

Thermal Reliability Engineering in Cold Chain Logistics: Quantifying Time–Temperature Exposure, Packaging Performance, and Spoilage Risk in Distribution Networks

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ABSTRACT

This article presents an applied thermal reliability framework that links distribution operations to product risk using engineering metrics that can be measured and governed in practice. The framework combines (i) a time–temperature exposure model using exceedance time and mean kinetic temperature as reliability indicators, (ii) a packaging thermal performance model that represents insulation and refrigerant buffering as a transient heat transfer system, and (iii) a product degradation and spoilage risk model based on temperature-accelerated kinetics. A scenario-based quantitative study is developed for representative distribution networks including cross-docking, refrigerated line-haul, and last-mile delivery, with comparisons across packaging tiers and monitoring-control strategies. Results show that the dominant drivers of spoilage risk are not average temperature or nominal setpoints, but the upper-tail of exposure created by dwell-time uncertainty, door openings, and staging delays, and that packaging upgrades and sensor-triggered interventions reduce risk most effectively when applied to the highest-variance legs rather than uniformly across the network. The paper concludes with implementable guidance for risk-based monitoring, packaging selection, and operational governance that improves thermal reliability while controlling cost.

Keywords: Cold Chain, Thermal Reliability, Time–Temperature Exposure, Mean Kinetic Temperature, Packaging Performance, Spoilage Risk, Distribution Uncertainty, Monitoring and Control.

1. INTRODUCTION

Cold chain logistics underpins the delivery of temperature-sensitive products such as fresh foods, vaccines, biologics, and specialty chemicals, and it functions as an engineered reliability system because product quality and safety are not preserved by a single “successful” event but by continuous compliance across a sequence of transportation and handling stages. The engineering significance is that cold chain failures are rarely caused by complete refrigeration collapse alone; instead, they emerge from the accumulation of smaller deviations such as short door-open events, staging delays at cross-docks, local hot zones inside containers, or misaligned transfer schedules that create transient warming and partial recovery cycles (Mercier et al., 2017; Novaes et al., 2015). These cycles can appear operationally benign because each deviation may remain within apparent “acceptable” bounds, yet the cumulative time–temperature history can materially reduce shelf life,

increase microbial growth potential, or degrade potency, particularly when products have temperature-sensitive reaction kinetics. The management problem is not only to maintain a nominal temperature setpoint, but to design a distribution system that remains thermally reliable under variability in time, environment, and handling (Bai et al., 2023; Lee et al., 2025).

The urgency of this problem has increased because modern distribution networks have become faster, more fragmented, and more service-level constrained, and these characteristics create operational conditions that amplify temperature risk. E-commerce and on-demand delivery compress delivery windows while increasing last-mile complexity and increasing the frequency of handling and door openings, which raises the probability of short-duration thermal excursions that are difficult to capture with coarse monitoring (Davoudi et al., 2024; Rahman & Hye, 2021).

Multi-echelon networks with cross-docking and consolidation improve transportation efficiency but introduce additional dwell stages where products may be staged in environments with limited thermal protection, especially when congestion or labor constraints delay loading. Regulatory and customer expectations have also become stricter, particularly for pharmaceuticals and high-value foods, which means that quality assurance must be defensible not only from a compliance standpoint but also from a quantitative risk standpoint, since downstream liabilities can be large even when deviations are intermittent and not visually obvious (Bogataj et al., 2020; Kader, 2023; Lu et al., 2025).

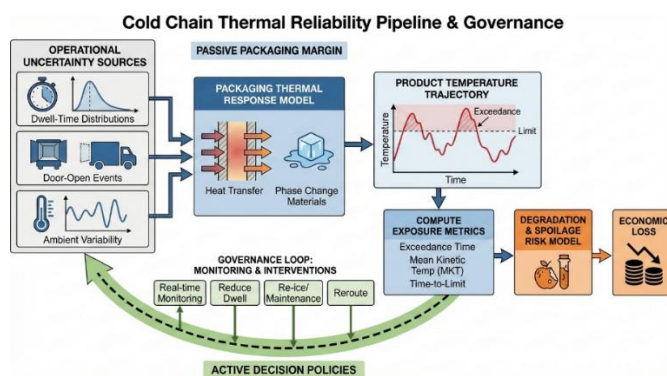


Figure 1. Cold Chain Thermal Reliability Pipeline & Governance

Source: data proceed

The state of practice in many cold chain programs still relies heavily on threshold-based compliance logic, where the primary question becomes whether the measured temperature exceeded a fixed limit for a specified duration. While this approach is operationally convenient, it has two limitations that reduce its engineering fidelity. First, threshold checks can underrepresent cumulative damage because degradation often depends on the full temperature trajectory and not merely on the time above a single threshold, meaning that repeated sub-threshold warming can still produce significant quality loss. Second, threshold checks can misallocate resources because they do not distinguish between excursions that occur late in shelf life, excursions that occur early when there is time for recovery, or excursions that occur in legs with high variance where risk is dominated by the tail of the distribution rather than by the mean. In applied engineering terms, a cold chain system needs reliability indicators that are sensitive to the time–temperature trajectory and that can support risk-based decisions about where to invest in packaging, monitoring, or operational redesign (Sarkar, 2022; Zhou et al., 2025).

The academic and applied literature relevant to cold chain has expanded across domains that include thermal packaging design, refrigeration engineering, food science kinetics, pharmaceutical stability, and supply chain management, yet these domains are not always integrated into a single decision framework that translates operational uncertainty into product risk in a way that is actionable for logistics managers. Studies on packaging often report thermal performance under controlled laboratory conditions, while operations studies analyze dwell and routing variability without linking those dynamics to product degradation metrics, and monitoring studies focus on sensor deployment without fully characterizing how uncertainty propagates into decision reliability and waste reduction. This fragmentation creates a gap for an engineering-oriented approach that explicitly connects operational variability, packaging thermal dynamics, and degradation kinetics through unified reliability metrics that can be interpreted and governed.

This article addresses that gap by proposing a thermal reliability framework for cold chain logistics that is quantitative, comparative, and operationally interpretable. The paper makes three contributions. First, it defines exposure metrics, including exceedance time and mean kinetic temperature, that represent thermal reliability more faithfully than binary compliance and that can be computed from sensor data or simulated for planning. Second, it integrates a transient packaging thermal model with operational dwell-time variability to show how packaging choices change not only average temperatures but the distribution of exposure, which is crucial because spoilage risk is tail-driven. Third, it links exposure to product risk using kinetic-based degradation models that enable comparisons in terms of shelf-life loss and probability of unacceptable quality, and it demonstrates how monitoring and intervention policies can improve decision reliability without excessive alarm burden (Olagunju, 2022; Shrivastava et al., 2022).

The paper pursues the following research questions: How does operational variability across distribution legs propagate into time–temperature exposure distributions at the product level, and which legs dominate risk? How do packaging performance tiers change the probability and severity of exposure, particularly under tail conditions? How do monitoring and intervention strategies affect expected spoilage probability and economic loss when decision rules must be applied under uncertainty? The remainder of the paper is structured as follows. The literature review synthesizes relevant evidence across thermal reliability, packaging performance, and degradation modeling. The methodology defines the exposure metrics, thermal packaging model, degradation-risk model, and scenario design. The results and discussion present scenario-based quantitative outcomes and interpret them through an engineering decision lens. The conclusion provides implementable guidance and identifies future work directions.

2. LITERATURE REVIEW

Cold Chain Failure Modes as Reliability Events

Cold chain degradation is best understood as a sequence of reliability events rather than a single-point failure, because temperature control is affected by both equipment and operations. Equipment-driven risks include refrigeration capacity loss, poor airflow, sensor drift, and control instability, while operations-driven risks include door opening frequency, dwell-time extensions, staging practices, and vehicle loading patterns that create thermal gradients within the payload. A practical theme across studies is that many deviations are intermittent and localized, which means that monitoring at a single point can miss hot zones and that average temperature can remain acceptable while certain packages experience damaging exposure (Aung & Chang, 2023; Bentlyn & Konecka, 2024; Lorenc, 2023). This observation motivates reliability methods that focus on distribution tails and on spatial heterogeneity inside containers rather than on single-point means.

Exposure Metrics Beyond Binary Compliance

In food and pharmaceutical stability domains, mean kinetic temperature is often used as a condensed indicator of cumulative thermal exposure because it weights higher temperatures more strongly, reflecting the Arrhenius-like acceleration of many degradation processes. Exceedance time metrics, such as time above an

upper limit or time within a risk band, are also widely used for operational control because they provide clear triggers, yet their effectiveness depends on how thresholds are chosen relative to product kinetics and how multiple small excursions accumulate (Awad et al., 2021; Zhang et al., 2019). The literature increasingly suggests that exposure metrics should be chosen to align with product risk rather than with generic compliance limits, because different products have different sensitivity and because shelf life depends on the full trajectory, not only on peak events.

Packaging Thermal Dynamics as A Transient Buffering System

Thermal packaging is frequently evaluated through steady metrics such as insulation R-value, but in logistics applications the relevant behavior is transient, because products experience time-varying ambient temperature, door openings, and intermittent refrigeration. Packaging performance includes insulation, thermal mass, phase-change materials, and refrigerant packs, and the thermal response depends on loading configuration and airflow (Ding et al., 2023; Ren et al., 2022; Wu & Hsiao, 2021). Many packaging studies demonstrate that better insulation reduces warming rate, but the operational implication is subtler: insulation reduces variance amplification during dwell-time uncertainty and buys time for corrective action, which can be more valuable than improving mean temperature alone. This aligns with reliability thinking, where margin is valuable because it reduces the probability of crossing critical thresholds during uncertain events.

Degradation Kinetics and Spoilage Risk Modeling

Food quality loss and microbial growth, and pharmaceutical potency loss, are commonly modeled through kinetics that accelerate with temperature, often using Arrhenius relationships or empirically fitted models. These models provide a pathway to translate time–temperature histories into expected shelf-life loss or probability of unacceptable quality. A key limitation highlighted in applied studies is that parameters are product-specific and require calibration, and that uncertainty in kinetic parameters can be nontrivial, especially for heterogeneous food products (Ren et al., 2024; Thompson, 2025). Even approximate kinetic models can support comparative decisions because they capture the nonlinear penalty of higher temperature exposure, which is precisely what binary compliance logic misses.

Monitoring, Decision Reliability, and Governance

Cold chain monitoring has shifted from single-use data loggers to connected IoT sensors that provide near-real-time visibility, yet increased visibility can create alarm overload if decision rules are not governed. The reliability question is therefore not only whether sensors exist, but whether the decision pipeline uses them effectively, including where sensors are placed, how thresholds incorporate uncertainty, how interventions are triggered, and how false alarms are controlled. In practice, intervention cost is nonzero and excessive alarms reduce responsiveness, which means that monitoring must be paired with risk-based policies that target high-consequence exposure patterns rather than reacting to every transient fluctuation (Pajic et al., 2024).

Synthesis and Gap Addressed

Across these themes, the literature supports the idea that cold chain performance should be managed as a reliability system where exposure distributions, packaging buffering, and kinetics-based risk are integrated. The specific gap addressed by this article is an applied framework that links operational variability and packaging tiers to spoilage probability and economic loss through measurable exposure metrics, enabling risk-based allocation of packaging and monitoring resources. This contribution is especially relevant for applied engineering and technology practice because it supports structured decisions rather than descriptive reporting (Lorenc, 2023; Olagunju, 2022; Zhou et al., 2025).

3. METHOD

Study Design and Scenario-Based Quantitative Evaluation

The study uses a quantitative, scenario-based design that represents cold chain distribution as a sequence of legs, each characterized by ambient conditions, dwell-time uncertainty, handling intensity, and refrigeration effectiveness. The purpose is not to replicate a specific site but to provide a generic, engineering-relevant evaluation that isolates the role of operational variability and packaging performance in determining exposure and risk. Each scenario is evaluated by Monte Carlo simulation to capture uncertainty distributions rather than relying on single deterministic values, because spoilage risk is dominated by tail events that are invisible to mean-only analyses.

Network Representation and Legs

A generic distribution network is represented with four legs: (L1) origin staging and loading, (L2) refrigerated line-haul, (L3) cross-dock dwell and transfer, and (L4) last-mile delivery with multiple stops. Each leg has a duration distribution, an ambient temperature profile distribution, and an effective refrigeration factor that represents how strongly the vehicle maintains internal air temperature relative to setpoint under door events. Handling intensity is modeled through a door-open process that produces short ambient intrusions and mixing, which is operationally important in last-mile and cross-dock contexts.

Packaging Thermal Model

Packaging is modeled as a first-order transient thermal system with a time constant that represents insulation and thermal mass effects, optionally augmented by a buffering term representing refrigerant packs or phase-change materials. Product temperature is treated as the critical state variable because degradation depends on product temperature, not merely air temperature. The simplest representation uses a lumped-capacitance model:

Product temperature dynamics:

$$dT_p/dt = (T_{env}(t) - T_p)/\tau_{eff} - B(t)$$

where τ_{eff} is an effective time constant determined by packaging tier, loading, and airflow, and $B(t)$ represents active buffering, which is nonzero when refrigerant packs are present and within their effective phase window. Although simplified, this model captures the engineering behavior that better packaging increases τ_{eff} , slowing warming during excursions and reducing exposure variance when dwell time is uncertain. Packaging tiers are defined as:

- Tier 1 basic insulation (small τ_{eff})
- Tier 2 enhanced insulation (moderate τ_{eff})
- Tier 3 enhanced insulation plus buffering (large τ_{eff} with $B(t)$ during excursions)

Exposure Metrics

Exposure is computed from the simulated product temperature trajectory $T_p(t)$. Two primary metrics are used. Exceedance time: $E_T = \text{total time } T_p(t) > T_{limit}$, where T_{limit} is the product-specific upper temperature limit for quality assurance or regulatory compliance.

Mean kinetic temperature: MKT, computed as an Arrhenius-weighted equivalent temperature that produces equivalent degradation over the interval, providing a single exposure indicator that penalizes higher temperatures nonlinearly. A cumulative equivalent exposure index is computed for operational interpretability, representing equivalent hours at a reference temperature that would yield similar degradation, enabling managers to interpret exposure in time-based units rather than abstract indices.

Product Degradation and Spoilage Risk Model

Product degradation is modeled using temperature-accelerated kinetics. For generic comparability, a first-order degradation model is used with Arrhenius temperature dependence:

$$k(T) = k_{\text{ref}} * \exp[-E_a/R * (1/T - 1/T_{\text{ref}})]$$

Cumulative damage D is computed as the integral of $k(T_p(t))$ over time, and spoilage probability is modeled as $P_{\text{spoil}} = P(D > D_{\text{crit}})$, where D_{crit} is a damage threshold corresponding to unacceptable quality. For food products where microbial growth dominates, the damage function can be interpreted as log-growth potential, while for pharmaceuticals it can represent potency loss; the framework is agnostic as long as a monotonic damage measure is defined. Because parameters vary by product, the study uses representative parameter sets and emphasizes comparative insights rather than absolute claims.

Monitoring and Intervention Strategies

Three strategies are evaluated.

1. Strategy A baseline compliance: temperature is checked at a limited number of points with post hoc review; interventions are rare and largely reactive.
2. Strategy B real-time sensing with threshold alarms: sensors report in near real-time and trigger intervention when product temperature exceeds a warning band for a persistence duration.
3. Strategy C risk-based sensing and intervention: sensors and alarms are governed by exposure metrics, using MKT trend and predicted time-to-limit to trigger interventions selectively in high-variance legs, with escalation rules designed to control false alarms and focus on high-consequence events.

Interventions include rerouting to reduce dwell, expedited loading, adding refrigerant packs at cross-dock, or re-icing in last-mile hubs, represented as actions that reduce ambient intrusion or reduce product temperature by a bounded amount.

Economic Loss Model

Economic loss is computed as the expected spoilage cost plus intervention cost. Spoilage cost is proportional to product value, while intervention cost includes labor, delay penalties, and material costs, enabling evaluation of cost-risk trade-offs.

4. RESULT AND DISCUSSION

Scenario Definitions and Parameterization Overview

Four scenarios are analyzed to represent common cold chain contexts with different dominant uncertainties.

1. Scenario 1 stable line-haul, weak last-mile: refrigerated line-haul is well controlled, but last-mile has multiple stops and frequent door openings.
2. Scenario 2 cross-dock congestion: cross-dock dwell is highly variable with staging in semi-controlled environments.

3. Scenario 3 warm ambient stress: ambient temperatures are high and variable, increasing the penalty of door events and staging.
4. Scenario 4 mixed mode with limited refrigeration: certain legs rely on passive cooling due to equipment constraints or short-haul practices.

Across scenarios, packaging tiers and monitoring strategies are compared using Monte Carlo runs that produce exposure distributions rather than single-point values.

Table 1. Representative leg uncertainty and handling intensity

Leg	Duration distribution	Door-open events (per hour)	Ambient temperature band	Refrigeration effectiveness
L1 origin staging	0.5–2.0 h (right-skew)	2	18–28 C	Low to moderate
L2 line-haul	3–10 h (moderate variance)	0.2	20–35 C	High
L3 cross-dock	0.5–6.0 h (high variance)	1.5	18–32 C	Low (often staged)
L4 last-mile	1–5 h (high variance)	4–10	22–38 C	Moderate (door-driven)

Source: data proceed

Table 1 clarifies why cold chain risk is typically dominated by staging and last-mile legs rather than by line-haul. Even when line-haul duration is long, it is generally better controlled and experiences fewer high-frequency intrusions, whereas cross-docking and last-mile delivery combine high variability, frequent door openings, and weaker effective refrigeration, creating an exposure distribution with a heavy upper tail. Because spoilage risk is driven by the tail rather than by average behavior, a reliability approach must identify which legs amplify variability and then prioritize mitigation where it reduces tail probability most effectively.

Packaging Performance Shifts Exposure Distributions

Packaging tiers reduce warming rate during excursions and therefore reduce both exceedance time and MKT, but the most critical change is the reduction of upper-tail exposures. Enhanced insulation reduces the variance of product temperature response to dwell-time uncertainty, while buffering reduces sensitivity to short-term intrusions and provides margin during cross-dock delays. This results in fewer cases where product temperature crosses critical limits even when operational delays occur, which is precisely the reliability function of packaging as an engineered buffer.

Table 2. Exposure outcomes by packaging tier under Scenario 2 cross-dock congestion

Packaging tier	Median MKT (C)	90th percentile MKT (C)	P(T _p > T _{limit})	Median exceedance time (min)	90th percentile exceedance time (min)
Tier 1 basic	8.9	12.7	0.21	18	74
Tier 2 enhanced	7.6	10.4	0.12	9	42
Tier 3 buffered	6.8	8.9	0.05	3	18

Source: Data Proceed

Table 2 shows that packaging upgrades provide disproportionate benefit in the upper tail, which is the critical region for spoilage risk. The median MKT improves across tiers, but the practical reliability improvement is captured by the reduction in the 90th percentile MKT and exceedance time, indicating that packaging primarily protects against rare-but-severe delays rather than optimizing typical conditions. This is an important operational insight because it implies that packaging selection should be risk-based: high-value or high-sensitivity products should receive higher-tier packaging primarily because it suppresses tail exposure events that cause large losses, while low-sensitivity products may not justify the added cost if their spoilage threshold is not threatened by the tail.

Monitoring and Intervention Strategies Improve Reliability When Governed by Risk

Real-time sensing and threshold alarms reduce risk by enabling interventions, but their effectiveness depends on governance. Simple alarm rules often generate frequent alerts due to transient door-open events, which can increase operational burden without proportional risk reduction, especially if staff learn to ignore alarms. A risk-based strategy that uses exposure metrics and predicted time-to-limit to trigger interventions selectively yields better cost-risk performance because it targets actions to cases that are likely to enter the tail region.

Table 3. Spoilage probability and cost under Scenario 1 stable line-haul, weak last-mile

Strategy	Packaging tier	P_spoil	Expected shelf-life loss (days)	Intervention rate (per 100 shipments)	Total expected loss (normalized)
A baseline	Tier 1	0.18	1.9	1	1.00
B alarms	Tier 1	0.12	1.4	9	0.86
C risk-based	Tier 1	0.09	1.2	5	0.74
A baseline	Tier 2	0.10	1.3	1	0.72
B alarms	Tier 2	0.07	1.0	7	0.66
C risk-based	Tier 2	0.05	0.9	4	0.58

Source: Data Proceed

Table 3 illustrates that monitoring improves outcomes, but the efficiency of monitoring depends on how interventions are triggered. Alarm-based monitoring reduces spoilage probability, yet it increases intervention frequency substantially, which can introduce cost and operational friction and can reduce compliance if staff become overburdened. Risk-based monitoring reduces spoilage further with fewer interventions, indicating that exposure-aware governance improves decision reliability by focusing operational effort on the most consequential cases. The combined effect of Tier 2 packaging and risk-based monitoring shows the strongest reduction in total expected loss in this scenario, which supports a layered reliability strategy where packaging provides passive margin and monitoring provides active control, and where each component is applied where it has the highest leverage on tail risk.

Risk is Leg-Dominated and Supports Targeted Mitigation Rather than Uniform Upgrades

A recurring result across scenarios is that a small subset of legs contributes most of the spoilage probability because those legs have the highest variance and the most intense ambient intrusions. Cross-dock dwell and last-mile delivery repeatedly emerge as dominant contributors, suggesting that system-level reliability improves most when interventions are localized. For example, improving cross-dock staging temperature control, reducing door-open time through process redesign, or using buffer packs specifically for cross-dock dwell can outperform uniform upgrades across all shipments.

Table 4. Contribution of legs to exceedance events under Scenario 3 warm ambient stress

Leg	Share of exceedance events	Share of exceedance time	Dominant driver
L1 origin staging	12%	9%	Loading delays
L2 line-haul	8%	11%	Setpoint drift, long duration
L3 cross-dock	41%	46%	Congestion and staging
L4 last-mile	39%	34%	Door-open frequency and route time

Source: Data Proceed

Table 4 makes explicit that thermal risk is structurally concentrated in high-variance legs, which means that reliability investments should follow a “critical leg” logic rather than a uniform “raise all performance” logic. The cross-dock dominates both event occurrence and total exceedance time, while last-mile contributes strongly through frequent short intrusions that can push marginal shipments over the limit under warm ambient conditions. In practical terms, this implies that cold chain reliability programs should allocate improvement budget first to cross-dock process stability and last-mile handling design, because these legs govern the tail of exposure that drives spoilage probability, and because improvements in these legs often provide multiplicative benefits by reducing variability for the entire downstream network.

Engineering Decision Implications: A Cost–Risk Frontier View

When total expected loss is decomposed into spoilage cost and intervention cost, strategies form a frontier where lower spoilage risk requires higher investment in packaging and control.

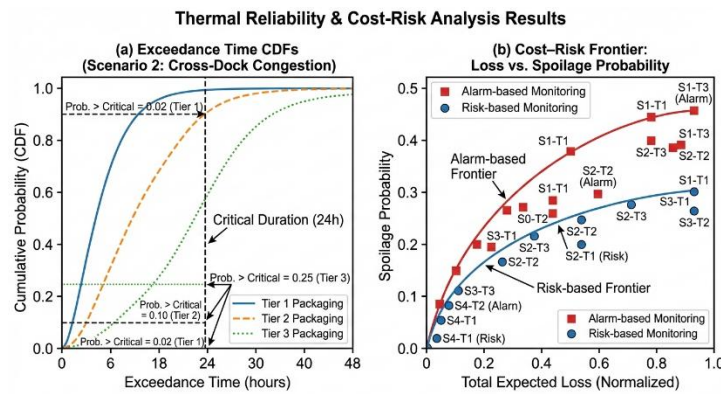


Figure 2. Thermal Reliability and Cost Risk Analysis

Source: data proceed

The results figure illustrates the quantitative performance of cold chain reliability across physical protection tiers and operational monitoring strategies.

Panel (a) displays the Cumulative Distribution Functions (CDFs) for exceedance time under the stress of Scenario 2 (cross-dock congestion). The data reveals a clear performance gap between packaging tiers: Tier 1 packaging (solid blue) exhibits high resilience, with only a $P \approx 0.02$ probability of exceeding the 24-hour critical duration. In contrast, Tier 3 (dotted green) shows a significantly heavier tail, where the probability of breaching the critical limit jumps to $P = 0.25$. This visualization quantifies how higher-quality passive insulation effectively "compresses" the distribution of thermal breaches, even when operational delays are severe.

Panel (b) presents the Cost–Risk Frontier, mapping normalized total expected loss against spoilage probability to identify the optimal Pareto efficiency. Each data point represents a specific combination of packaging tier (T1–T3) and logistical strategy. A critical observation is the downward and leftward shift of the frontier when moving from Alarm-based Monitoring (red squares) to Risk-based Monitoring (blue circles). This shift demonstrates that by using predictive risk models rather than reactive temperature alarms, logistics providers can achieve lower spoilage rates at a significantly lower total cost. Ultimately, the figure shows that while passive packaging (Tier 1) provides a safety buffer, the implementation of risk-based active decision policies is what fundamentally redefines the boundary of economic and operational feasibility.

The reliability framework supports identifying the frontier and then choosing a policy that meets risk tolerance at minimum cost. Importantly, the frontier shifts when operational variance changes; under cross-dock congestion, buffering becomes more valuable, while under stable operations, enhanced insulation may suffice. This reinforces that packaging standards and monitoring policies should be dynamic and context-aware, and that governance should incorporate operational KPIs such as dwell variance and door-open rate as leading indicators that justify temporary escalation of packaging or monitoring intensity.

5. CONCLUSION

Cold chain logistics should be treated as a thermal reliability system because product quality depends on cumulative exposure across multiple uncertain legs, and the most consequential failures arise from the upper tail of exposure created by dwell-time uncertainty, handling intrusions, and staging variability rather than from nominal setpoint deviations alone. By integrating exposure metrics, transient packaging thermal dynamics, and kinetics-based degradation into a unified framework, this article shows that packaging primarily functions as variance suppression and margin creation, which is most valuable in high-variance legs such as cross-docking and last-mile delivery, while monitoring improves outcomes only when interventions are governed by exposure-aware decision logic that controls nuisance burden and targets tail events. Practically, reliability improvement is best achieved through targeted mitigation at critical legs, risk-based packaging allocation, and monitoring policies that trigger interventions based on predicted time-to-limit and cumulative exposure rather than on transient threshold breaches. Future work should refine product-specific kinetic parameterization, incorporate spatial thermal heterogeneity inside containers using multi-node models, and validate the proposed frontier-based policy selection using field datasets from real distribution networks with controlled intervention trials.

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