A Supply Chain Perspective on Product Safety Risk

Roman Schumacher
University of Cambridge
Department of Engineering, Institute for Manufacturing (IfM)
17 Charles Babbage Rd, Cambridge, CB3 0FS, United Kingdom
rers3@cam.ac.uk

Maximilian Klöckner
Bain Company
Sihlporte 3, 80001 Zurich, Switzerland
maximilian.klockner@bain.com

Stephan M. Wagner, Member IEEE
ETH Zurich
Department of Management, Technology, and Economics
Weinbergstrasse 56/58, 8092 Zurich, Switzerland
stwagner@ethz.ch

Mukesh Kumar
University of Cambridge
Department of Engineering, Institute for Manufacturing (IfM)
17 Charles Babbage Rd, Cambridge, CB3 0FS, United Kingdom
mk501@cam.ac.uk

Manuscript received 2 August 2024; revised 5 February 2024 and 28 April 2024; accepted 29 April 2025. Date of publication ; Review of this manuscript was arranged by Department Editor Thanos Papadopoulos. (Corresponding author: Stephan M. Wagner.)

This work was generously supported by the Engineering and Physical Science Research Council (EPSRC) [grant number EP/R513180/1] and the Research and Development Management Association (RADMA) [grant number RADMA/2020DSP/R20]

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This study investigates the relationship between supply chain complexity, operational efficiency, and product safety risk. We consider three different dimensions of supply chain complexity – horizontal, technological, and spatial complexity – and examine their effect on product safety risk, proxied by severe product recalls. We also examine the effect of operational efficiency in this context. Our analysis is based on regression modeling, using financial, supply chain, and recall data from the medical device industry. Our findings indicate that all three dimensions of supply chain complexity increase product safety risk and that operational efficiency reduces product safety risk. We also provide evidence that operational efficiency serves as a critical moderator for the relationship between supply chain complexity and product safety risk. Given the increasing frequency of high-profile recalls caused by product failures in upstream supply chains, our study makes a timely contribution to the operations management literature.

Keywords: product safety risk; product recall; supply chain complexity; operational efficiency; engineering management; robustness checking

Managerial Relevance Statement

Companies can suffer significantly from necessary product recalls due to unsafe products they sell to their customers. This study helps managers understand that supply chain complexity is an important driver of product safety risk. By managing the horizontal, technological and spatial complexity of supply chains in supply chain design decisions, managers can prevent product safety problems and thus avoid the costly product recalls. In addition, our study highlights that operational efficiency, which can be improved through the implementation of lean management, tight inventory control or operational cost reductions, can further limit the likelihood of product safety risks materializing. Overall, the study provides managers with suggestions on how strategic and operational measures can be used to reduce product safety risk. Our findings can be used in risk management projects aimed at ensuring compliance, and show managers how supply chain and operations functions can reduce product risk.

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1 Introduction

Product safety risk reflects a product's potential to harm the product users. It can arise when a product is defective, contaminated, or misused. Product safety risk is associated with a plethora of root causes, such as internal manufacturing complexity [67], firm innovation [80], product competition [6], and outsourcing [73]. Supply chains that are globalized and subject to rapidly changing technologies and competitive pressures are difficult to manage, and the factors that contribute to product safety risks emanating from these supply chains are increasing. As supply chains become more interconnected through the involvement of different actors, potential disruptions can propagate along the supply chain, affecting multiple firms and sectors [8], [36]. Disruptions such as Brexit, COVID-19, and the U.S.-China trade war, have further exposed vulnerabilities, leading to shortages of critical supplies such as pharmaceuticals and medical devices due to restricted logistics flows, surges in demand, and loss of production capacity [66]. Furthermore, deficiencies in the efficacy of globally sourced medical equipment have called into question their product conformance and safety [66]. Despite recent moves towards re-shoring due to disruptions and political pressures [13], supply chains are likely to remain highly globalized and interconnected, making complex supply chains an ongoing reality for businesses and consumers. However, these disruptions indicate that supply chain complexity and many of its negative implications, including product safety risk, are still poorly understood and inadequately managed, making research into supply chain complexity and its impact on product safety timely.

Product safety risk is often measured by recalls, which can be initiated either voluntarily by a firm or mandated by a regulator [40]. In the U.S., the markets for food, pharmaceutical and medical device products are regulated by the Food and Drug Administration (FDA). The regulator documented that pharmaceutical recalls surged from 166 per year in 2004 [63] to over 1,500 in 2022 [23], often due to deficiencies in Good Manufacturing Practices (GMP), which outline *"minimum requirements for the methods, facilities and controls used in manufacturing, processing and packaging of a drug product"* [22]. As many ingredients for drug products are produced by contract manufacturers, increasing manufacturing-related recalls indicate that these deficiencies may be rooted at supplier sites. In fact, a major pharmaceutical recall was caused by several contract manufacturers as a result of nitrosamine impurities found in blood pressure drugs, that were formed during the production of an ingredient at various contract manufacturing sites in India and China [23], [24]. The drug was later labelled and sold by multiple OEMs that were also affected by the recall. The medical device industry follows a similar trend, with FDA-reported recall incidents tripling from 400 in 2000 to over 1,200 in 2011 [25], while remaining on a high level between 1,000 and 1,200 incidents per year since then [23].

The consequences of these recalls for firms are well studied [67]. For example, recalls negatively impact sales [76] and long-term firm value [47]. Yet, the safety risk to consumers can vary. For example, medical device failures can range from minor issues, such as labelling errors (Class III recalls), to potentially causing serious adverse events for patients (Class I recalls), such as uncontrolled shocks from implanted defibrillators [75].

Prior literature has acknowledged that global supply chains can have detrimental effects on product safety [34], [44], [61], [73]. However, it remains fragmented, with a limited scope of studies on supply chain structure and its impact on product safety. In particular, prior research mainly focuses on isolated complexity metrics and its impact on product safety. At the same time, considering product safety from a supply chain perspective is pertinent today, and an effective evaluation of contemporary supply chain challenges requires recognition of the multidimensional nature of supply chain complexity [28]. Yet, an investigation of multiple complexity dimensions in the context of product safety risk remains unaddressed. Additionally, supply chain complexity - performance relationships are under-researched, with a limited breadth of dependent variables examined [2].

We aim to fill these gaps by providing a comprehensive construct to capture the multidimensional nature of supply chain complexity and the different risks arising from it. Additionally, our study captures product safety risk by considering severe product recalls, which represents an objective metric to capture product failures in supply chains and a novel measure in the context of supply chain complexity. Furthermore, this research focuses on the medical device industry, which is uniquely vulnerable to product safety risks due to the critical nature of its products and the potential for catastrophic consequences if devices fail [5], the rapid pace of technological advancements [52], and the need for innovative and responsive global supply chains [4]. In particular, medical device supply chains have experienced high margin pressure, leading to increased outsourcing activities [50]. Additionally, medical devices become more complex, integrating software, electrical and mechanical systems in a single product, further increasing supply chain complexity [50].

We further use Complexity Theory and Information Processing Theory to hypothesize the effects of information processing requirements induced by upstream supply chain complexity on product safety risk in the medical device industry. In doing so, this study sheds light on product safety risks in an industry where it is of crucial importance.

Our quantitative research contributes to the engineering and supply chain management literature in several ways. First, we capture multiple upstream supply chain complexity dimensions [8], and conceptualize a novel dimension capturing technological aspects. Thereafter, we investigate the individual effects of horizontal, technological, and spatial supply chain complexity on product safety risk. Our findings indicate that technological and spatial complexity both have a strongly significant and positive impact on product safety risk, while the effect of horizontal supply chain complexity is relatively weaker, but still significant. Furthermore, we examine the effect of operational efficiency on product safety risk and find a negative relationship. Lastly, hypothesizing the relationship between operational efficiency and supply chain complexity, we find that operational efficiency also serves as a moderator for the effects of supply chain complexity on product safety risk.

The results of our research have several implications for theory and practice. First, we use Complexity Theory and Information Processing Theory to explain the implications of supply chain complexity for coordination and information processing requirements of firms. Our results suggest that supply chain complexity increases information processing needs and information asymmetry between buyers and suppliers that may translate into a detrimental impact on product safety. Second, firms' abilities to process information and coordinate complexity in supply chains are reflected by operational efficiency. This suggests that firms can manage product safety risks by increasing their efforts to improve operational efficiency. Lastly, the mitigating effect of operational efficiency for the positive association between supply chain complexity and product safety risk suggests that operational efficiency becomes particularly important for firms that are exposed to high levels of supply chain complexity.

2 Literature Review

Global supply chains are essential for competitiveness, as cost pressure and rapid technological change drive firms to rely on specialized, often foreign, suppliers. At the same time, global supply chains have been impacted by a series of large-scale events in the recent past, ranging from geopolitical tensions such as trade wars, climate-impacted shortages, or the COVID-19 pandemic, which exposed the vulnerabilities emanating from the reliance on diverse suppliers, global interconnection, and technological innovation. Among these risks, product safety has become an area of increasing concern [81]. A literature summary of product safety in the context of supply chains is depicted in Table 1. The summary includes literature related to effects of inter- and intra-organizational complexity on multiple measures of firm performance. From this summary, several observations can be made. Recent research such as Ateş et al. [2] emphasize that supply chain complexity is multidimensional in nature, including upstream, internal, and downstream complexity, while its effect on firm performance shows mixed results. Additionally, Bode and Wagner [8] show that supply chain complexity increases supply chain disruption risks. Tse et al. [77] examine the impact of several supply chain uncertainty factors on perceived quality risk and find a significant positive association. At the same time, research specifically dealing with *product safety* and supply chain complexity remains fragmented, without recognizing its multidimensional nature. Yet, several studies consider isolated complexity metrics and its impact on product safety.

For example, existing studies indicate that outsourcing and offshoring are associated with higher product recall rates [72], [73]. Kini et al. [44] use the number of upstream suppliers as a control variable and show a positive association with product recalls. These findings suggest that product safety risks may be rooted in the complexity of globalized supply chains. Beyond studies directly addressing isolated complexity dimensions, multiple studies address complexities in manufacturing settings and their impact on product conformance, such as manufacturer heterogeneity in inter-firm settings (which refers to the degree of product and process diversity in a plant) [38] or language differences in intra-firm settings [33]. These settings have in common that supply chain complexity either increases through outsourcing [32] or by a spatial separation of entities, such as the R&D and manufacturing plant of an organization [35]. The results of these studies suggest that certain barriers associated with complex settings may have a detrimental impact on product conformance. However, despite their contributions to understand complexity in manufacturing environments, these studies mainly focus on manufacturing performance rather than product safety from a supply chain perspective.

Collectively, the reviewed literature provides some indications that operational and supply chain complexity may be drivers of product safety risk. At the same time, these indications remain fragmented, revealing a lack of empirical research that comprehensively captures the multidimensional construct of supply chain complexity as well as the role of operational efficiency and its impact on product safety risk. This study aims to address this gap.

Table 1: Overview of prior studies on intra- and inter-organizational complexity on various measures of firm and product performance (sorted by relevance, structure adopted from Shah et al. [67]).

Article	Industry	Research aim	Variables (selected)			Results (selected)	Scope
			Dependent	Independent	Control		
Ateş et al. [2]	Cross-industry (meta)	Effect of supply chain complexity (SCC) on firm performance	Operational, innovation, and financial performance	Upstream, downstream, and internal SCC	–	Negative impact of SCC on operational performance, positive impact on innovation and financial performance	Inter-firm (multi-dim. SCC)
Boder and Wagner [8]	Cross-industry	Effect of SCC on disruption risk	Disruption frequency	Horizontal, vertical, and spatial SCC	Firm size, firm age, competitive intensity	Horizontal, vertical, and spatial SCC is positively associated with disruption frequency	Inter-firm (multi-dim. SCC)
Tse et al. [77]	Electronics	Effect of uncertainty factors on perceived supply chain quality risk	Risk probability (RP), risk magnitude (RM)	Technology uncertainty, product complexity	–	Technological uncertainty is positively associated with RP and RM; product complexity is positively associated with RP	Inter-firm (multi-dim. SCC)
Steven et al. [73]	Cross-industry (consumer products)	Effect of global sourcing on product recalls	No. of a firm's recalls over a year	Outsourcing intensity, offshore outsourcing intensity, supplier and national concentration	R&D intensity; Capital Intensity; Prior recalls; Firm size	Offshoring and outsourcing is positively associated with product recalls	Inter-firm
Steven and Britto[72]	Cross-industry (consumer products)	Effect of outsourcing, in-house offshoring, and sales to emerging markets on product recalls and inventory	No. of recalls over a year, inventory performance, inventory levels	Emerging market (EM) outsourcing intensity, EM offshoring intensity, sales penetration to EM	R&D intensity, Capital Intensity; Prior recalls; Firm size; Industry effects	Outsourcing to EM is positively associated with recalls; Sales penetration into EM reduces recalls	Inter-firm
Kini et al. [44]	Cross-industry	Effect of firm financial condition on product safety	Firm recall (dummy variable)	Book leverage, market leverage, Altman Z	Free cash-flow shock, unionization, number of suppliers, vertical integration (dummy variable), R&D intensity, total factor productivity, Herfindahl index, firm size	Leverage/ distress likelihood is positively associated with product recalls; incidents of recalls is higher if number of suppliers is higher; vertical integration is negatively associated with product recalls	Inter-firm
Gray and Handley [32]	Food, drugs, and medical devices	Effect of quality performance ambiguity on contract manufacturer (CM) quality performance	Buyer's assessment of CM quality performance	Product quality performance ambiguity	CM size; ISO certification status; intensity of federal regulation, level of heterogeneity of products and processes	Quality performance ambiguity is negatively associated with CM conformance quality performance	Inter-firm
Handley and Gray [38]	Food, drugs, and medical devices	Effect of CM heterogeneity on CM conformance quality performance	CM conformance quality performance	Degree of CM manufacturing heterogeneity	Regulation intensity; plant size; plant age; performance ambiguity; difficulty to switch to other buyer; length of relationship between buyer and CM	CM heterogeneity is negatively associated with CM conformance quality performance	Inter-firm
Gray et al. [35]	Pharmaceutical	Effect of colocation of manufacturing and R&D plants on manufacturing conformance quality	FDA inspection outcomes	R&D and manufacturing plant colocation	R&D intensity, capital intensity; Tobin's Q, no. of plants; inspection frequency	Colocation of manufacturing and R&D is associated with higher product conformance quality	Intra-firm
Gray and Massimo [33]	Pharmaceutical	Effect of language differences between plant location and the firm's headquarters on plant process compliance	Process compliance level	Language difference; cultural difference	Plant's previous inspection outcome; time since previous inspection; inspection type; HQ-plant geographic distance; industry dummy variables	Language differences are negatively associated with process compliance at the plant	Intra-firm

3 Theory and Hypotheses Development

This section introduces Complexity Theory (CT) and Information Processing Theory (IPT) to explain product failures in supply chains. These theories have been applied in prior operations management literature and are pertinent as they explain the emergence and consequences of information asymmetry, a typical challenge in global supply chains [9]. As such, an integrative theoretical angle using these two theories combined enables us to explain the emergence of supply chain complexity and its implication for product safety risk as information asymmetry grows. Based on these theoretical angles, we derive a set of hypotheses, summarized in our conceptual model (see Figure 1).

To understand the potential impact of global and complex supply chains on product safety risk, a study of the different aspects of complexity and their manifestation in supply chains is required. The term "complexity" has been used for over 20 years in the supply chain literature, but recently gained increasing attention as one of the subjects of investigation for disruption risks [8], [73]. While Handley and Benton [39] state that *"complexity is generally considered a multidimensional construct; resulting in a lack of consensus on how complexity should be defined and operationalized"* (p. 113), there is yet a consensus that the complexity of supply chains increased over the last decades [8]. Furthermore, prior research shows that upstream supply chain complexity is negatively associated with operational performance [2] and positively associated with disruption frequency [8].

Complexity Theory (CT) suggests that complexity is defined by two variables, N, referring to the number of elements that define an entity and K, referring to the number of elements of N, with which a given attribute interacts [42], [46]. In other words, complexity comprises the number of elements of a system and the intensity of interaction between these elements.

Supply chain management research has widely embraced similar features to define complexity [79], where elements N can be defined as the organizations or supply chain nodes within a network, and K the number of interactions between these organizations. In other words, supply chains exhibit

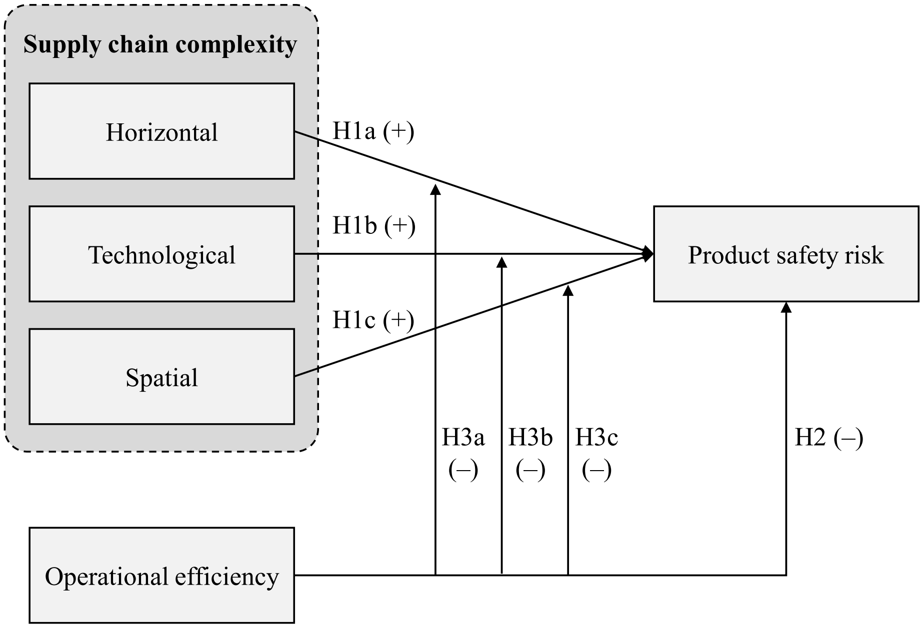

Figure 1: Conceptual model.

complexity due to their structure as numerous firms interact which each other. The interaction between organizations in a network is further defined by the way *how* these elements are linked together ("coupling") and refers to the level of looseness between supply chain elements. For instance, buyer-supplier relationships that are associated with high uncertainty, such as newly established or arms-length relationships, are more loosely coupled and therefore associated with higher complexity. This is due to the fact that the predictability of a network's output decreases with increasingly uncertain relationships. In this context, Choi and Hong [14] propose that a loose coupling between supply chain elements requires higher efforts to coordinate a supply chain. They show that higher complexity can lead to a loss of information downstream in the supply chain, thereby driving information asymmetry between supply chain members.

While CT helps to explain the emergence of complexity in supply chains, Information Processing Theory (IPT) addresses the challenges of managing this complexity. According to IPT, organizations are limited in their abilities to prepare for contingencies and to optimize activities in an environment of high complexity and uncertainty [31], [49]. Applied to a supply chain context, higher complexity is associated with greater efforts to coordinate the supplier base [16] and greater information processing needs [27]. This means that firms that experience elevated supply chain complexity by a larger number of suppliers N or interactions K are faced with higher information processing needs and may experience higher information asymmetry and eventually lower firm performance [27], [78]. In a real-world context, these interactions can include supplier qualifications, component specifications, or supplier audits, among others. To mitigate this effect, firms seek measures to improve their information processing capabilities. Information processing capabilities can be enhanced by a variety of activities facilitating operational efficiency, such as coordination of decision making, product design simplicity, or just-in-time practices [27]. Accordingly, operational activities represent adequate means of increasing information processing capabilities to respond to highly complex environments. On the other hand, a lack of information processing capabilities to deal with complexity may lead to elevated product safety risk. For example, a lack of information processing capabilities increases the likelihood of product failures remaining unnoticed as buyers lack the capabilities of monitoring the supply chain. Information asymmetry can lead to opportunistic behavior and incentive misalignments, eventually resulting in under-investments into product quality. Owned to the high degree of uncertainty and complexity of today's global supply chains [65], this research appreciates the challenges in terms of coordinative alignment in an inter-firm context, thus taking a CT and IPT perspective.

3.1 Supply Chain Complexity and Product Safety Risk

Supply chain complexity can manifest itself in various dimensions and increases with higher product variety, new technology adoption, and the global extension of the supplier base, among other drivers [2]. In the following, we conceptualize (1) horizontal, (2) technological, and (3) spatial supply chain complexity and hypothesize their effect on product safety risk.

Horizontal supply chain complexity. Upstream horizontal supply chain complexity can be defined as the number of first-tier suppliers of a firm [8]. The diversification of the first-tier supplier base is a common practice to reduce the risk of major disruptions caused by high supplier dependencies of the buying firm [74]. According to CT, complexity is elevated by the number of suppliers N and the number of interactions K between supply chain members. Accordingly, a higher number of suppliers is associated with higher upstream supply chain complexity. Prior research suggests that up to a certain level, horizontal supply chain complexity can have benefits for firms. For example, horizontal supply chain complexity has a positive but diminishing effect on product innovation performance [71] and international business performance [70], demonstrating that firms can gain a competitive advantage when they are able to leverage the diversity advantages of a larger supplier pool. Other findings indicate that diversification of the first-tier supplier level is positively associated with disruption frequency [8] and negatively associated with operational performance [2].

These findings suggest mixed relationships between horizontal supply chain complexity and different firm performance indicators. Steven et al. [73] find that a more concentrated supplier base is linked to fewer product recalls at moderate outsourcing levels, suggesting that greater concentration reduces coordination risks through better inter-firm communication. Product safety risks could also emanate from the complexity of a product [77] and broader product portfolios, which are characterized by high modularity and may be elevated by a greater corresponding horizontal supply chain complexity, in which many components come from different suppliers.

Considering IPT, information processing and coordination requirements increase with an increasing number of suppliers (N) and interactions (K), and even rise non-linearly in sub-tier structures with a growing first-tier supplier base. Accordingly, a growing number of suppliers of a firm exponentially raises the difficulty of coordination as interactions increase exponentially. In this context, coordination burdens for component integration and quality monitoring of sourced components could be a possible contributor to increasing product safety risk. For example, building redundancy in a medical device supply chain by adding a supplier requires a buyer to conduct a qualification assessment, to specify interfaces of sourced components, to test product functionalities, to communicate changes in product designs to its suppliers, and vice versa. Maintaining a desired level of product quality may be more challenging considering these elevated levels of communication and coordination requirements. Furthermore, firms that operate in regulated industries are often mandated to guide their first-tier suppliers in their choice of qualified sub-tier suppliers and raw materials for safety-critical components. These efforts increase with an increasing first-tier supplier base, as the number of sub-tier suppliers that have to be qualified grows disproportionately. Considering these arguments, we hypothesize the following relationship:

Hypothesis 1a *Horizontal supply chain complexity is positively associated with product safety risk.*

Technological supply chain complexity. We understand technological supply chain complexity as the level of industry variety of the focal firm's supplier base, driven by technological specialization. This need for specialization is associated with the technological complexity of many products, which is increasing together with a general trend towards products that integrate a variety of different technologies. An example from the automotive industry shows how problematic the in-house development of specialized technology can be: "CARIAD" is a platform that is a central part of Volkswagen's digital strategy and is designed to enable product features such as autonomous driving. Due to significant problems in the development, the roll-out of the platform was postponed several times, which also delayed the launch of new Porsche, Audi and Bentley product generations and eventually led to the dismissal of the CEO [10]. For this reason, suppliers of different industries are increasingly involved in R&D activities as requirements for specialized know-how increase, while OEMs switch into the role of lead integrators of these technologies. It is considered to be one of the key elements of accelerated innovation and time-to-market in supply chains [82]. At the same time, this involvement may cause risks of misalignment between development activities of suppliers and OEMs, as efforts in processing information from *different* industries may increase [7]. This situation is aggravated if underlying components, designs or technologies change frequently, and thus cause uncertainty [77]. Ellis et al. [20] define technological uncertainty as *"the rate of change in underlying technologies of a purchased product"* (p. 37). In this context, the integration of continuously changing heterogeneous inputs from a variety of different industries may hinder information processing [38], besides problems of opportunistic behavior of suppliers regarding purchased material quality, which have been investigated by prior research [77].

In addition to these effects caused by technological uncertainty, challenges may be elevated by a lack of technological overlap between buyers and suppliers (referred to as *"technological distance"*), which can complicate integration efforts and cooperation [60] and therefore may increase the risk of misalignment. Accordingly, as per IPT, technological supply chain complexity may elevate coordination costs due to specialized knowledge requirements, and the cadence of acquiring this knowledge. Additionally, risks may be elevated by technology barriers such as different technology standards used by buyers and suppliers. As per CT, these requirements and barriers increase with the number of supplier industries as the number of interactions K to handle technological uncertainties increases. If increased information processing capabilities are not met by the buyer, this may cause information asymmetry between buyers and suppliers, which may be particularly present in buyer-supplier relationships that are characterized by technological distance and uncertainty.

For example, medical devices such as pacemakers and cardioverter-defibrillators (ICDs) show high technological complexity as many high-tech components are used for the production. In 2021, a safety notice regarding ICDs was issued by multiple medical device companies. The associated product failure was caused by multiple innovations in the battery design of these ICDs, which included a change in the shape and materials used for the battery. The innovation led to a phenomenon called "lithium-plating" which can cause a higher rate of battery drain. In this case, the batteries were supplied by an external supplier who implemented the innovation to the product and vividly shows how a lack of specialized knowledge in buying firms can lead to multiple, industry-wide product safety risks. Considering these effects from a supply chain perspective suggests that firms with an upstream supply chain, which is characterized by high technological complexity, may face increased product safety risk. Therefore we hypothesize:

Hypothesis 1b *Technological supply chain complexity is positively associated with product safety risk.*

Spatial supply chain complexity. Spatial supply chain complexity can be defined as the geographical spread of a supply chain [8], [14] and is driven by a firm's outsourcing and offshoring activities [72]. Taking a CT lens, the geographical spread of a supply chain exhibits complexity due to its exposure to different environments such as social, economic, regulatory, and climatic environments. The result is a longer supply chain where physical flows need to travel longer distances and cross more borders, whereas non-physical flows need to cross other barriers, such as language differences or regulatory hurdles.

Anecdotal evidence demonstrates the substantial impact of outsourcing in globalized supply chains. The Takata recall, for instance, was a major caesura in the automotive industry. It was caused by a design change of airbags by the Japanese first-tier supplier Takata, enjoying a market share of over 20% for airbags at that time. The supplier changed the standard inflator granulate tetrazole with the cheaper granulate ammonium nitrate while buyers worldwide remained unknowing. Ammonium nitrate decays over time, increasing the risk that the granulate ignites with explosive force. The product failure led to at least 16 fatalities, Takata's bankruptcy, and over 70 million recalled airbags built into over 42 million recalled cars between 2014 and 2017 [51]. It is important to mention here that this design change was the result of an incentive misalignment between buyer and supplier, where the supplier took advantage of a lack of visibility of the buyer to save costs. The recall exemplifies the importance of supply chain visibility, especially for safety critical components, where design and manufacturing are outsourced.

In this context, several empirical studies explore the impact of spatial supply chain characteristics on product safety in intra- and inter-firm settings [33]–[35], [72], [73]. The results suggest a negative association between spatial distance between the supplier base and the focal firm and multiple measures of quality performance. Taking an IPT lens, information processing and coordination of global supply chains may also become more difficult due to an interplay of a variety of these complexity drivers, such as language differences [33] or greater physical and cultural distance [73]. CT indicates that it is more challenging to establish supply chain transparency and visibility in spatially complex supply chains because of looser coupling between buyers and suppliers.

Lastly, spatial complexity can have direct negative effects on supply chain operations that may also manifest in product safety risks. As supply chains get longer, inventories and lead times increase, causing longer transportation and stock waiting times for products. This increases the risk for adulteration, contamination, and manipulation of the product. These may arise from undetected logistics hazards related to faulty storage and transportation conditions, such as extreme temperatures or humidity, affecting the functionality of products. In fact, the FDA identified inadequate storage conditions as one of the top issues causing product recalls in the U.S. [64]. The exposure to these risks may be higher and less visible for products sourced from greater distance. Collectively, these arguments support the following hypothesis:

Hypothesis 1c *Spatial supply chain complexity is positively associated with product safety risk.*

3.2 Operational Efficiency and Product Safety Risk

In our study, operational efficiency refers to *"the aspiration level to minimize costs to improve operational margins"* [56, p. 681]. It has been extensively studied and identified as a key component in the context of lean management [17]. In prior literature, operational efficiency is sought to be achieved by implementing managerial practices such as just-in-time, or quality management and associated with superior business outcomes such as cost, quality, delivery, and flexibility [2], [59].

It can be proxied by a plethora of measures such as inventory turnover, production and delivery lead-times, machine and labor productivity, or quality scrap rates [58].

Research examining the effect of operational efficiency on product quality performance show mixed results. For example, while Marucheck et al. [50] argue that efficiency improvements through technological advancements in production lead to more quality problems going unnoticed, empirical evidence indicates a positive relationship between operational efficiency and quality performance [58], [69]. However, quality performance metrics in the context of these studies refer to firm-internal standards, such as quality scrap rates, rather than product safety risk as measured by recalls.

For example, Khanchanapong et al. [43] show that product quality can benefit from efficient operations, for instance through uncovering operational deficiencies in manufacturing that would remain undetected with high levels of internal slack resources such as excess capacity or inventory. In their study, quality performance is measured by durability, reliability and customer perception. Further evidence from the automotive industry supports this narrative: Small lot-production with rapid feedback loops and in-line worker-led quality inspections leads to faster learning, reduced defects and fewer inspection staff [17]. These effects of operational efficiency on internal quality standards may eventually also be reflected in reduced product safety risk. This empirical evidence is also supported by practical examples. For example, Toyota developed the Toyota Production System with its strong emphasis on operational efficiency principles and today builds cars that are considered to be among the safest worldwide. A study examining the implementation of the Toyota Production System in hospitals show that lean principles applied in hospitals can lower infection rates and emergency-department-wait times [12]. Similarly, Dobrzykowski et al. [19] find that a comprehensive lean orientation in hospitals has a direct and positive impact on patient safety.

Furthermore, according to CT and IPT, a firm's organizational complexity is directly linked to its information processing needs. This is due to a higher number of interactions K between supply chain members and increasing uncertainty originating from this setting as well as internal settings, such as manufacturing complexity (internal, plant level complexity of a firm). Higher uncertainty related to complex settings is negatively associated with plant level manufacturing performance [27], [30]. Considering that many medical device products require highly complex manufacturing processes, coordinating actions internally and in the supply chain for the enhancement of operational efficiency may help to increase a firms' capability to process information, thereby reducing product safety risk as well. In this context, operational efficiency reflects a firm's ability to process information [83], thereby enhancing response times and decision-making speed. This may ultimately also be reflected in a firm's ability to deliver safe products as safety critical information flows faster, reducing the lag between data collection, analysis, and execution.

Lastly, operational efficiency can have direct effects on product safety risks in our specific medical device context, arising from improper storing conditions of products. For example, some coronary stents are coated with drugs to increase their bio-compatibility and are sensitive to extreme temperatures and moisture. Higher operational efficiency may therefore reduce the risk of undetected product adulteration or contamination through higher inventory turnover. These arguments support the following hypothesis:

Hypothesis 2 *Operational efficiency is negatively associated with product safety risk.*

3.3 The Moderating Role of Operational Efficiency

Prior studies indicate a negative effect of supply chain complexity on operational performance. This is caused by higher work loads for the coordination of activities and looser coupling between buyers and their upstream partners as search and evaluation costs increase [2]. As a result, the requirements for extracting, processing and integrating information become more challenging with more complex supply chains. When firms are exposed to higher supply chain complexity, operational efficiency may become particularly important to reduce product safety risk.

Coordination in complex supply chains can be enhanced by relational coordination and feedback coordination. The former refers to shared goals, shared knowledge, and mutual respect, whereas the latter is based on information exchange and particularly suitable for handling uncertainty [68]. Results from Shah et al. [68] show that the implementation of lean principles in healthcare supply chains improve operational performance as relational and feedback coordination among supply chain members intensifies. Similarly, Fan et al. [21] show that information processing capability is positively associated with operational performance. As such, operational efficiency may reflect a firm's information processing capabilities, where high levels of capabilities lead to superior performance. This reasoning is supported by prior findings from De Campos et al. [18], who show that firms who have learned to operate their supply chain efficiently, are also more successful in extracting the associated benefits. In their study, the authors examine the effect of inventory turnover on a firm's financial performance. Excess inventory is considered as "waste" in the lean management literature, because it does not directly contribute to value adding activities [17], [69]. Consequently, inventory turnover is being used as an indicator for operational efficiency, reflecting a firm's ability to effectively coordinate activities and optimize throughput, thus reducing inventory and maximizing turnover [58], [69]. The authors' findings suggest that a firm's competence to efficiently coordinate its inventory turnover is also associated with its ability to manage horizontal supply chain complexity, thereby improving its financial performance. Taking a CT and IPT lens, this competence may reflect a firm's ability to effectively process product safety-critical information and coordinate interactions in the supply chain more successfully, thereby also reducing product safety risks arising from information asymmetry. In this context, integration and cooperation with suppliers reduce the risk of opportunistic behavior arising from information asymmetry and reduce costs associated with collaboration and information sharing with suppliers [55].

Further benefits of operational efficiency in the context of highly complex supply chains may include the leverage of product safety-relevant know-how in the supplier base, for instance, extracting and utilizing specialized information about safety features of sourced components or country-specific product safety regulations. In addition, the upstream communication of safety-critical information to the supplier base may become particularly challenging in relatively complex supply chains. In such settings, operational efficiency can help a focal firm to communicate quality and product integration requirements more efficiently [2], thus leveraging the benefits of specialized supplier components. Collectively, these arguments support the following hypotheses:

Hypothesis 3a *Operational efficiency mitigates the positive effect of horizontal supply chain complexity on product safety risk.*

Hypothesis 3b *Operational efficiency mitigates the positive effect of technological supply chain complexity on product safety risk.*

Hypothesis 3c *Operational efficiency mitigates the positive effect of spatial supply chain complexity on product safety risk.*

4 Methodology

4.1 Data Collection

To establish an empirical basis for the hypothesis testing, we build our sample from two main data sources. We first construct a sample based on a publicly available product recall database. We then retrieve financial and supply chain data from Refinitiv Eikon.

4.1.1 Product Recall Sample Construction

We use the U.S. Food and Drug Administration (FDA) database on medical device product recalls as our primary data source. The selection of this database is guided by three main reasons. First, medical devices are an integral element of healthcare, and thus highly regulated by the FDA [75]. As product recalls in this area can have substantive consequences, we deem this empirical context suitable to study product safety risk. Second, compared to other industries with transparent product recall databases (e.g., automotive), medical device supply chains involve a larger number of different focal firms, increasing the cross-sectional breadth of our data collection pool. Third, product recall reasons vary significantly in the medical device industry, enabling us to take a more comprehensive perspective on product safety risk.

FDA medical device recalls are categorized into three main types, Class I, Class II, and Class III recalls, based on their severity [26], [75]. Class III recalls usually stem from minor issues, potentially causing no or minimal adverse health effects (e.g., packaging errors or incorrect power connectors). Class II recalls may result in situations where the health consequences are temporary or medically reversible, such as incorrect prosthesis sizing or compromised sterile barriers. Finally, for Class I recalls, there is a reasonable chance of serious adverse health impact [26], [75]. Class I recalls are the most serious type of recall, and include, for instance, ill-functioning cardiac pacemakers or toxic material separation of implant devices.

We consider the years 2020 and 2019 as our data collection period. In line with prior research conducted by Muralidharan et al. [57], we view Class I and Class II medical device recalls as severe, as minor issues arising from Class III recalls are conceptually inconsistent with our key construct product safety risk. In sum, 5,706 potential product recall events meet these conditions. Removing duplicate content, we reduce this number to 1,905 unique recall events. Duplicate content is common in the FDA database and include multiple products from the same product line, from the same firm and on the same day, which explains the significant reduction of incident counts [75]. These events are associated with 711 distinct firms. From these 711 firms, we consider 175 corporations that are publicly traded, allowing us access to corresponding financial and supply chain data.

4.1.2 Financial Data

For all 175 firms, we identify and collect corresponding International Securities Identification Numbers (ISINs), serving as our primary identifier to access financial data and merge this data with our product recall dataset. Consistent with prior research, we use the Refinitiv Eikon database to retrieve financial and supply chain data for our sample firms [45], [48]. We find financial data entries for 131 out of the 175 firms, leaving us with a final sample of 131 firms.

4.1.3 Structural Supply Chain Data

Beyond key financial metrics, we access supply chain data using the value chain interface of Refinitiv Eikon [15]. The value chain data enables us to retrieve a current list of first-tier suppliers for each of our sample firms. To identify and map buyer-supplier relationships, Refinitiv Eikon uses a web scraping-based algorithm, drawing from multiple publicly available news sources or firm announcements. The algorithm indicates a supplier-buyer relationship, if it finds evidence in the form of text snippets that support this. The interface provides data on a variety of categories, such as the type of relationship (buyer/ supplier), the number of evidence pieces supporting the relationship, and when a relationship has been updated with evidence. Based on these datasets, we describe the construction of our measurements in detail in the following.

4.2 Variables and Operationalization

We structure the description of our variable operationalization according to three groups, (1) our dependent variable, (2) our hypothesized variables, and (3) control variables. Appendix Table B1 presents a summarizing overview of all variables and their operationalization details. Appendix Table B2 provides descriptive summary statistics for all non-binary variables and Appendix Table B3 shows a correlation matrix. Our dependent variable is *product safety risk.* To measure this construct, we use the number of severe Class I and II product recalls in the medical device industry for 2019-2020 [75]. The mean (median) product recall frequency across our sample of 131 firms is 7.67 (3.00) for the two-year period.

Our first hypothesized constructs relate to different dimensions of supply chain complexity. For *horizontal supply chain complexity*, we use the number of our sample firms' first-tier suppliers. Relatedly, we proxy *technological supply chain complexity* using the number of unique industries, in which the focal firm's first-tier suppliers operate. Finally, we use the number of *different* first-tier supplier countries, based on the reported headquarter location, to measure *spatial supply chain complexity*. Beyond supply chain complexity, a core construct is *operational efficiency*. We measure this variable using the firm's inventory turnover, given by the ratio of cost of goods sold (COGS) to the average inventory [49].

We consider several control variables to adequately account for any confounding effects that potentially influence a firm's product recall frequency. First, we control for *firm size*, measured by the natural logarithm of the firm's total assets [45]. Based on scaling effects, it is reasonable to assume that larger firms simply experience more product recalls. Second, relatedly, *firm age* is a key structural characteristic that has been included in prior studies to proxy experience, potentially affecting the number of product recalls [6]. Third, we account for a potentially confounding effect of *R&D intensity* [1], [75]. A firm's R&D intensity reflects its focus on new product development, potentially elevating the probability of product recalls. Finally, to capture macro differences on the geographical level, we include regional headquarter dummy variables for sample firms operating in *Europe* or *Asia*, whereas the U.S. serves as the base category.

4.3 Data Analysis

To empirically test our hypothesized associations, we use a standard ordinary least squares (OLS) regression approach. Our model specification is primarily guided by the cross-sectional structure of our dataset (i.e., one observation corresponds to one unique firm). In addition, we also estimate and report results obtained from a nonlinear negative binomial model (Poisson) specification, considering the count structure of our dependent variable [8]. We present the corresponding estimation results along with other robustness and sensitivity checks in our results section.

Our main OLS regression model takes the following form:

$$
\begin{aligned}
\mathit{RECALLS}_i = \beta_1 &+ \beta_{2a-c}\mathit{HOR/TECH/SPA\ SCCPX}_i + \beta_3\mathit{OPSEFC}_i \\
&+ \beta_4\mathit{FIRMSIZE}_i + \beta_5\mathit{FIRMAGE}_i + \beta_6\mathit{RDINTENS}_i \\
&+ \beta_7\mathit{EUHQ}_i + \beta_8\mathit{ASHQ}_i + u_i,
\end{aligned}
\tag{1}
$$

where β_{1-8} denote the regression coefficients and u_i is the residual error. Similar to Bode and Wagner [8], we estimate different regression models in hierarchical order, allowing us to account for potential multicollinearity biases due to significant correlative relationships between our supply chain complexity dimensions. We first present a control model, including only our set of control variables and the corresponding coefficients β_{4-8}. We then sequentially add our hypothesized effects. We present models including our *operational efficiency* construct and its coefficient β_3 (denoted as Model 1) and models, where we add each supply chain complexity measure separately, along with the corresponding coefficients β_{3a-c} (denoted as Models 2a–2c). We intentionally test the supply chain complexity measures using separate models, accounting for potential multicollinearity issues.

To test our hypothesized moderation (Hypotheses 3a–3c), we sequentially add interaction terms to our main model (Equation 1). Specifically, we add the interaction term of *horizontal supply chain complexity* and *operational efficiency* to Model 2a, the interaction term of *technological supply chain complexity* and *operational efficiency* to Model 2b, and the interaction term of *spatial supply chain complexity* and *operational efficiency* to Model 2c (the resulting models are denoted as Models 3a–3c). We also generate interaction plots and compute confidence intervals for the slope of each *supply chain complexity* dimension, dependent on the level of the *operational efficiency* moderator, illustrated by Johnson-Neyman plots [62].

To further rule out any remaining multicollinearity concerns, we also compute and report variance inflation factors [54]. For the testing of all regression estimates, we deploy and report two-tailed t-tests with robust standard errors.

5 Results

We structure the presentation of our results into two parts. First, we introduce our main empirical findings related to our hypothesized effects. Second, we present multiple robustness checks that assess the sensitivity of certain design choices and the risk of potential biases.

5.1 Regression Results

Table 2 provides the estimates of our regression analysis. Column 1 shows the control model, Column 2 contains Model 1 including our operational efficiency construct, and Columns 3–5 provide the estimates from Models 2a–2c, where the different supply chain complexity dimensions are sequentially added.

The maximum variance inflation factor (VIF) is 1.49 (see Model 2b, Column 4), well below the threshold of 2 and indicating that multicollinearity is not biasing our estimates [54]. In view of the control model (Column 1), we note that the coefficient of *firm size* is positive and significant ($\beta_4 = 3.060$, $p < 0.01$), suggesting that larger firms experience more product recalls. The effect is consistent across all models. In addition, the dummy indicator *Asian headquarter* shows a significantly negative coefficient ($\beta_8 = -4.279$, $p < 0.10$), which indicates that our Asian sample firms have experienced fewer product recalls than the base category of U.S. firms.

Our first hypotheses relate to the context of supply chain complexity, where Model 2a (Column 3 of Table 2) suggests that *horizontal supply chain complexity* is positively associated with product safety risk ($\beta_{2a} = 0.345$, $p < 0.10$), confirming Hypothesis 1a. Analogously, Model 2b (Column 4 of Table 2) supports Hypothesis 1b, as we see that higher levels of *technological supply chain complexity* are associated with higher levels of product safety risk ($\beta_{2b} = 1.657$, $p < 0.01$). Finally, Model 2c (Column 5 of Table 2) shows a significantly positive coefficient of our *spatial supply chain complexity* variable ($\beta_{2c} = 2.048$, $p < 0.05$). Accordingly, greater spatial complexity is positively associated with product safety risk, confirming Hypothesis 1c.

Table 2: Linear regression results.

Dependent variable: Product safety risk (*RECALLS*)

	Predicted sign	Controls (1)	Model 1 (2)	Model 2a (3)	Model 2b (4)	Model 2c (5)
Intercept		-56.546^{***}	-56.405^{***}	-32.710^{***}	-13.482	-27.544^{**}
		(18.310)	(17.818)	(10.796)	(10.010)	(10.869)
Hypothesized variables						
Horizontal SC complexity (*HORSCCPX*)	+			0.345^{*}		
				(0.184)		
Technological SC complexity (*TECHSCCPX*)	+				1.657^{***}	
					(0.450)	
Spatial SC complexity (*SPASCCPX*)	+					2.048^{**}
						(0.830)
Operational efficiency (*OPSEFC*)	–		-1.325^{***}	-2.632^{***}	-2.388^{***}	-2.067^{***}
			(0.475)	(0.946)	(0.750)	(0.704)
Control variables						
Firm size (*FIRMSIZE*)		3.060^{***}	3.257^{***}	2.286^{***}	1.182^{**}	1.885^{***}
		(0.945)	(0.948)	(0.621)	(0.543)	(0.591)
Firm age (*FIRMAGE*)		-0.024	-0.016	-0.037	-0.041	-0.056
		(0.058)	(0.057)	(0.053)	(0.046)	(0.062)
R&D intensity (*RDINTENS*)		1.807	1.316	-0.796	-1.211	-0.671
		(1.457)	(1.611)	(1.258)	(0.923)	(0.981)
European headquarter (*EUHQ*)		1.078	0.532	0.269	1.732	0.387
		(2.995)	(2.976)	(2.661)	(2.543)	(2.636)
Asian headquarter (*ASHQ*)		-4.279^{*}	-5.826^{**}	-5.258^{**}	-4.444^{*}	-4.188
		(2.352)	(2.449)	(2.379)	(2.592)	(2.706)
F		8.23^{***}	8.00^{***}	11.94^{***}	17.31^{***}	12.55^{***}
R^2		0.25	0.28	0.40	0.50	0.42
VIF_{max}		1.28	1.29	1.37	1.49	1.43
N		131	131	131	131	131

$^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$; Robust standard errors in parentheses.

In our second hypothesis, we proposed a negative association between *operational efficiency* and product safety risk. In Model 1 (Column 2 of Table 2), we see that this relationship is indeed significant. The estimated coefficient is also significantly negative across all other models (Columns 3–5 of Table 2), implying that operational efficiency reduces product safety risk ($\beta_3 = -1.325$, $p < 0.01$ in Model 1). These results provide support for Hypothesis 2.

In Hypotheses 3a–3c, we also proposed operational efficiency as a moderating factor for the effect of supply chain complexity on product safety risk. To test a moderating effect, we extend our main model (Equation 1), adding terms that express interactions between our operational efficiency variable and the respective supply chain complexity dimension as explanatory variables.

Appendix Table B4 presents the regression results including the hypothesized interaction effects. Model 3a (Column 1) corresponds to Model 2a from our main analysis (see Table 2), extended by an interaction between operational efficiency and horizontal supply chain complexity, Model 3b (Column 2) corresponds to Model 2b including the interaction with technological supply chain complexity, and Model 3c (Column 3) corresponds to Model 2c and further considers the interaction effect related to spatial supply chain complexity. We note that the estimates shown in Appendix Table B4 consistently support our previous findings (Hypotheses 1a–1c and Hypothesis 2). In addition, we find all three interaction term coefficients to be negative and highly significant ($p < 0.01$ for Interactions 1–2; $p < 0.05$ for Interaction 3). Collectively, these estimates provide support for Hypotheses 3a–3c, suggesting that operational efficiency mitigates the positive effect of (horizontal, technological, or spatial) supply chain complexity on product safety risk. The interaction plots for all three interactions (see Appendix Figures A1–A3) and the Johnson-Neyman plots for each interaction (see Appendix Figures A4–A6) [62] provide further support for Hypotheses 3a–3c.

5.2 Robustness Checks

To ensure the validity of our empirical results and their corresponding implications, we design and implement multiple robustness checks. These checks evaluate the sensitivity of our estimates to specific design choices or assess the risk of certain biases.

5.2.1 Alternative Model Specification

In our main model, we use OLS regression to test our hypothesized relationships, due to the cross-sectional design of our data set and the distribution of our dependent variable. We use the frequency of Class I and II product recalls to proxy our dependent variable product safety risk. As the product recall frequency measurement only takes positive integer values, the use of count regression may be an adequate alternative model specification.

The standard count regression specification follows a Poisson distribution [8], [11]. For our case of product recall events R_i, the corresponding distribution is given by,

$$Pr(R_i = r_i) = \frac{\lambda_i^{r_i} e^{-\lambda_i}}{r_i!} \quad (r_i = 0, 1, 2, ...), \tag{2}$$

where both mean and variance are modelled through the parameter λ_i with $E(R_i) = \mu_i = \lambda_i = Var(R_i)$, making the strong assumption of true mean and variance equivalence.

In our empirical setting, however, this assumption will most likely not hold. We thus follow previous research [e.g., 8], [67] and use negative binomial regression as an alternative model specification. The results are depicted in Appendix Table B5. All of our hypothesized relationships can be confirmed, as we see structurally consistent estimation results.

5.2.2 Alternative Supply Chain Complexity Measures

In our study, a core construct is supply chain complexity, which we measure based on three distinct sub-dimensions, horizontal, technological, and spatial supply chain complexity. Our corresponding measurements are count variables, such as the number of first-tier suppliers, the number of different first-tier supplier industries, and the number of different first-tier supplier countries. As such count variables often tend to correlate with firm size, we present alternative supply chain complexity measures as a robustness check. As shown in Appendix Table B6, all of our empirical findings hold.

5.2.3 Log-transformation of Count Measures

To assess the sensitivity of our results in the context of our count data constructs, we present OLS regression results with logarithmized constructs. Specifically, we estimate models, in which our dependent variable (i.e., the product recall frequency) and the three count-based supply chain complexity metrics are logarithmized (i.e., transformed using the natural logarithm function). Conceptually, this approach reduces the marginal effect of each additional unit of the respective construct.

Appendix Table B7 provides the corresponding linear regression results. According to Models 1–2b (Columns 2–4), the proposed effects of *operational efficiency*, *horizontal supply chain complexity*, and *technological supply chain complexity* still hold. Only the coefficient of *spatial supply chain complexity* exceeds the significance threshold ($p = 0.24$).

5.2.4 Missing Supply Chain Data

To construct the supply chain complexity constructs, we retrieve value chain data from the Refinitv Eikon database. While all firms of our final sample of 131 observations have database records (e.g., industry affiliation and financial metrics), 33 firms are listed without upstream supply chain information. This may be because these companies have no suppliers or because our data source has not identified them. The latter could lead to a biased result in our main analysis, where we consider these firms with a value of zero suppliers, since their general database entry exists.

However, to examine the sensitivity of our results to the consideration of these 33 firms, we re-estimate our main regression models with the reduced sub-sample of 98 firms that are listed with one or more suppliers. Appendix Table B8 presents the estimation results. Although the estimation looses some statistical power due to the reduced sample size, all hypothesized associations can be confirmed (see Models 1–2c, Columns 2–5, of Appendix Table B8). In sum, this analysis indicates that the consideration of the larger sample does not structurally alter our main findings.

5.2.5 Regression Sensitivity to Outliers

As regression estimates are known to be particularly sensitive to outliers when dealing with secondary data, we follow previous studies and provide two corresponding robustness checks [e.g., 3], [53], [54]. Specifically, we use the $dffits_i$ diagnostic and winsorizing. The results are presented in Appendix Table B9 and Appendix Table B10. Both robustness checks indicate that outliers are not a source of bias in our analysis.

6 Discussion

Our study provides a new perspective on product safety risk in the context of supply chain complexity. Managing product safety risk has become a challenge for many firms, and the involvement of diverse actors in the manufacturing of products make a supply chain perspective on product safety imperative. By comprehensively examining the effects of supply chain complexity and operational efficiency on product safety risk, our study makes a timely contribution, considering the increasing frequency of high-profile recalls in various industries.

6.1 Theoretical Implications

Our study makes several theoretical contributions. First, it examines how multiple dimensions of supply chain complexity affect product safety, addressing a key research gap by recognizing the multidimensional nature of supply chain complexity [28]. Second, we use Complexity Theory (CT) and Information Processing Theory (IPT) as theoretical lenses, allowing us to hypothesize the different effects of supply chain complexity and operational efficiency on the coordination and information processing requirements and capabilities of firms to deliver safe products.

Prior studies showed that supply chain complexity has a negative impact on operational performance [2], and specifically disruption frequency [8]. Additionally, research examined isolated metrics of supply chain complexity and their impact on product recalls and found a positive association [44], [72], [73]. Lastly, several scholars addressed bilateral or intra-organizational relationships and investigated the impact of manufacturing complexity metrics on product performance such as conformance quality [32], [33], [35], [37]. The review indicates that prior literature is fragmented, not sufficiently recognizing the pertinence of viewing product safety risk from a supply chain complexity perspective. Therefore, we hypothesize the effect of horizontal and spatial supply chain complexity on product safety and introduce technological supply chain complexity as a novel variable, extending prior research on supply chain complexity and firm performance. We find that each individual supply chain complexity dimension is positively associated with product safety risk, while technological supply chain complexity accounts for the strongest effect.

In this respect, this research underscores the growing importance of technological supply chain complexity, embodying technological uncertainty [20] and distance [60] from a supply chain perspective to understand elevated product safety risk. While products integrate a growing number of technologies from different industries, our findings indicate that this integration is associated with a trade-off in product safety. In particular, our results suggest that technological supply chain complexity increases information processing and coordination efforts for integrating inputs from different industries, resulting in higher product recalls. This implication is crucial, as it provides insight into the relationships between innovation and product safety, which are not found at the company level but at a supply chain level. A lack of structured forms of acquiring and using technological supplier knowledge not only negatively affects innovation performance [60], but may also increase product safety risk.

Furthermore, we have empirically explored that spatially complex supply chains have a positive effect on product safety risk. We find a strongly significant relationship between these two constructs. We also find support in anecdotal evidence and research associated with spatial supply chain characteristics and product safety metrics [72], [73]. While prior research indicates that physical and cultural distance [34], [35], and language differences [33] are associated with reduced product quality performance, we extend these findings in several ways. First, we highlight the critical role of spatial complexity as a driver of these factors in contemporary supply chains. Spatially complex supply chains need to cross more physical and non-physical barriers, making communication and coordination in the supply chain more challenging. Second, we examine the effect of these challenges on product safety as measured by severe product recalls. Our findings are further in line with prior research, suggesting that both outsourcing and offshoring drive product recalls [73].

In addition, our findings show a consistent positive relationship between horizontal supply chain complexity and product safety risk, supporting prior findings from Kini et al. [44]. We proposed a two-fold theoretical mechanism: First, horizontal supply chain complexity makes information processing more difficult as the number of suppliers N and interactions K increases, thus also increasing the risk of undetected product failures. Second, a higher level of horizontal supply chain complexity reflects higher product complexity and portfolio variety, increasing the likelihood of a product failure due to increasing integration efforts and information processing needs. Our findings support our hypothesis. This is an important contribution, as the implications of product complexity on product safety risk have been largely overlooked. In empirical manufacturing settings, findings from Handley and Gray [38] give an indication of the detrimental effects of product and associated process complexity on product safety. As much of the value creation is nowadays outsourced to suppliers, we take a supply chain perspective, indicating that product safety risks are rooted in complex products with fragmented inputs from a variety of different first-tier suppliers.

Lastly, we find that operational efficiency has a strongly significant and negative impact on product safety risk. Interestingly, our results show a significant direct mitigation effect on product safety risk as well as a moderating effect for the relationship between supply chain complexity and product safety risk. This is an important finding, as prior literature suggests that operational efficiency reflects a firm's ability to coordinate its supply chain to achieve superior financial performance [18]. Our finding indicates that firms, which manage deploying resources for coordination more efficiently, can leverage these abilities to also better manage complexities in upstream supply chain operations. Our findings provide support that these abilities also manifest in reduced product safety risk, particularly in settings of high supply chain complexity.

6.2 Managerial Implications

Our research shows that supply chain structures and practices have a strong impact on product safety risk. This contribution is timely as the sustainable reduction of product safety risk requires in-depth knowledge of a company's supply chain and operations [61]. Our research offers managers actionable recommendations on how to reduce product safety risk and the likelihood of product recalls.

First, our findings on how multiple dimensions of supply chain complexity impact product safety risk should motivate managers to scrutinize the structure of their upstream supply chain and supplier base. In this regard, supplier diversification as a common practice to diversify disruption risk should consider elevated product safety risk as a trade-off. Additionally, technological supply chain complexity seems to be a particularly important driver of product failures. Consequently, our findings suggest a prioritization on managing the risks associated with this form of complexity and may assist practitioners in assessing their choice of suppliers and product designs. For example, risk mitigation measures could include the establishment or stricter handling of technology integration standards and product life cycle management practices from product design to final delivery for critical components. This could reduce information processing requirements originating from innovative product designs and improve the oversight of product safety throughout the life cycle.

Furthermore, our research has revealed the importance of coordination capabilities of firms in relation to product safety. On the one hand, all forms of complexity increase the need for coordination and lead to information asymmetry. On the other hand, our investigation of the relationship between operational efficiency and product safety risk provides an indication that coordination capabilities can reduce product safety risks. This results in a twofold practical contribution. Practitioners should evaluate complexity in the supply chain dimensions we have conceptualized in order to take steps to reduce the needs for coordination, for example by reviewing and streamlining supply chain design where possible, eliminating segments that add complexity without significant value. This may be achieved by using artificial intelligence, identifying possibilities to consolidate sourcing in the existing supplier base. Furthermore, we have shown that efficient operations reduce product safety risk. Consequently, firms can manage product safety risks effectively by increasing their efforts to improve operational efficiency, for example, by implementing lean management practices and increasing cooperation with suppliers. In particular, firms should foster close, collaborative relationships with suppliers to enhance alignment on quality control measures and technological requirements. This could include the establishment of new, tightened communication channels and information sharing on emerging risks and technological innovations.

Finally, we found that the positive baseline effect of horizontal, technological and spatial supply chain complexity on product safety risk is mitigated by operational efficiency. This suggests that operational efficiency is an important and actionable moderator that firms should consider for product safety management. Firms that are exposed to high levels of supply chain complexity should put a particular focus on the improvement of operational efficiency, given its mitigating effect on product safety risk in these settings.

6.3 Limitations and Future Research

Our work has several limitations that need to be taken into consideration, while also providing opportunities for future research. Developing measures to capture upstream supply chain complexity is linked to several challenges, as buyer-supplier relationship data is very fragmented. Additionally, the confidence of the relationships provided by our data source varies, as the number of evidence pieces supporting a single buyer-supplier relationship varies significantly from case to case. Accordingly, we have to assume that the first-tier supplier lists from the Refinitiv Eikon value chain database for our sample firms are largely complete, or at least cross-sectionally representative.

Our data set is further limited to the U.S. medical device industry. Although this reference market is the most suitable in terms of size and availability of supply chain-, financial- and recall data, the inclusion of further manufacturers in other regions of the world would increase the generalizability of the study, as regional idiosyncrasies cannot be completely ruled out. The restriction of our sample to firms from the medical device industry may also limit generalizability. To enhance generalizability, future studies may use our complexity dimensions in other contexts, such as the pharmaceutical, automotive, or consumer goods industry by either analyzing them separately or in a cross-industry study. Although products in these industries have different physicalities and may pose different safety risks to the consumer, their supply chains are also highly complex and subject to regulation. For example, pharmaceutical supply chains are globally dispersed and highly complex as ingredients for drug substance manufacturing are often sourced globally and from a wide variety of different suppliers [50]. On the other hand, the technological supply chain complexity between these industries may vary as automotive products increasingly rely on the integration of different technologies, representing an interesting research opportunity. Past recall rates in the automotive industry further suggest that there are differences in automobile safety related to geography [50]. Examining to what degree the supply chains of these manufacturers are globalized or localized and what impact this has on product safety presents a further research opportunity. At the same time, recalls published by the NHTSA are not categorized into severity classes, making the examination of product safety risk based on a recall measure more challenging.

We focus on Class I and II recalls in the medical device industry, capturing product failures that have a severe potential impact on consumer health. Although the categorization provided by the FDA serves as an indicator of the safety hazard emanating from a product, it may be subject to failure and imprecision, potentially biasing our results. To develop a more comprehensive picture about the specific risks associated with the different dimensions of supply chain complexity, future research could categorize product recalls into different classes, such as manufacturing, design, or logistics related. Findings that link specific recalls to different types of supply chain complexity could make an important contribution to theory and practice. Furthermore, examining links between supply chain complexity dimensions and product safety risks associated with individual, isolated recall classes presents a further research opportunity. For instance, a large quantity of Class II recalls in the past were caused by deficiencies in GMPs [29] and often by contract manufacturers, suggesting that individual supply chain complexity dimensions could have a dominant impact on certain recall classes.

External effects, such as changes in regulatory requirements, the COVID-19 pandemic, or technological advances in relation to the measurability of certain product characteristics are possible influences on our results that cannot be adequately controlled for. Such effects might affect a certain group of products or firms, and can therefore affect the results of the study. For instance, recently, there has been a wave of recalls due to nitrosamine contamination in products from the pharmaceutical industry, as the technology for measuring these contaminants has improved [24]. Since our data set reflects recall data from 2020 and 2021, COVID-19 related recalls and recall policies [66] could further impact our results. In addition, product recalls can occur with a substantial time delay. Therefore, our supply chain data may not reflect the actual complexity of the supply chain at the time of the product failure. Instead, the product defect may have occurred at a point in time when the supply chain was more or less complex. We have used the data on the assumption that supply chain complexity remains relatively constant over time, and is not subject to major changes in the short and medium term. However, given these potential influences and the limitations of our data, it is likely that confounding factors are present in our empirical setting. As such, we cannot claim causality in our results. A study using longitudinal data instead of cross-sectional data could empirically examine the robustness of our results over a longer time period.

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Online Appendix

A Appendix Figures

Figures A1–A3 show interaction plots for all three interactions, differentiating between a relatively lower (i.e., mean − one standard deviation) and a relatively higher (i.e., mean + one standard deviation) level of the operational efficiency moderator. As illustrated, higher levels of operational efficiency mitigate the positive association between (horizontal, technological, or spatial) supply chain complexity and product safety risk (i.e., flatten the fitted curve's slope).

Figures A4–A6 show the Johnson-Neyman plots [62] for each interaction. As all three plots show, higher levels of operational efficiency lead to reduced slopes for the positive impact of supply chain complexity on product safety risk. In fact, as operational efficiency increases, the negative impact of supply chain complexity on product safety becomes insignificant (red colored areas in Figures A4–A6). The interaction plots and Johnson-Neyman plots [62] provide additional support for Hypotheses 3a–3c.

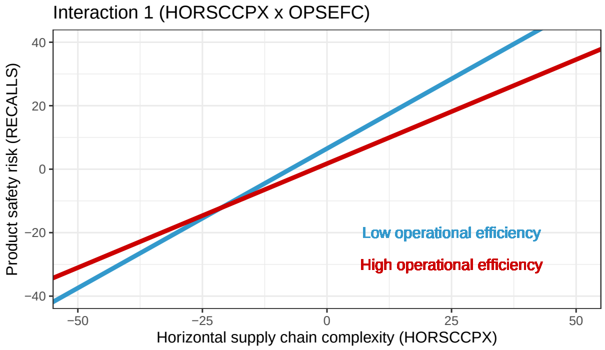

Figure A1: Interaction effect between horizontal SC complexity and operational efficiency.

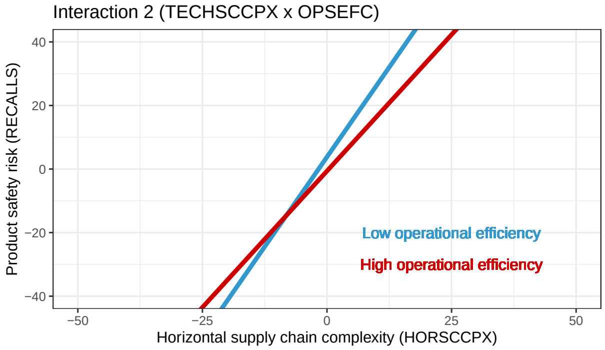

Figure A2: Interaction effect between technological SC complexity and operational efficiency.

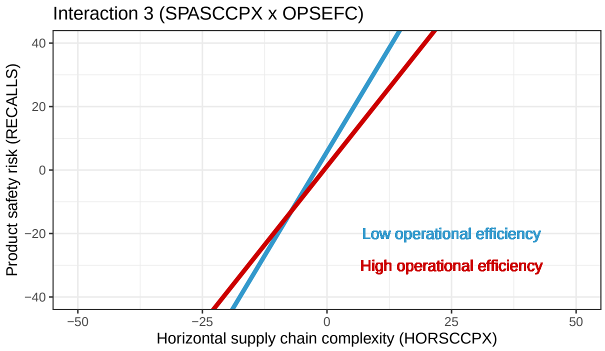

Figure A3: Interaction effect between spatial SC complexity and operational efficiency.

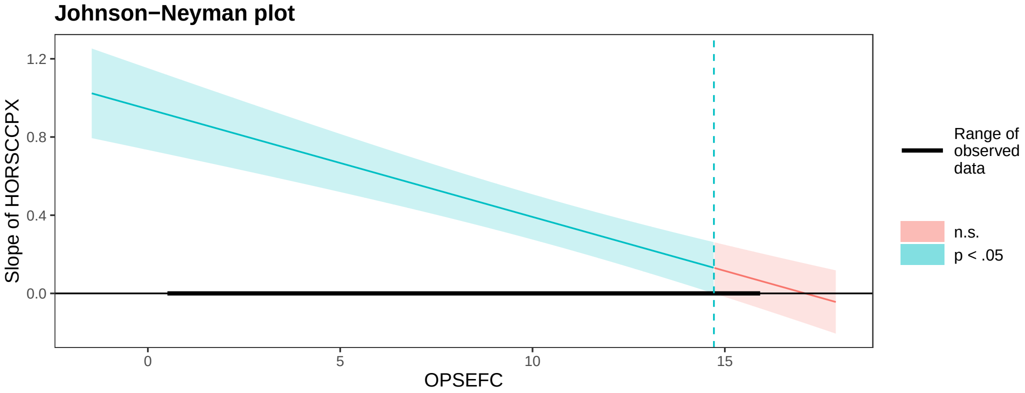

Figure A4: Johnson-Neyman plot for Interaction 1 (horizontal SC complexity).

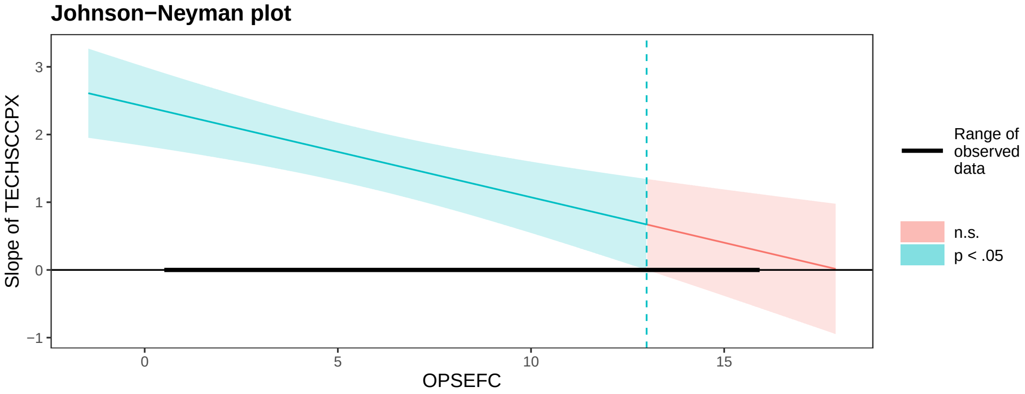

Figure A5: Johnson-Neyman plot for Interaction 2 (technological SC complexity).

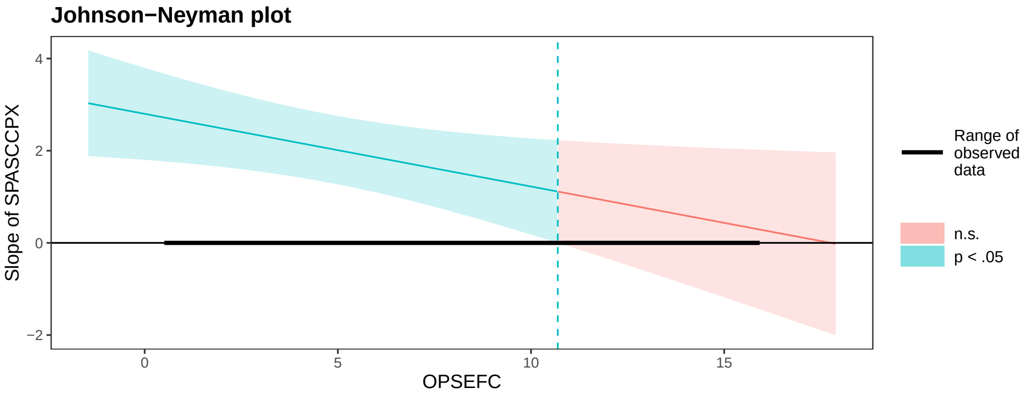

Figure A6: Johnson-Neyman plot for Interaction 3 (spatial SC complexity).

B Appendix Tables

Table B1: Overview of variables and operationalization.

Variable (label)	Operationalization	Source	Reference
Product safety risk (*RECALLS*)	Cumulative number of Class I and Class II product recall incidents in the medical device industry in 2019 and 2020	U.S. Food and Drug Administration (FDA) recall database	[75]
Horizontal SC complexity (*HORSCCPX*)	Number of first-tier suppliers of focal firm (database access 2022)	Refinitiv Eikon value chain database	[8]
Technological SC complexity (*TECHSCCPX*)	Number of different industries in first-tier supplier pool of focal firm (database access 2022)	Refinitiv Eikon value chain database	-
Spatial SC complexity (*SPASCCPX*)	Number of different headquarter countries in first-tier supplier pool of focal firm (database access 2022)	Refinitiv Eikon value chain database	-
Operational efficiency (*OPSEFC*)	Inventory turnover, based on ratio of COGS to average inventory, fiscal year 2019	Refinitiv Eikon financials	[49]
Firm size (*FIRMSIZE*)	Natural logarithm of total assets, fiscal year 2019	Refinitiv Eikon financials	[45]
Firm age (*FIRMAGE*)	Duration in years since company foundation, fiscal year 2019	Refinitiv Eikon financials	[6]
R&D intensity (*RDINTENS*)	Ratio of research and development expenses to revenues, fiscal year 2019	Refinitiv Eikon financials	[49]
Regional headquarter (*EUHQ*, *ASHQ*)	Dummy indicators for focal firm headquarter region (Europe, Asia, U.S. is base category), fiscal year 2019	Refinitiv Eikon financials	[45]

Table B2: Descriptive statistics for non-binary variables.

Variable	Mean	Stdev.	Median	Min.	Max.
Dependent variable					
Product safety risk (*RECALLS*)	7.67	14.27	3.00	1.00	95.00
Hypothesized variables					
Horizontal SC complexity (*HORSCCPX*)	7.05	19.02	2.00	0.00	172.00
Technological SC complexity (*TECHSCCPX*)	3.44	5.48	2.00	0.00	31.00
Spatial SC complexity (*SPASCCPX*)	2.26	3.46	1.00	0.00	18.00
Operational efficiency (*OPSEFC*)	3.18	2.02	2.89	0.56	15.86
Control variables					
Firm size (in billions) (*FIRMSIZE*)	16.53	38.45	2.20	0.01	265.18
Firm age (*FIRMAGE*)	42.68	35.56	28.61	0.09	183.00
R&D intensity (*RDINTENS*)	0.16	0.37	0.08	0.01	2.73

Firm size variable is not logarithmized; N=131.

Table B3: Correlation matrix.

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
(1) Product safety risk (*RECALLS*)							
(2) Horizontal SC complexity (*HORSCCPX*)	0.44*						
(3) Technological SC complexity (*TECHSCCPX*)	0.60*	0.89*					
(4) Spatial SC complexity (*SPASCCPX*)	0.53*	0.85*	0.94*				
(5) Operational efficiency (*OPSEFC*)	−0.04	0.50*	0.39*	0.36*			
(6) Firm size (*FIRMSIZE*)	0.47*	0.48*	0.62*	0.60*	0.25*		
(7) Firm age (*FIRMAGE*)	0.19*	0.35*	0.41*	0.46*	0.17*	0.56*	
(8) R&D intensity (*RDINTENS*)	−0.10	−0.07	−0.11	−0.11	−0.11	−0.32*	−0.22*

*p < 0.10, N=131.

Table B4: Linear regression results. Interaction effects.

Dependent variable: Product safety risk (*RECALLS*)	Predicted sign	Model 3a (1)	Model 3b (2)	Model 3c (3)
Intercept		−15.646*	−10.867	−27.835**
		(9.173)	(9.480)	(10.803)
Hypothesized variables				
Horizontal SC complexity (*HORSCCPX*)	+	0.943***		
		(0.138)		
Technological SC complexity (*TECHSCCPX*)	+		2.415***	
			(0.489)	
Spatial SC complexity (*SPASCCPX*)	+			2.800***
				(1.043)
Operational efficiency (*OPSEFC*)	–	−1.171**	−1.095**	−1.135*
		(0.579)	(0.544)	(0.580)
Hypothesized interaction effects				
Interaction 1 (*HORSCCPX* x *OPSEFC*)		−0.055***		
		(0.009)		
Interaction 2 (*TECHSCCPX* x *OPSEFC*)			−0.134***	
			(0.036)	
Interaction 3 (*SPASCCPX* x *OPSEFC*)				−0.158**
				(0.075)
Control variables				
Firm size (*FIRMSIZE*)		1.197**	0.823	1.746***
		(0.514)	(0.524)	(0.603)
Firm age (*FIRMAGE*)		−0.043	−0.035	−0.054
		(0.049)	(0.044)	(0.060)
R&D intensity (*RDINTENS*)		−1.432*	−0.754	−0.326
		(0.808)	(0.848)	(0.922)
European headquarter (*EUHQ*)		−0.882	1.585	0.065
		(2.225)	(2.287)	(2.476)
Asian headquarter (*ASHQ*)		−3.584	−3.772	−3.830
		(2.309)	(2.636)	(2.706)
F		20.00***	18.55***	11.95***
R^2		0.57	0.55	0.44
VIF_{max}		2.36	1.90	1.93
N		131	131	131

*p < 0.10, **p < 0.05, ***p < 0.01; Robust standard errors in parentheses.

Comparing the observed variance with the observed mean of our dependent product recall frequency variable in our main model leads to a ratio of $\sigma/\mu = 26.54$, indicating strong overdispersion [8], [11]. A dispersion test according to [11] based on a Poisson regression model supports this indication ($p < 0.01$). Negative binomial regression is a generalized form of the classic Poisson model, relaxing the assumption that mean and variance must be equal. We use a maximum likelihood approach to estimate the model, leading to the following log-likelihood function based on the negative binomial distribution [41],

$$\mathcal{L}(\beta) = ln\left[\prod_{i=1}^{N} \frac{\Gamma(\alpha^{-1} + r_i)}{\Gamma(\alpha^{-1})\Gamma(r_i + 1)} \left(\frac{\alpha^{-1}}{\alpha^{-1} + \mu_i}\right)^{1/\alpha} \left(\frac{\mu_i}{\mu_i + \alpha^{-1}}\right)^{r_i}\right], \tag{3}$$

where we use the exponential parameterization of $\mu_i = E(R_i \mid \mathbf{x}_i) = exp(\mathbf{x}_i'\beta)$ with $\mathbf{x}_i$ denoting our vector of explanatory variables. The variance is given by $Var(R_i) = \mu_i + \alpha\mu_i^2$, where α is a parameter to be estimated, indicating the level of overdispersion.

In our estimated model, the parameter α is significantly positive ($p < 0.001$), confirming our presumption of overdispersion. Table B5 further presents the estimation results based on the negative binomial specification. As shown by Models 1-2c (Columns 2–5) of Table 2, all of our hypothesized relationships can be confirmed, as we see structurally consistent estimation results. It hence appears reasonable to conclude that our model specification choice does not drive our findings.

Table B5: Negative binomial regression results.

Dependent variable: Product safety risk (*RECALLS*)						
	Predicted sign	Controls (1)	Model 1 (2)	Model 2a (3)	Model 2b (4)	Model 2c (5)
Intercept		-5.795^{***}	-5.398^{***}	-4.124^{***}	-3.353^{***}	-4.203^{***}
		(0.992)	(0.973)	(1.041)	(1.099)	(1.081)
Hypothesized variables						
Horizontal SC complexity (*HORSCCPX*)	+			0.011^{**}		
				(0.005)		
Technological SC complexity (*TECHSCCPX*)	+				0.051^{***}	
					(0.019)	
Spatial SC complexity (*SPASCCPX*)	+					0.051^{*}
						(0.031)
Operational efficiency (*OPSEFC*)	–		-0.100^{**}	-0.132^{***}	-0.133^{***}	-0.119^{***}
			(0.045)	(0.050)	(0.045)	(0.046)
Control variables						
Firm size (*FIRMSIZE*)		0.355^{***}	0.349^{***}	0.290^{***}	0.249^{***}	0.291^{***}
		(0.048)	(0.048)	(0.050)	(0.054)	(0.053)
Firm age (*FIRMAGE*)		−0.001	−0.000	0.000	0.000	0.000
		(0.003)	(0.003)	(0.003)	(0.003)	(0.003)
R&D intensity (*RDINTENS*)		−0.164	−0.199	−0.297	−0.331	−0.285
		(0.302)	(0.293)	(0.295)	(0.294)	(0.296)
European headquarter (*EUHQ*)		0.085	0.116	0.065	0.078	0.049
		(0.203)	(0.199)	(0.197)	(0.194)	(0.197)
Asian headquarter (*ASHQ*)		-0.733^{***}	-0.825^{***}	-0.812^{***}	-0.804^{***}	-0.832^{***}
		(0.272)	(0.272)	(0.267)	(0.264)	(0.270)
ΔAIC			-2.43	-4.50	-8.48	-3.90
$\tilde{R}^2$		0.11	0.12	0.12	0.13	0.12
VIF_{max}		1.25	1.27	1.36	1.49	1.43
N		131	131	131	131	131

$^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$; Robust standard errors in parentheses.

ΔAIC is the difference in AIC to the control model.

In Table B6, we present the regression results based on alternative supply chain complexity measures. We compute ratio-based metrics, dividing our count measures by the firm's total assets (i.e., firm size). This approach reduces the association with firm size and contextually captures the firm's supply chain complexity *relative* to its size. As indicated by Models 1–2c (Columns 2–5) of Table B6, all of our empirical findings still hold, providing further robustness.

Table B6: Linear regression results. Alternative supply chain complexity measures.

Dependent variable: Product safety risk (*RECALLS*)

	Predicted sign	Controls (1)	Model 1 (2)	Model 2a (3)	Model 2b (4)	Model 2c (5)
Intercept		-56.546^{***}	-56.405^{***}	-59.473^{***}	-60.289^{***}	-59.868^{***}
		(18.310)	(17.818)	(18.937)	(19.262)	(19.109)
Hypothesized variables						
Horizontal SC complexity (*HORSCCPX*)	+			0.042^{**}		
				(0.020)		
Technological SC complexity (*TECHSCCPX*)	+				0.065^{**}	
					(0.031)	
Spatial SC complexity (*SPASCCPX*)	+					0.066^{**}
						(0.032)
Operational efficiency (*OPSEFC*)	–		-1.325^{***}	-1.377^{***}	-1.382^{***}	-1.379^{***}
			(0.475)	(0.492)	(0.493)	(0.491)
Control variables						
Firm size (*FIRMSIZE*)		3.060^{***}	3.257^{***}	3.410^{***}	3.448^{***}	3.428^{***}
		(0.945)	(0.948)	(1.003)	(1.017)	(1.010)
Firm age (*FIRMAGE*)		−0.024	−0.016	−0.020	−0.021	−0.021
		(0.058)	(0.057)	(0.058)	(0.058)	(0.058)
R&D intensity (*RDINTENS*)		1.807	1.316	0.578	0.598	0.612
		(1.457)	(1.611)	(1.174)	(1.166)	(1.173)
European headquarter (*EUHQ*)		1.078	0.532	0.521	0.504	0.553
		(2.995)	(2.976)	(2.964)	(2.957)	(2.970)
Asian headquarter (*ASHQ*)		-4.279^{*}	-5.826^{**}	-5.598^{**}	-5.534^{**}	-5.562^{**}
		(2.352)	(2.449)	(2.493)	(2.505)	(2.501)
F		8.23^{***}	8.00^{***}	6.98^{***}	7.01^{***}	7.00^{***}
R^2		0.25	0.28	0.28	0.29	0.28
VIF_{max}		1.28	1.29	1.34	1.35	1.35
N		131	131	131	131	131

$^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$; Robust standard errors in parentheses.

Table B7: Linear regression results. Log-transformed count data.

Dependent variable: Product safety risk (*RECALLS*)	Predicted sign	Controls (1)	Model 1 (2)	Model 2a (3)	Model 2b (4)	Model 2c (5)
Intercept		-2.949^{***}	-2.939^{***}	-1.696^{**}	-1.862^{***}	-2.437^{***}
		(0.864)	(0.831)	(0.691)	(0.692)	(0.749)
Hypothesized variables						
Horizontal SC complexity (*HORSCCPX*)	+			0.219^{**}		
				(0.086)		
Technological SC complexity (*TECHSCCPX*)	+				0.247^{**}	
					(0.104)	
Spatial SC complexity (*SPASCCPX*)	+					0.158
						(0.134)
Operational efficiency (*OPSEFC*)	–		-0.090^{**}	-0.110^{**}	-0.103^{**}	-0.099^{**}
			(0.042)	(0.044)	(0.042)	(0.043)
Control variables						
Firm size (*FIRMSIZE*)		0.215^{***}	0.228^{***}	0.162^{***}	0.168^{***}	0.200^{***}
		(0.045)	(0.045)	(0.039)	(0.039)	(0.042)
Firm age (*FIRMAGE*)		−0.001	−0.000	−0.001	−0.001	−0.001
		(0.003)	(0.003)	(0.003)	(0.003)	(0.003)
R&D intensity (*RDINTENS*)		−0.055	−0.088	-0.143^{*}	−0.119	−0.105
		(0.091)	(0.100)	(0.076)	(0.082)	(0.087)
European headquarter (*EUHQ*)		−0.008	−0.045	0.021	0.042	−0.020
		(0.186)	(0.190)	(0.195)	(0.199)	(0.197)
Asian headquarter (*ASHQ*)		-0.403^{**}	-0.508^{***}	-0.410^{**}	-0.425^{**}	-0.471^{**}
		(0.170)	(0.175)	(0.183)	(0.186)	(0.184)
F		11.00^{***}	10.53^{***}	10.27^{***}	10.04^{***}	9.30^{***}
R^2		0.31	0.34	0.37	0.36	0.35
VIF_{max}		1.28	1.29	1.60	1.60	1.50
N		131	131	131	131	131

$^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$; Robust standard errors in parentheses.

All count data variables (*RECALLS*, *HORSCCPX*, *TECHSCCPX*, *SPASCCPX*) logarithmized.

Table B8: Linear regression results. Observations with sufficient supply chain data only.

Dependent variable: Product safety risk (*RECALLS*)

	Predicted sign	Controls (1)	Model 1 (2)	Model 2a (3)	Model 2b (4)	Model 2c (5)
Intercept		-77.936^{***}	-76.386^{***}	-41.010^{***}	-17.211	-40.582^{**}
		(23.834)	(22.895)	(14.947)	(15.546)	(16.573)
Hypothesized variables						
Horizontal SC complexity (*HORSCCPX*)	+			0.342^{*}		
				(0.179)		
Technological SC complexity (*TECHSCCPX*)	+				1.686^{***}	
					(0.471)	
Spatial SC complexity (*SPASCCPX*)	+					1.911^{**}
						(0.914)
Operational efficiency (*OPSEFC*)	–		-1.604^{**}	-3.206^{***}	-2.962^{***}	-2.443^{***}
			(0.618)	(1.217)	(0.895)	(0.891)
Control variables						
Firm size (*FIRMSIZE*)		4.068^{***}	4.227^{***}	2.760^{***}	1.422^{*}	2.551^{***}
		(1.201)	(1.178)	(0.773)	(0.782)	(0.841)
Firm age (*FIRMAGE*)		−0.044	−0.029	−0.042	−0.039	−0.060
		(0.071)	(0.069)	(0.062)	(0.054)	(0.072)
R&D intensity (*RDINTENS*)		6.357	7.327	3.219	0.379	2.336
		(4.031)	(4.494)	(3.386)	(2.718)	(3.088)
European headquarter (*EUHQ*)		2.575	2.121	1.745	2.825	1.210
		(4.091)	(4.112)	(3.718)	(3.401)	(3.478)
Asian headquarter (*ASHQ*)		-7.162^{**}	-9.421^{***}	-7.861^{**}	-7.151^{*}	-7.119^{*}
		(3.116)	(3.286)	(3.558)	(3.859)	(3.976)
F		7.23^{***}	7.19^{***}	9.62^{***}	13.28^{***}	9.43^{***}
R^2		0.28	0.32	0.43	0.51	0.42
VIF_{max}		1.28	1.28	1.43	1.58	1.48
N		98	98	98	98	98

$^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$; Robust standard errors in parentheses.

Following the approach from [53], we identify and exclude the most estimation-influential observations and re-estimate our main models based on the resulting sub-sample. To identify the most influential data points, we use the $dffits_i$ diagnostic, which proxies the sensitivity of the regression estimates to the exclusion of the corresponding data point. We exclude all observations with $|dffits_i| > 2\sqrt{p/N}$, where p is the number of explanatory variables and N our sample size. Depending on the specific model, we thus exclude 10-12 observations. Table B9 shows our main regression results for the corresponding sub-samples. As suggested by Models 1–2c (Columns 2–5), three out of our four hypothesized relationships can be confirmed, suggesting that influential data points most likely do not bias our estimates.

Table B9: Linear regression results. Influential data points excluded.

Dependent variable: Product safety risk (*RECALLS*)						
	Predicted sign	Controls (1)	Model 1 (2)	Model 2a (3)	Model 2b (4)	Model 2c (5)
Intercept		-20.180^{***}	-22.156^{***}	-9.908^{*}	-7.009	-16.234^{**}
		(7.199)	(6.930)	(5.903)	(6.446)	(6.821)
Hypothesized variables						
Horizontal SC complexity (*HORSCCPX*)	+			0.344^{***}		
				(0.124)		
Technological SC complexity (*TECHSCCPX*)	+				1.106^{***}	
					(0.319)	
Spatial SC complexity (*SPASCCPX*)	+					0.600
						(0.439)
Operational efficiency (*OPSEFC*)	–		-1.061^{***}	-1.458^{***}	-1.403^{***}	-1.331^{***}
			(0.303)	(0.378)	(0.396)	(0.377)
Control variables						
Firm size (*FIRMSIZE*)		1.188^{***}	1.431^{***}	0.870^{**}	0.632^{*}	1.164^{***}
		(0.383)	(0.385)	(0.354)	(0.379)	(0.401)
Firm age (*FIRMAGE*)		0.013	0.026	0.014	0.025	0.013
		(0.032)	(0.029)	(0.023)	(0.025)	(0.025)
R&D intensity (*RDINTENS*)		0.220	0.933	-0.856	-0.544	-0.350
		(0.778)	(1.278)	(0.660)	(0.667)	(0.790)
European headquarter (*EUHQ*)		-0.041	-1.084	-0.781	0.155	-0.688
		(1.461)	(1.445)	(1.362)	(1.473)	(1.551)
Asian headquarter (*ASHQ*)		-2.900^{**}	-4.321^{***}	-3.890^{***}	-3.429^{**}	-3.945^{***}
		(1.307)	(1.465)	(1.304)	(1.344)	(1.360)
F		5.66^{***}	7.33^{***}	9.13^{***}	14.56^{***}	7.07^{***}
R^2		0.20	0.28	0.36	0.48	0.31
VIF_{max}		1.30	1.32	1.40	1.43	1.36
N		121	119	120	120	119

$^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$; Robust standard errors in parentheses.

We also report regression results based on winsorized variables [e.g., 3]. Specifically, we transform all count and continuous explanatory variables and our outcome variables by winsorizing them at the 1st and 99th percentiles. We then re-estimate our main regression models. Table B10 presents the estimation results, based on the winsorized variables. According to Models 1–2c (Columns 2–5), all effects are consistent with our main analysis.

Table B10: Linear regression results. Winsorized sample.

Dependent variable: Product safety risk (*RECALLS*)						
	Predicted sign	Controls (1)	Model 1 (2)	Model 2a (3)	Model 2b (4)	Model 2c (5)
Intercept		-49.169^{***}	-48.506^{***}	-22.531^{**}	-17.105^{*}	-28.464^{***}
		(14.320)	(13.741)	(9.844)	(9.684)	(10.391)
Hypothesized variables						
Horizontal SC complexity (*HORSCCPX*)	+			0.435^{***}		
				(0.156)		
Technological SC complexity (*TECHSCCPX*)	+				1.218^{***}	
					(0.376)	
Spatial SC complexity (*SPASCCPX*)	+					1.409^{**}
						(0.657)
Operational efficiency (*OPSEFC*)	–		-1.412^{**}	-1.934^{***}	-1.994^{***}	-1.846^{***}
			(0.550)	(0.687)	(0.656)	(0.667)
Control variables						
Firm size (*FIRMSIZE*)		2.667^{***}	2.852^{***}	1.647^{***}	1.310^{**}	1.891^{***}
		(0.741)	(0.739)	(0.559)	(0.548)	(0.576)
Firm age (*FIRMAGE*)		0.001	0.006	−0.019	−0.016	−0.023
		(0.053)	(0.051)	(0.047)	(0.044)	(0.054)
R&D intensity (*RDINTENS*)		1.798	1.283	−1.060	−0.859	−0.349
		(1.420)	(1.604)	(1.149)	(1.079)	(1.172)
European headquarter (*EUHQ*)		0.328	−0.123	−0.535	0.850	−0.174
		(2.600)	(2.605)	(2.345)	(2.359)	(2.457)
Asian headquarter (*ASHQ*)		-4.817^{**}	-6.274^{***}	-4.906^{**}	-4.948^{**}	-4.998^{**}
		(2.259)	(2.364)	(2.266)	(2.401)	(2.503)
F		8.63^{***}	8.46^{***}	12.74^{***}	13.50^{***}	10.38^{***}
R^2		0.26	0.29	0.42	0.43	0.37
VIF_{max}		1.28	1.30	1.44	1.50	1.44
N		131	131	131	131	131

*p < 0.10, **p < 0.05, ***p < 0.01; Robust standard errors in parentheses.
All variables except dummies winsorized at 1% tails.