptions: Design characteristics and mitigation capabilities. *Decision Sciences*, 38(1), 131–156.

Electronic Code of Federal Regulations. (2024). *Title 21, Part 1—General Enforcement Regulations*. eCFR.

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399i (1938).

Food and Agriculture Organization of the United Nations. (2021). *The State of Food and Agriculture 2021*. FAO.

Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011).

Garvin, D. A. (1993). Building a learning organization. *Harvard Business Review*, 71(4), 78–91.

International Organization for Standardization. (2018). *ISO 31000:2018 Risk Management—Guidelines*. ISO.

Ivanov, D. (2021). Supply chain viability and the COVID-19 pandemic: A conceptual and formal generalisation of four major adaptation strategies. *International Journal of Production Research*, 59(12), 3535–3552.

Ivanov, D., & Dolgui, A. (2020). Viability of intertwined supply networks: Extending the supply chain resilience angles toward survivability. A position paper motivated by COVID-19 outbreak. *International Journal of Production Research*, 58(10), 2904–2915.

Jüttner, U., Peck, H., & Christopher, M. (2003). Supply chain risk management: Outlining an agenda for future research. *International Journal of Logistics: Research and Applications*, 6(4), 197–210.

Kleindorfer, P. R., & Saad, G. H. (2005). Managing disruption risks in supply chains. *Production and Operations Management*, 14(1), 53–68.

Manuj, I., & Mentzer, J. T. (2008). Global supply chain risk management. *Journal of Business Logistics*, 29(1), 133–155.

Ponomarov, S. Y., & Holcomb, M. C. (2009). Understanding the concept of supply chain resilience. *The International Journal of Logistics Management*, 20(1), 124–143.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002).

Scholten, K., Scott, P. S., & Fynes, B. (2014). Mitigation processes—Antecedents for building supply chain resilience. *Supply Chain Management: An International Journal*, 19(2), 211–228.

Senge, P. M. (1990). *The Fifth Discipline: The Art and Practice of the Learning Organization*. Doubleday.

Sheffi, Y. (2005). *The Resilient Enterprise: Overcoming Vulnerability for Competitive Advantage*. MIT Press.

Sheffi, Y., & Rice, J. B. Jr. (2005). A supply chain view of the resilient enterprise. *MIT Sloan Management Review*, 47(1), 41–48.

Snyder, H. (2019). Literature review as a research methodology: An overview and guidelines. *Journal of Business Research*, 104, 333–339.

Tang, C. S. (2006). Perspectives in supply chain risk management. *International Journal of Production Economics*, 103(2), 451–488.

Tang, C. S., & Tomlin, B. (2008). The power of flexibility for mitigating supply chain risks. *International Journal of Production Economics*, 116(1), 12–27.

Torraco, R. J. (2005). Writing integrative literature reviews: Guidelines and examples. *Human Resource Development Review*, 4(3), 356–367.

U.S. Customs and Border Protection. (2024). *Cargo Security, Cargo Control, and Import Procedures*. U.S. Department of Homeland Security.

U.S. Food and Drug Administration. (2024a). *Food Facility Registration*. U.S. Department of Health and Human Services.

U.S. Food and Drug Administration. (2024b). *Food Safety Modernization Act (FSMA)*. U.S. Department of Health and Human Services.

U.S. Food and Drug Administration. (2024c). *Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals*. U.S. Department of Health and Human Services.

U.S. Food and Drug Administration. (2024d). *Import Alerts*. U.S. Department of Health and Human Services.

U.S. Food and Drug Administration. (2024f). *Import Refusal Reports*. U.S. Department of Health and Human Services.

U.S. Food and Drug Administration. (2024g). *Prior Notice of Imported Foods*. U.S. Department of Health and Human Services.

U.S. Food and Drug Administration. (2024h). *Regulatory Procedures Manual*. U.S. Department of Health and Human Services.

U.S. Food and Drug Administration. (2024i). *Warning Letters*. U.S. Department of Health and Human Services.

United States Department of Agriculture. (2024). *Food Safety and Inspection Service Regulations*. USDA.

Wagner, S. M., & Bode, C. (2008). An empirical examination of supply chain performance along several dimensions of risk. *Journal of Business Logistics*, 29(1), 307–325.

Whittemore, R., & Knafl, K. (2005). The integrative review: Updated methodology. *Journal of Advanced Nursing*, 52(5), 546–553.

Wieland, A., & Wallenburg, C. M. (2012). Dealing with supply chain risks: Linking risk management practices and strategies to performance. *International Journal of Physical Distribution & Logistics Management*, 42(10), 887–905.

World Health Organization. (2022). *Global Strategy for Food Safety 2022–2030*. WHO.

World Trade Organization. (2023). *World Trade Statistical Review 2023*. WTO.