Research on Cold Chain Packaging Risk Management Based on Fuzzy Bayesian Network and TOPSIS

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Abstract

Cold chain disruptions can lead to adverse consequences, damaging product quality and endangering safety. Packaging plays an important role in cold chain management, but the scope of cold chain packaging is still unclear, and its role in the safety and risk management of cold chain needs to be investigated. Therefore, this research aims to propose a conceptual framework for research on cold chain packaging, comprising key metrics assessing the performance of cold chain packaging and an integrated risk management model for cold chain packaging. Multiple approaches have been utilized for the integrated risk management model, including fuzzy Bayesian networks and fuzzy TOPSIS for the assessment of risk factors and risk mitigation strategies. An case study on the risk management of vaccine cold chain packaging is conducted to illustrate the application of the proposed risk management model. Risk factors identified include product quality risk, occupational safety risk, handling risk, container risk, etc., and the causal relationships are analysed, as well as the occurrence probabilities of the risk factors, using the fuzzy Bayesian Network technique. Supply chain risk mitigation strategies identified include multi-workforce skills, multi-sourcing, and quality management systems, and are ranked based on a fuzzy TOPSIS approach.

Knowledge in the area of cold chain packaging is still lacking, and this study fills the knowledge gaps by defining the term 'cold chain packaging' and its scope. The research framework takes into account packaging, cold chain management and supply chain risk management, analysing the topic of cold chain packaging from different perspectives. This is the first integrated risk management model proposed in the field of cold chain packaging. It can add to the knowledge of the cold chain packaging sector and can serve as a guideline for the definition of important terms in cold chain packaging and the scope of the topic. The risk factors identified, interelationships and probabilities of the risk factors, and risk mitigation

strategies provide some insights and guidelines for professionals in cold chain packaging. The overall effectiveness and efficiency of cold chain packaging systems can be improved through this proposed risk management model, improving product quality and occupational safety.

Keywords: Cold chain, Packaging, Risk management, Supply chain management, Fuzzy Bayesian Network, Temperature sensitive products

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Table of Contents

List of figures

LIST OF TABLES

Abbreviations

AHP	Analytical Hierarchy Process
AI	Artificial Intelligence
BN	Bayesian Network
CCM	Cold Chain Management
CCPRMS	Cold Chain Packaging Risk Management System
CPT	Conditional probability tables
CCRM	Cold Chain Risk Management
EPS	Expanded Polystyrene
FIS	Fuzzy Inference System
FMEA	Failure mode and effect analysis
FNIS	Fuzzy Negative Ideal Solution
FPIS	Fuzzy Positive Ideal Solution
HFC	Hydrofluorocarbon
HOR	House of risk
GPS	Global Positioning Aystem
GRP	Glass Reinforced Plastics
LTT	Low Temperature Transport
MCMD	Multi-Criteria Decision-Making
IMO	International Maritime Organisation
IoT	Internet of Things
IT	Information Technology
ISM	Interpretive Structural Modelling
PCM	Phase Change Materials
PIR	Polyisocyanurate
PUR	Polyurethane
R&D	Research and Development
RFID	Radio Frequency Identification
RTMD	Remote Temperature Monitoring Devices
SCM	Supply Chain Management

SCOR	Supply Chain Operation Reference
SCRM	Supply Chain Risk Management
SVM	Support Vector Machine
TEU	Twenty-Foot Equivalent Unit
TTI	Time Temperature Indicator
TRM	Thermal Regulating Materials
TOPSIS	Technique for Order Preference by Similarity to Ideal Solutions
VIP	Vacuum Insulation Panels
VVM	Vaccine Vial Monitoring
VR	Virtual Reality
WSN	Wireless Sensor Network

CHAPTER 1 - INTRODUCTION

1.1 INTRODUCTION TO THE CHAPTER

This chapter covers the general research background, which provides information and context required to understand the research topic. Then research aims and objectives are stated, followed by the description of the scope of research. The research methods used for the study are introduced, and an overview of the thesis structure is provided.

1.2 RESEARCH BACKGROUND

Refrigerated transportation and storage of temperature-sensitive products can be traced back to the 18th century, when ice and salt were used by fishermen to preserve fish at sea. With the emergence of the ice trade in the 19^{th} century from New England to the Caribbean, Latin America and Asia, refrigerated transportation became more and more achievable. Wood chips were used as a form of insulation (Notteboom, 2022). Then, with the invention of refrigeration systems in the 20^{th} century, refrigerated ships and cargos became more and more commonly seen. France began to receive frozen meat from South America; the UK began to receive frozen meat from Australia and New Zealand; and North America began to receive tropical fruits from Central America. Then the globalization in the late 20^{th} century further reinforced the development of refrigerated cold chain containers, or 'reefers': in 2018, about $2.9 billion twenty-foot equivalent units (TEUs) of reefers were used, taking up about 5% of the global ISO container capacity (Notteboom, 2022). Nowadays, cold chains are more and more commonly seen, thanks to globalization.

A cold chain can be defined as a series of activities to transport and store certain products from harvest or production to consumption or end use, and stakeholders of cold chain management include employees, suppliers, government, financial institutions, third party logistic providers, distributors, retailers, customers, hospitals and clinics (Cerchione et al., 2018). Cold chains differ from other supply chains due to their rigid perishability characteristics, for which low temperature preservation is constantly needed. Temperature-sensitive products often need cold chains to ensure their quality and safety from deterioration due to temperature disruption. Failure to keep them in the required temperature ranges can lead to quality deterioration, safety issues and harm to the environment.

Driven by the boom of e-commerce, the advancement of people's living standards and increasing healthcare needs, the demand for cold chain products and the number of cold chain logistic providers have increased greatly in the past few years (Singh et al., 2017; Ren et al., 2022a). Common temperature-sensitive products are listed in Table 1.1, and include fresh agricultural products, refrigerated and frozen food, medical and pharmaceutical products, chemicals and laboratory products. Different products have different cold chain transportation and storage requirements.

Common pharmaceutical cold chain products include vaccines, biologics and blood, which normally require a storage temperature of 2-8℃ or below -20 ℃ to maintain the product potency, efficacy and safety. For example, Pfizer and Sinopharm COVID- 19 vaccines both require to be kept below -20℃ during storage. Fresh produce includes fruits and vegetables, which are highly seasonal and perishable. Common fresh produce cold chain products include post-harvest fruits and vegetables or seafood, and they need to be kept within a temperature range of -5°C to 5°C. They normally need to be transported and consumed within a short period of time so the taste does not deteriorate.

Table 1.1: Cold chain product classification and preservation temperature ranges

Product types	*Examples*	*Aim of the cold chain*	*Preservation temperature ranges*
Pharmaceuticals	*Vaccines, biologics, blood*	*Maintain potency, efficacy and safety*	*2 to 8 ℃, below -20 ℃*
Fresh produce & seafood	*Fruits & vegetables & seafood*	*Prevent spoilage and maintain freshness*	*-5 ℃ to 5 ℃*
Refrigerated/Frozen food products	*Refrigerated/Frozen meat & vegetables & diary & seafood*	*Prevent bacterial growth and maintain quality*	*-5 ℃ to 5 ℃, Below -18 ℃*
Chemicals	*Liquid nitrogen/oxygen/ carbon dioxide, liquefied natural gas*	*Prevent explosion and maintain quality*	*Below -160 ℃*

Sources: (Kuiper et al., 2020; Han et al., 2021)

Refrigerated or frozen cold chain products include refrigerated/frozen meat, vegetables, dairy and seafood. They need to be kept within a temperature range of -5 ℃ to 5 ℃ or below -18 ℃, depending on the specific products, to prevent bacterial growth and maintain the quality (Han et al., 2021). Some chemicals, like liquid nitrogen, oxygen, carbon dioxide and liquefied natural gas, need to be stored at ultra-low temperatures below -160℃ during transportation and storage. The gas needs to be liquefied and then kept in tanks for transportation. The tanks are double walled, with insulation materials and vacuum filled between the walls. Insulation materials commonly used include Polyisocyanurate (PIR), Polyurethane (PUR) in rigid foam or cellular glass forms, cladding with stainless steel, aluminized steel and UV cured glass reinforced plastics (GRP) (Kuiper et al., 2020).

There has been increased quality demand for cold chain products, which increases the complexity and associated risks of cold chains (Li et al., 2020). Global immunization programmes have expanded in the past few years, increasing the need to expand or upgrade related infrastructure and the vaccine supply chain management systems. The administration and distribution costs of vaccines are usually greater than the cost of production. Many vaccines require cold chains, but some still struggle to maintain and monitor the required cold chain (Bajrovic et al., 2020).

The impact of the sudden occurrence of a pandemic, such as the COVID-19 pandemic, can pose an additional threat to the already fragile cold chain (Li et al., 2020). Also, about 1/3 of food gets wasted annually due to lack of proper handling after harvesting. Temperature control and monitoring is very important for cold chain products during transportation and storage, and cold chain disruption can lead to product quality decay and safety concerns.

1.3 RESEARCH AIM AND OBJECTIVES

The ability of national and international agencies to cope effectively with cold chain packaging risk is becoming more and more important for many industrial sectors such as food, medical, marine industries, in which Low Temperature Transport (LTT) is critical (Mahalik and Nambiar, 2010). An advanced Cold Chain Packaging Risk Management System (CCPRMS) has a crucial role in promoting the effective application of LTT and cold chain management evolving from conventional supply chains. The development of CCPRMS requires interdisciplinary research input in engineering, sensors and data science, among which the use of new packaging design and material plays a pivoting role (Perez-Masia et al., 2014).

A systematic review has shown that research in cold chain risk management and CCPRMS incorporating most recent new engineering technologies is particularly underdeveloped (Kuorwel et al., 2015). This thesis will develop a decision support framework to help the development of a novel CCPRMS, to capture and minimize the vulnerability of cold chain, and to increase the system resilience when impacted by adverse circumstances. The study will develop a new framework to improve packaging systems in order to reduce the risks of cold chain packaging. Important questions to be established:

- What are the major factors impacting the performance of cold chain packaging?
- What risk factors can lead to adverse consequences of cold chain packaging performance?
- What risk mitigation strategies can be used to assist industry and government to alleviate the risk factors above and help produce more sustainable andsafer cold chain packaging?

To answer the questions listed above, the research aims and objectives for this research are proposed here. The research aims to propose an integrated method to evaluate and reduce risks from cold chain packaging management and to increase knowledge on the best way to improve the sustainability of cold chain packaging. The main objectives are:

- To analyze the whole lifecycle of the cold chain packaging, review existing cold chain packaging solutions or systems, and develop a conceptual framework to measure the cold chain packaging system performance.
- To review the existing cold chain risk management and packaging management systems in order to establish an integrated risk management system for the cold chain packaging system, which the key risk factors and risk mitigation strategies are identified and assessed, contributing to safe and sustainable cold chain packaging development.

- To conduct a case study to demonstrate the effectiveness of the above framework and models incorporating both supply chain risk and global engineering/material data.

The first objective is to develop a conceptual framework of the key performance metrics of the cold chain packaging system. To understand a system, it is important to identify the key influencing factors of the system. First of all, an overview of the cold chain packaging sector will be conducted which the components of the cold chain packaging system and the existing industry solutions are summarized. Then key performance metrics of the cold chain packaging system are proposed. Another objective is to review the existing cold chain risk management and packaging management systems and then construct an integrated cold chain packaging risk management model incorporating key risk factors and risk mitigation strategies identification and assessment.

Safety and risk management is a good tool for measuring and analyzing uncertainties. Therefore, risk management of the cold chain packaging system will be conducted for assessing the risk factors and identifying relative risk mitigation strategies. This can contribute to the development of safer and more sustainable cold chain packaging. Risk management of product related and occupational safety related risks can alleviate the environmental burden of traditional cold chain refrigeration and improve the personnel safety. Finally, a case study will be conducted utilizing the proposed risk management model to demonstrate the effectiveness of the model.

1.4 RESEARCH SCOPE

Supply chain management is a very broad topic, including risk management, life cycle assessment, etc., and involves many stakeholders, e.g. suppliers, distributors, government, customers, etc. Therefore, it is essential to set up boundaries for research. Packaging involves almost all the stages of the supply chain but sometimes is overlooked during manufacturing and supply chain management. For cold chain management, the role of packaging is especially important since proper cold chain packaging use can reduce the risk of temperature disruption which may lead to huge damage to cold chain products.

Many studies on cold chain risk management have identified packaging as a risk factor, but not many have covered the topic of risk management of cold chain packaging. Most of the studies in the field of cold chain packaging tend to focus on the material aspects, e.g. novel materials or how to improve material properties, etc. Therefore, this study focuses on the risk management of cold chain packaging, or low-temperature packaging.

Fresh agricultural produce continuously loses its water after harvest without proper temperature control. Drying can lead to hardening, probable cell damage, gelatinization and surface hardening of agricultural produce. Therefore, maintaining the temperature and keeping the humidity at a level that is good for the preservation of crop quality is essential (Atuhaire et al., 2020). Temperature disruption of refrigerated or frozen food during storage and transportation can lead to food loss, food spoilage, bacterial growth, food-borne illness and even food poisoning, so it is important to closely maintain and monitor the temperature, thereby keeping the quality of the cold chain food.

Vaccines are also very sensitive to temperatures, and insufficient temperature control can lead to the loss of vaccine efficacy and potentially cause health hazards. Some vaccines are very freeze-sensitive, and temperature disruption can lead to over-thawing of vaccines, harming their potency and effectiveness (Chatterjee and Sasidharan, 2019). Temperature control and safety management are critical for vaccine cold chains. Chemical and biological products, such as temperature-sensitive reagents (e.g. enzymes, antibodies, growth media), DNA, RNA, proteins, etc., need to be stored at a certain temperature range to keep from degradation. Also, cold chain workers face potential safety hazards due to the extraordinarily cold working environment (Singh et al., 2017).

Cold chains are essential to store and transport temperature sensitive products. There are many ways to preserve the temperature during storage and transportation, e.g. fridges, freezers, cold rooms, ice, cold storage boxes, etc. Packaging plays an important role in the whole cold chain design since it is involved almost throughout the whole cold chain, and it has been identified as one of the main risks of cold chain disruption (Cerchione et al., 2018). However, packaging is often overlooked in cold chain systems and safety management. The complex nature of cold chain packaging makes it hard to monitor, and cold chains still face many risks during transportation, storage and handling. Therefore, it is important to delve deeper into the topic of cold chain packaging.

The cold chain packaging market is expected to reach $40 billion by 2026, with an annual growth rate of 12.92% (Wood, 2022). It is vital to study the role of packaging in cold chains and its impact on their overall safety and efficiency. Packaging performs many functions, including containment, protection, transportation, and storage, etc, and its main goal varies, depending on the perspective. For example, from an economic point of view, the goal of packaging is to maximize profits while minimizing the costs of delivery (Sohrabpour et al., 2016). From the perspective of efficiency and personnel safety, packaging should maximize ergonomic design and ensure safety.

Comprehensive cold chain shipping solutions are often offered by cold chain providers. A cold chain shipping solution often includes providing suitable pallets, containers, monitoring devices and accessories, as well as training and recycling programs if needed (Ren et al., 2022b). It is highly demand-driven, and customized shipping containers are often provided to meet specific end needs. For instance, due to the COVID-19 pandemic and expansion of global immunization programs, the demand for vaccine cold chain shipping containers has increased dramatically in the past few years (Cold Chain Technologies, 2022; Csafe, 2024). However, vaccine cold chains are not risk-free. The rate of COVID-19 vaccine failure due to poor storage, scheduling and preparation is reported to be about 50% (Hall et al., 2023). Many factors can affect the overall performance of the cold chain, e.g. product types, transport route, transportation modes, packaging used, etc. (Badia-Melis et al., 2018).

1.5 RESEARCH METHOD

This research will follow a deductive research approach utilizing both qualitative and quantitative research methods. The goal of the research is to develop a comprehensive framework and integrated risk management model for cold chain packaging using multi-criteria decision-making methods based on primary and secondary data. A conceptual framework of the cold chain packaging performance will be developed as well as a risk management system based on fuzzy Bayesian network and TOPSIS methods. Main risk factors will be identified and assessed in the field of cold chain packaging, and then risk mitigation strategies are identified and analyzed.

A case study is conducted to verify the proposed risk management model. Since cold chain packaging is a complex system, a real-life example will be a good demonstration for the system, which benefits other researchers or practitioners in the field. Particularly, the case study explores the utilization of the proposed risk management model in vaccine cold chain packaging settings. Due to the expansion of the global immunization programs and outbreaks of the Covid 19 pandemic, vaccine cold chains are facing a great number of challenges today, and the cold chain packaging plays an important role in the transportation and storage of the vaccines.

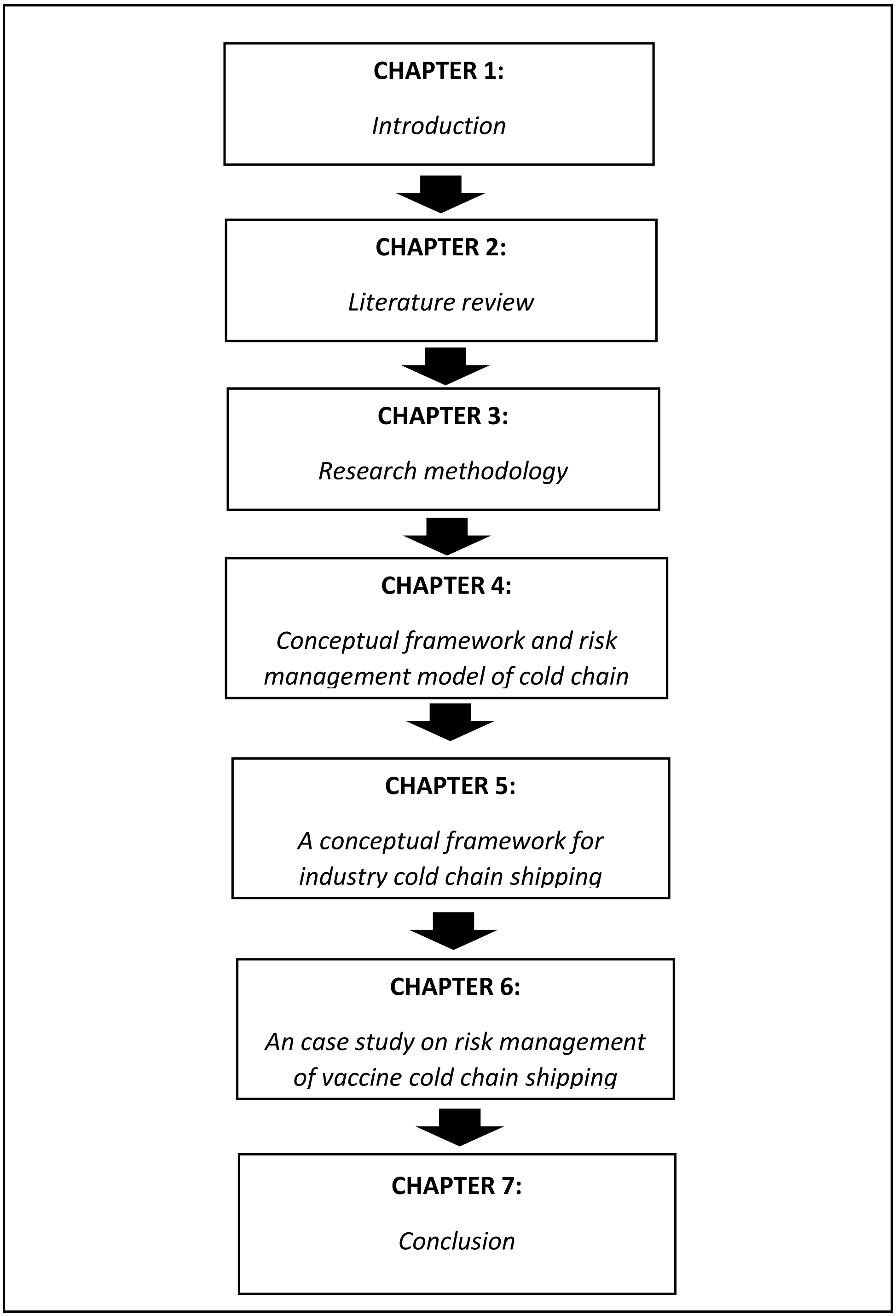
Case studies of the cold chain packaging related risks are rare in academia. Therefore review of the studies of cold chain risk management and cold chain packaging systems will be done to identify the relative risks in cold chain packaging. Other documents like industry and company reports, official documents, patent documents, direct observations, and other published materials will be included in the identification of the risk factors. Questionnaires will be sent out to experts as well to include any factors that cannot be found in published materials. The questionnaires will be pilot tested and the contents will be modified according to the results. The questionnaires will be sent out via emails and web links (google sheet).

The risk factors and risk mitigation strategies will be first identified through literature review. Then a risk factor questionnaire will be sent out to expert participants from both academia and industry. The purpose of the questionnaire is to validate the results of the literature review and add any factors that have been missed from the literature. Then the casual relationships and probabilities of the risk factors are assessed using the Fuzzy Bayesian network approach. For the risk mitigation strategy assessment, Fuzzy TOPSIS method is used which the strategies are ranked. Fuzzy number sets are used which linguistic terms are turned into numbers for the Bayesian network and TOPSIS inferencing since some people may not be very comfortable with giving out numbers.

This research can add new knowledge to the field of cold chain packaging since there was limited studies done in this area. The scope and key terms of cold chain packaging are defined in this research which can attract more research attention to the field. The conceptual framework developed has indicated the key performance metrics for the performance of the cold chain packaging systems, and this can be used as practical guidelines for industry practitioners and managers for assessing the cold chain packaging performance. The risk management model developed can identify, assess and mitigate relative risks in cold chain packaging which can improve the overall performance, efficiency and safety of cold chain packaging. And it can be applied in more case studies.

1.6 STRUCTURE OF THE THESIS

This thesis consists of seven chapters shown in Figure 1.1, and the details of each chapter is stated



below.

Figure 1.1: The structure of the thesis

Chapter 1 - Introduction

This chapter covers the overview of the research background, aims, objectives, the scope of the research, methodologies used, and the structure of the thesis. It briefly outlines how the research will be conducted.

Chapter 2 - Literature review

This chapter reviews the existing literature on the topic of cold chain management and the role that risk management and packaging play in it. This chapter discusses the currently existing studies in cold chain risk management and technologies and innovations in cold chain packaging. The current trends, characteristics, challenges and opportunities of cold chain packaging and their associations with supply chain risk management are discussed. Then the current research trend and research gaps are identified in this chapter.

Chapter 3 - Research methodology

This chapter discusses the overall research design, covering research methodology, philosophy, approach, strategies and choices. The reasons why certain research methodologies are used in this research are also explained, which lays out the foundation on which this research will be conducted.

Chapter 4 - Conceptual framework and risk management model of cold chain packaging

This chapter presents the conceptual framework of this research, which incorporates cold chain management, cold chain packaging and the supply chain risk management process to provide decision support in the field of cold chain packaging. Based on the proposed framework, the integrated risk management model will cover three main steps: risk identification, risk assessment and risk mitigation. The decision-making process of each step and the method used will also be detailed in this chapter.

Chapter 5 - A conceptual framework for industry cold chain shipping solutions

This chapter reviews the existing industry cold chain shipping solutions. The components and structure of cold chain shipping solutions are assessed, analysed and summarized. A Pallet-Parcel-Coolant- PCM cold chain shipping solution structure is proposed and is discussed in detail.

Chapter 6 – A case study of risk management of vaccine cold chain shipping solutions

This chapter conducts an case study of vaccine cold chain solutions, utilizing the proposed integrated risk management model. Risk factors and risk mitigation strategies are both first identified through literature review and validated by experts. Then the risk factors are assessed using Fuzzy Bayesian Network methods, and the risk mitigation strategies are analysed using the Fuzzy TOPSIS method.

Chapter 7– Conclusion

This chapter summarizes the findings of the research, including the framework of the existing shipping solutions, risk factor identification, risk assessment and risk mitigation from previous chapters. The theoretical and practical contributions of the research are stated, as well as the limitations of the research. Finally, further work and research directions are recommended.

CHAPTER 2 LITERATURE REVIEW

2.1 INTRODUCTION TO THE CHAPTER

This chapter provides detailed results of literature reviews that are critical to this research, which includes two main areas: cold chain management and cold chain risk management. In this way, current research trends of the topics can be seen, and relevant research gaps can be then identified.

Within this chapter, an exhaustive exploration of literature reviews is presented, intricately linked to the foundations of the current research. The dual emphasis lies on the pivotal realms of cold chain management and cold chain risk management. This meticulous examination not only unveils the prevailing research trends in these areas but also enables a discerning identification of pertinent research gaps. By delving into these gaps, the study gains a nuanced understanding of the lacunae in the existing body of knowledge.

To bolster the comprehensive nature of this exploration, the chapter strategically highlights the intersectionality of various scholarly perspectives on cold chain intricacies. It synthesizes diverse viewpoints, providing a well-rounded view that enhances the depth and breadth of the research context. Furthermore, the inclusion of contrasting viewpoints contributes to a more robust understanding of the complexities inherent in cold chain logistics.

As the chapter unfolds, it systematically elucidates the research problems articulated by this study. These problems are carefully crafted to address the identified gaps in the existing literature, setting the stage for a focused and purposeful investigation. This deliberate framing not only establishes the significance of the study but also positions it as a valuable contribution to the broader discourse on cold chain dynamics and risk management.

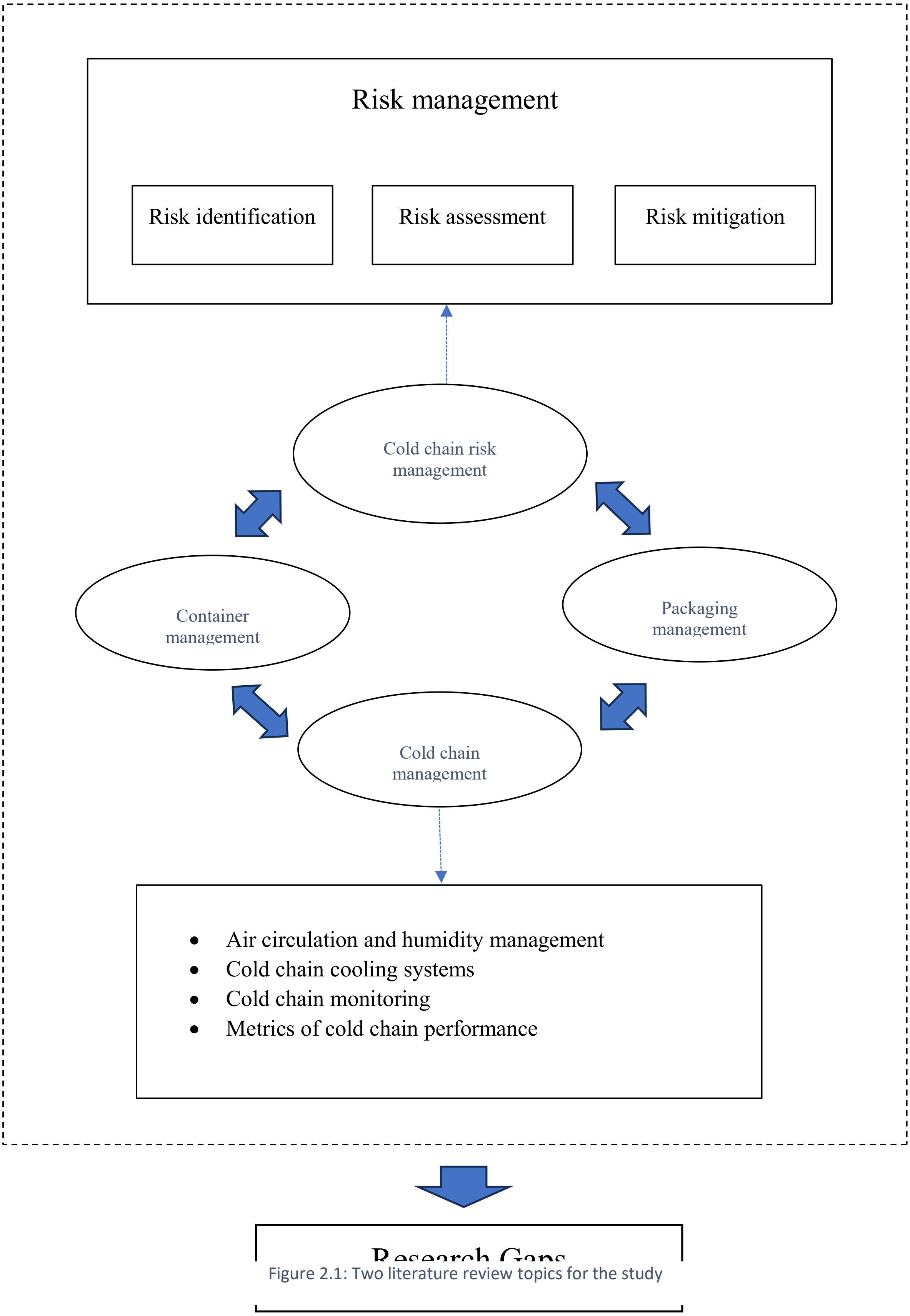


Figure 2.1: Two literature review topics for the study

Figure 2.1: Flowchart for literature review

To help better understand the concepts of the study, some background information is given at the beginning of the chapter in which the concepts of supply chain management, logistics and container management are discussed. Then literature reviews on cold chain management, packaging management and risk management are discussed. An overview of cold chain management and important related topics, such as air circulation and humidity management, cold chain cooling and monitoring systems, are discussed in detail. Next, the main functions and features of packaging are explained, including the concept of smart packaging.

After this, the findings of the literature review on cold chain risk management are stated and discussed, and the status of supply chain risk management in the cold chain context, or cold chain risk management (CCRM) is also explained. Finally, this chapter ends by summarising the key findings of the review, identifying trends in the literature, with the limitations of the existing studies and remaining research gaps. The contributions and implications of this study are discussed.

Databases like Web of Science, Google Scholar and commercial databases like WHO immunization databases and company databases are used. For cold chain management, keywords like “cold chain”, “food supply chain”, “pharmaceutical supply chain”, “vaccine supply chain”, “cold storage”, “cold shipping”, “refrigerated container”, “packaging cooling”, “packaging thermal analysis” are used. For cold chain risk management, keywords like “cold chain risk management”, “food supply chain risk” are used. Some of the results for cold chain management and packaging overlap. Content analysis is performed, and all literature related to cooling behaviours of the packaging design is listed under the cold chain section to avoid any confusion.

To help better understand the results of the literature review and scope of the study, some background information is included first in Section 2.2. The concepts of supply chain management, supply chain risk management, container management and packaging management are discussed in detail.

2.2 BACKGROUND INFORMATION

2.2.1 SUPPLY CHAIN MANAGEMENT (SCM) AND LOGISTICS

The concepts of supply chain management and logistics have gained more and more attention since they were first proposed in the 1980s. Supply chains are becoming more and more complex due to many factors, such as globalization, technology advancement, and their evolution has been hastened under the impact of Industry 4.0 and 5.0. Therefore, it is important to understand the context of Industry 4.0 and 5.0. Industry 4.0 started in 2011 and has been considered to be one of the main topics of many countries' development agenda. It refers to data-driven supply chains designed and managed by industry 4.0 technologies such as big data, smart sensors, blockchains, internet of things (IoT), machine learning and artificial intelligence to maximize performance and proficiency (Zekhnini et al., 2020). In the past few years, companies have shifted their attention to agility, sustainability, ethics, social responsibility, increasing personalization, etc., which is demonstrated by industry 5.0.

Industry 5.0 will further increase human-machine interaction and collaboration through technological advancement, and personalization will also be enhanced. Its goal is to create a balanced human-technological environment to develop a sustainable and smart society. This new generation of supply chain aims to minimize waste and improve sustainability and capability. However, some of the issues in supply chain 4.0 will remain or even become more complicated in supply chain 5.0, from ethical, psychological and legal perspectives (Frederico, 2021). The main difference between industry 4.0 and 5.0 is that industry 4.0 is more technology-focused, while industry 5.0 aims to also include sustainability and social aspects. The study of cold chain packaging needs to consider the impact of both industry 4.0

and 5.0 on it. Therefore, influence of technology advancements on the cold chain packaging development need to be investigated as well as what impact it can cause to the sustainable and safe development of the environment and personnel.

Terms like “Logistics” and “Supply chain management” are sometimes used interchangeably; however, they have distinctive concentrations. Logistics refers to the management of material, information, resource, and service flow from the point of production to consumption, aiming to maximize the effectiveness and efficiency of transportation, storage and distribution of goods. While logistics focuses on the physical movement of goods, supply chain management focuses on a wider perspective covering strategic integration of all activities (Gunasekaran and Kobu, 2007). The focus of supply chains has shifted from the manufacturing management level to the enterprise management level due to driving forces like globalization, outsourcing, information technology (IT), and increasing integration (Balfaqih et al., 2016, pp.1998–2015), involving many stakeholders, such as companies, third party logistics providers, policy makers, customers, etc.

There are many different types of supply chains, such as sustainable, resilient, agile, lean and cold supply chains, and they are usually not independent of each other. Resilient supply chains are designed to be robust and adaptable for any changes or uncertainties. Building a resilient supply chain is normally based on redundancy, which can increase robustness and flexibility. Proactive risk mitigation strategies can be implemented to increase supply chain robustness, while to increase flexibility, reactive actions can be taken (Xu et al., 2020). Agile supply chains aim to have the flexibility to accommodate changes and uncertainties and provide quick responses. Information is key for resilient and agile supply chains, since decisions can be based on data, and relevant actions can be taken in response (Shen et al., 2019; Razak et al., 2023).

Lean supply chains focus on cost and time minimization, operation optimization and continuous improvement of the supply chain. Leanness is the process of developing a value stream that reduces waste and ensures level scheduling (Ciccullo et al., 2018). Common lean supply chain methodologies include life cycle assessment, which analyses the entire process from when products are produced to when they are consumed. Terms like "Cradle to cradle" or "Cradle to grave" are sometimes use,. or sometimes it refers to the process from an order being placed to the product reaching the distribution sector. Sustainable supply chains aim to minimize environmental risk (Rizet et al., 2012; Schaltegger and Burritt, 2014).

In addition to sustainable, agile, lean and resilient supply chains, cold chains have received an increasing amount of attention in the past few years. The term 'cold chain' refers to the integrated process of all the procedures implemented for the purpose of preservation and temperature maintenance for perishable products after production until consumption (Sadeghi Asl et al., 2021). The main drivers of rapid development in this type of supply chain include the impact of the COVID-19 pandemic, the expansion of global immunization programs, rising demand for perishable products, etc. About 40% of all food requires some degree of refrigeration. The term 'traceability' refers to the possibility of tracing and tracking a product along all its stages from production until end use. An internet of things(IoT) refers to an integrated network that incorporates several objects capable of recognising and connecting with each other, facilitating information exchange (Badia-Melis et al., 2018).

A cold chain aims to protect perishable products and maintain their temperature within a certain range. The cold chain process includes the sorting, distribution and storage of cold, chilled, frozen and fresh products (Singh et al., 2017). With the boom in globalization, cold chains have been expanding rapidly in the past few years. Cold chains have huge market potential and provide many investment and employment opportunities globally. Taking the

UK as an example, over 100,000 people are directly employed by the cold chain industry, along with many other indirect employment openings (Cold Chain Federation, 2023). The past three years have posed a great many uncertainties for existing cold chains. The main challenge is how to maintain product quality during transportation and storage while minimizing cost, time and adverse impacts on the environment.

In today's world, supply chains are becoming more and more complex due to expansion of globalization and increasing amounts of outsourcing, which makes them more subject to supply chain disruption. Supply chain disruption will have a huge impact on the performance of companies, and a recent example is the disruption of supply chains during the COVID-19 pandemic. Geopolitical tensions have been another issue in the past few years that have had an impact on global supply chains. Cyber security issues have concerned many countries and companies, since many supply chains have utilized network technologies.

2.2.2 SUPPLY CHAIN RISK MANAGEMENT

Firms always strive to manage uncertainties and disruption, while continuously improving performance under a constantly changing business environment, and they depend closely on the complex supply chain network. Today, organisations are facing more and more disruption due to the increasing complexity and uncertainty of supply chains (Kungwalsong, 2013). As Snyder and Shen (2006) state, no supply chain or logistical infrastructure is risk free, due to their complex and uncertain nature. Supply chain disruption has a long-term negative impact on firms, and it has been found that such disruption can lead to about 40% drop in long-run stock price performance.

Fan and Stevenson (2018) define supply chain risk management as a process involving the identification, assessment, treatment and monitoring of supply chain risk through internal and external collaboration and implementation of tools and strategies. Ho et al. (2015) define supply chain risks as events that may adversely impact the supply chain performance on the operational, tactical or strategic levels and define supply chain risk management as a management system to identify, assess, evaluate, monitor and mitigate unexpected risk events that can lead to supply chain failure.

Risk management includes three main parts: risk identification, risk assessment and risk mitigation. Risks can be first identified from existing literature, documents, direct observations and expert opinions. Risk factors identified can then be assessed using selected decision-making tools, enabling risk mitigation strategies to be identified and assessed. Risk management studies can be theoretical or empirical and can cover any of the three parts of risk management. Risk monitoring is sometimes carried out, in which risk events and disruptions are monitored and assessed in real time (Tsang et al., 2018).

There are many types of supply chain risks, both man-made hazards and natural, at operational, strategic or tactical levels. Each study tends to focus on a specific supply chain or specific type of risks. For instance, Chukwuka (2023) developed a risk management model for emergency supply chains, while Wang (2018) developed a risk management model in the context of the healthcare supply chain.

There are also different ways to categorize supply chain risks. Christopher and Peck (2004) classify risk factors into 'External to supply chain network or environmental', 'External to firm' and 'Internal to firm'. 'External to firm' risks are environmental risks; 'External to supply chain network or environmental' risks are inter-organisational risks, which involve disruption of information, product, material or finance flows (Munir et al., 2020). Inter-organisational risks are affected by the collaboration and integration of the entire supply chain network, which can be categorized into supply- and demand-side related risks. Supply risks concern the availability of upstream raw materials within certain time periods and costs, while demand risks concern the current market conditions and the availability of products or services to meet end-customer demand (Manuj et al., 2014). ‘Internal to firm’ risks are intra-organisational risks.

Xu et al. (2020) categorize disruptions into ‘natural disasters’ and ‘man-made threats’. Natural disasters include earthquakes, fires, tornados, floods and other extreme weather conditions, while man-made threats include fires, strikes, sanctions, wars and other social or political instabilities. However, risks are not always isolated from each other; disruption or risk events can cause ripple effects which lead to the propagation of disruption throughout supply chains, which can change the structure dynamics of the supply chain network (Xu et al., 2020). Ho et al. (2015) summarize the risk types in Supply Chain Risk Management (SCRM) studies, including ‘supply’, ‘demand’, ‘manufacturing’, ‘financial’, ‘macro’, ‘information’ and ‘transportation’ risks.

Risk mitigation strategies can be proposed to alleviate the consequences of supply chain disruption. Various strategies have been discussed to mitigate and manage supply chain risks. Supply chain risk management is an information-intensive process, which requires collaboration and coordination among different supply chain partners, so information sharing can improve integration. Munir et al. (2020) suggest that internal, supplier and consumer integration have a positive impact on supply chain risk management, and supplier and customer integration can mediate internal integration.

To minimize supplier-related risks, Grötsch et al. (2013) identified strategies such as a mechanistic management system, a rational cognitive style, and relational buyer-supplier relationships. Chang et al. (2019) identified risk mitigation strategies such as “form alliances with other shipping companies”, “use more advanced infrastructure”, “choose partners very carefully” in container shipping operations. Dohale et al. (2022) identified visibility and transparency, relationship/partnerships/multi-sourcing and flexible contracts, redundancy, collaboration, postponement, flexibility, joint planning and coordination as risk mitigation strategies for handloom saree apparel industries during COVID- 19.

2.2.3 PACKAGING MANAGEMENT

2.2.3.1 Definitions of packaging

Packaging is a critical element in modern trade of goods and plays a key part in protecting goods from the external environment. Packaging is a barrier between a product and its external environment (Yildirim et al., 2018); its functions and features have evolved over time. The earliest forms of packaging were leaves, straw, skins, and hollowed-out tree limbs. Conventional functions of packaging include containment, protection and preservation (Lydekaityte and Tambo, 2020). The primary purpose is to contain and protect goods, to hold, carry, and envelop products to protect them from deteriorative effects during use and exposure to the external environment, while maintaining product quality and extending shelf life (Wyrwa and Barska, 2017). The main functions and figures of conventional packaging

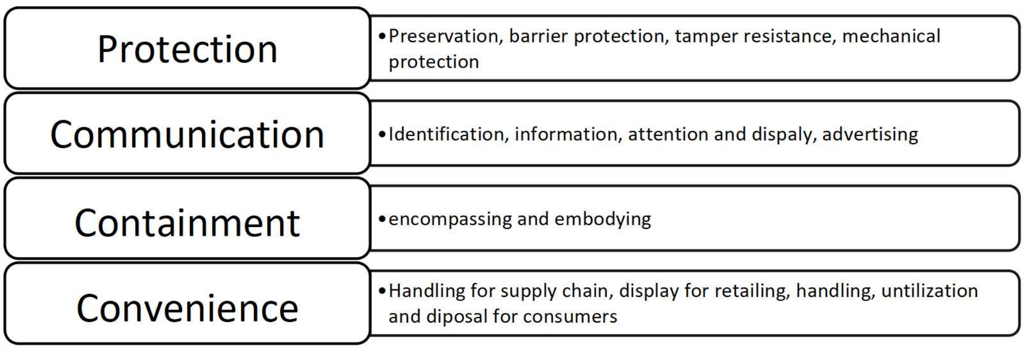


Figure 2.2: Main functions and figures of conventional packaging, derived from (Schaefer and Cheung, 2018; Lydekaityte and Tambo, 2020)

are listed below in Figure 2.2.

2.2.3.2 Levels of packaging

There are different levels of packaging: primary, secondary, tertiary, and quaternary packaging. Details of each packaging level are shown in Figure 2.3. Primary packaging offers protection from the environment and often contacts the products directly, which also refers to the retail/consumer units. For food products, moisture barrier and microbial growth inhibition properties are often considered (Biji et al., 2015). For vaccines and other pharmaceutical products, the design of the vials and other packaging-related accessories should consider preventing issues like freezing and fraud (Hanson et al., 2017). Secondary packaging offers additional protection from environmental and physical damage, and often refers to shipping units, such as shipping parcel systems. Tertiary and quaternary packaging are the packages used during distribution, such as pallet shipping systems or shipping containers, which refers to logistical units.

With technological advancement, the functions of packaging have been continuously expanding and has become more and more sophisticated. Apart from protection, preservation and containment, other functions like communication and convenience are also covered by packaging (Schaefer and Cheung, 2018). The concept of smart packaging will be explained in

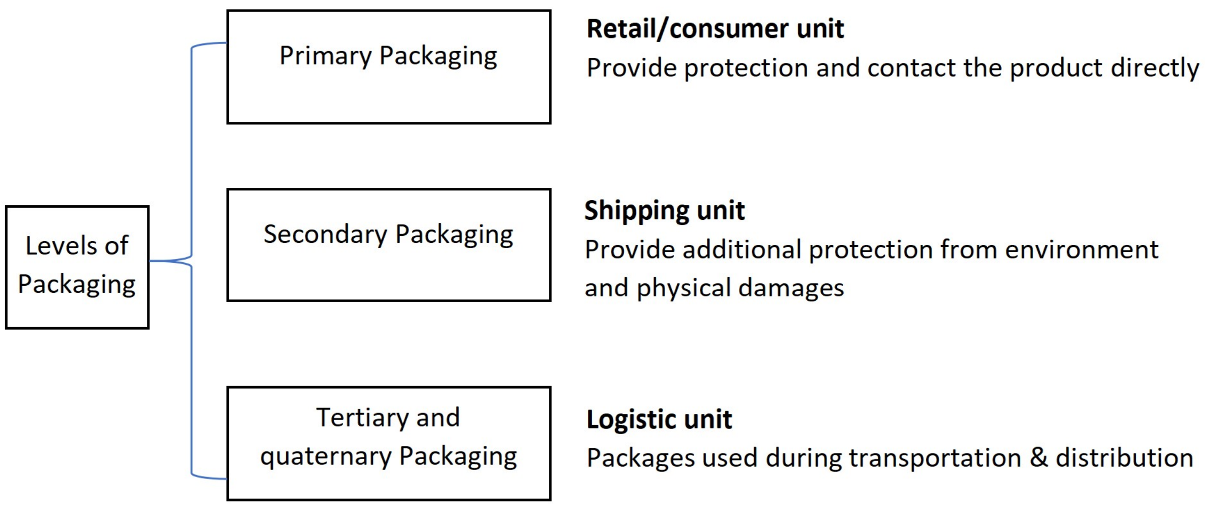


Figure 2.3: Details of levels of packaging

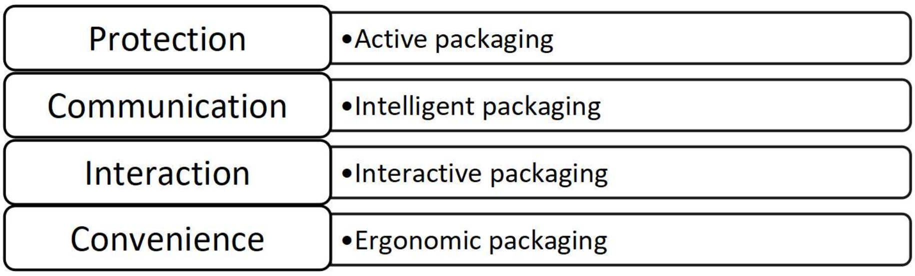
detail in the section below.

2.2.3.3 Smart packaging

Technology is a key driver for the growth of smart packaging. Some opportunities created by smart packaging include the application of nanotechnologies, Internet of Things (IoT), real-time monitoring, management and control, etc. Meanwhile, business models have evolved from product focused systems to product-service systems (Schaefer and Cheung, 2018). As technologies have continued to advance, packaging has developed with many other functionalities, such as convenience, communication and interaction (Lydekaityte and Tambo, 2020), and the term ‘smart packaging’ is often used for packaging that incorporates different ranges of features. Biji et al. (2015) defined ‘active and intelligent packaging’ as a smart food packaging system. Ziv (2018) defined ‘interactive packaging’ as smart packaging.

Smart packaging can be defined as packaging that incorporates technologies to achieve superior performance in protection, communication, interaction and convenience. Communication and interaction features aim to identify and notify market-related information. The convenience function aims to make the packaging easier for handling, transportation, and storage. The main functions and features of smart packaging are listed in Figure 2.4.

Figure 2.4: Main functions and features of smart packaging, (Lydekaityte and Tambo, 2020)



As in traditional packaging, protection, communication and convenience functions are included but with improved performance with the aid of technology. There are different types of smart packaging with different purposes, and common smart packaging capabilities include active, intelligent, interactive and ergonomic features. Research attention has concentrated on intelligent and active packaging in the past few years. The definitions and details of categories of smart packaging are listed in Table 2.1.

Table 2.1: Definitions and details of categories of smart packaging including active, intelligent, interactive and ergonomic packaging.

	Details	*Sources*
Active Packaging	*Release of substances to regulate the interior environment of the packaging*	*(Arvanitoyannis, 2012; Cerqueira et al., 2014; Adobati et al., 2015; Kuorwel et al., 2015; Wyrwa and Barska, 2017; Said and Sarbon, 2019; Bajić et al., 2020; Vilas et al., 2020)*
Intelligent packaging	*Real-time monitoring of the internal and external environment of the packaging*	*(Pavelková, 2012; Fuertes et al., 2016; Kim et al., 2016; Kalpana et al., 2019; Yousefi et al., 2019; Ding et al., 2020; Kuswandi et al., 2020; Nemes et al., 2020; Yong et al., 2020)*
Interactive packaging	*Enable brands to engage with consumers, mainly for marketing purposes*	*(Ziv, 2018; Pal and Kant, 2020)*

Ergonomic packaging	*The design of the packaging considers logistical and handling convenience*	*(García-Arca et al., 2014; Sohrabpour et al., 2016)*

Smart packaging has many advantages, such as the ability to interact reciprocally between product and people, capability to monitor smartly, and make handling of the package easier for workers and customers. Despite the merits of smart packaging, challenging issues still exist: problems like anti-microbial activity, active materials, thin-film electronics, packaging waste, product waste and information management need to be carefully assessed. Details of each category of smart packaging will be discussed below.

Intelligent Packaging

Real-time monitoring and management of internal and external conditions of the packaging can be achieved through the use of sensors and indicators, which is often referred as 'intelligent packaging' (Pavelková, 2012; Fuertes et al., 2016; Kim et al., 2016; Kalpana et al., 2019; Yousefi et al., 2019; Ding et al., 2020; Kuswandi et al., 2020; Nemes et al., 2020; Yong et al., 2020). Literature in intelligent packaging focuses on simulations and analysis of quality loss, temperature history, cooling rate and heat transfer rate of the packaging. As discussed in the previous section, 2.3.1.2 Cold chain monitoring, temperature monitoring is critical since temperature disruption can lead to quality- and safety-related issues. Cold chain links that are potentially at high risk of temperature disruption include precooling, ground operations during transportation, storage during display at retail and in domestic refrigerators, and commercial handling activities (Mercier et al., 2017).

Monitoring of temperature, humidity, pH, bacterial presence can be done with the assistance of sensors, indicators, data loggers, etc. Time temperature integrators (TTIs) are smart labels that monitor and manage the time and temperature data. Tsironi et al. (2015) proposed an optimization model for selecting the best TTIs for SME businesses. Kuswandi et al. (2020)

developed an edible pH sensor for red cabbages. Feng et al. (2020a) developed a multi sensor model based on blockchain to monitor the quality of shellfish. Besides temperature, carbon dioxide production, respiratory behaviour, ethylene production and sensitivity are also important factors that influence the perishability of food cold chain products and the environment.

Active packaging

Active substances can be released from cold chain packaging to regulate levels of bacteria, pH, humidity, etc. This is called 'active packaging', and aims to regulate or change the environment inside packaging (Arvanitoyannis, 2012; Cerqueira et al., 2014; Adobati et al., 2015; Kuorwel et al., 2015; Wyrwa and Barska, 2017; Bajić et al., 2020; Vilas et al., 2020).

Nanotechnologies are sometimes used for active packaging. Incorporating nano sized materials in packaging can inhibit and control microbial growth, control humidity, maintain safety, prevent liquid or gas penetration and extend shelf life. Sobhan et al. (2020) developed a carbon-based nanocomposite film with antibacterial properties. Kim et al. (2020a) assessed the use of ZnO nanoparticles on active antibacterial food packaging. Besides antibacterial active packaging, other forms of active packaging include oxygen scavengers, carbon dioxide scavengers/emitters, moisture absorbers, ethylene scavengers/absorbers, ethanol emitters, etc (Kuorwel et al., 2015).

Interactive packaging

Interactive packaging focuses on engaging with consumers in dynamic ways to provide a better user experience. It provides two-way communication between the user and the package, unlike intelligent packaging which only offers one-way information (Ziv, 2018; Pal and Kant, 2020). Interactive packaging can bridge physical shopping and digital marketing. Visual communication can be done through interactive packaging, focusing on the user experience.

Good design can create a positive emotional experience. Song et al. (2022) developed an interactive packaging design scheme for food packaging based on users' emotional experiences. Customers can receive useful information in a more fun way through interactive packaging. Instructions for how to properly handle the products, in terms of transportation, storage, opening, using and disposal, can be given in an interactive and visual way. Interactive packaging is also a good marketing strategy, since customers are more likely to be attracted by the visual appearance of the products (Lydekaityte and Tambo, 2020).

Ergonomic packaging

Ergonomic packaging, as the name suggests, focuses on embracing the convenience feature for all logistics partners, including manufacturers, retailers and consumers. In this way, it can ease the operating process of cold chain logistics (García-Arca et al., 2014; Sohrabpour et al., 2016). The design of packaging should meet moisture content and ventilation requirements for the specific products. The packaging should be easy for workers to handle, load and unload and not cause harm to any people. Efficient training should also be given for handling the packaging (Ismaila et al., 2020).

Packaging design should consider the requirements and conditions of the entire cold chain (Sohrabpour et al., 2016). Packaging is an essential interface between the product and the supply chain or logistical sides. However, packaging design sometimes overlooks supply chain conditions. Developing packaging that considers the supply chain perspective can make sure the supply chain needs are satisfied. The term "Supply chain packaging" is sometimes used for describing packaging design incorporating supply chain and logistics requirements. Supply chain packaging concerns all levels of packaging, including logistics-level shipping containers (Singh et al., 2018a). The functions of packaging in the supply chain include apportionment, communication, containment, convenience, information, preservation, promotion, protection, unitization, waste reduction, recycling, etc.

Packaging is sometimes not considered in the design phase of the product; however, it plays an essential role in the overall performance and cost of the supply chain. Sohrabpour et al. (2016) propose methods to decrease the gap between supply chain needs and the packaging of the products by three propositions: using an expanded operational life cycle; using four domains of design (customer, functional, physical, process) when designing the packaging; and integrating the product and packaging system with the overall supply chain process. Integrating the product and packaging system with the overall supply chain process can improve overall supply chain efficiency, making packaging more ergonomic and sustainable (Sohrabpour et al., 2016).

2.2.4 CONTAINER MANAGEMENT

2.2.4.1 Shipping containers

Shipping containers are large, standardized containers used to store goods during shipment (Rodrigue and Notteboom, 2020a). Starting from the mid-20th century, the trend of globalization and international trade has been continuously expanding, in which the scale, volume and efficiency have continued to improve. Maritime transportation plays a key role in international trade, since it handles about 80% of the volume and 70% of the value of such trade (Rodrigue and Notteboom, 2020a). Containers and associated maritime and inland transport systems are key components of maritime transportation. The history of containers can be traced back to 1956, when the first container, the Ideal X, was launched.

In the late 1960s, the standardization of container sizes led to their rapid development. The term 'containerization' is often used to describe the adoption of containers in transporting goods. Compared to other modes of transportation, maritime transport benefits from low cost and high flexibility, thanks to containerization. Containerization makes cargo distribution possible in unitized forms, allowing intermodal transport through a combination of rail, road, canal and sea (Rodrigue and Notteboom, 2020a). Today, standardized containers are transporting the majority of international cargo in bulk (Fitzgerald et al., 2011).

The most common containers are the twenty-foot equivalent unit (TEU). By 2015, the global inventory of containers was about 37.6 million TEUs. Each year, about 1.5 to 2.5 million TEUS are manufactured. There are three main categories of containers: dry containers, refrigerated containers (reefers) and tank containers. Dry containers are containers that do not require any particular conditions other than physical protection. Refrigerated containers use specially insulated containers aiming to transport temperature-sensitive goods by maintaining the temperature within a constant range. Tank containers carry liquids, such as wine, vegetable oil, juice or chemicals (Rodrigue and Notteboom, 2020a). Since the focus of this thesis is on cold chain packaging, refrigerated containers are discussed in the next section.

2.2.4.2 Refrigerated containers

Refrigerated containers have developed rapidly. In 1980, the containerization rate of refrigerated transport capacity in maritime shipping was about 33%: by 2017 it had increased to 82% due to the increase in global incomes and availability of refrigerated transportation. About 3 million TEUs of reefers were used by 2019 (Mohseni et al., 2023), although reefers are more costly than regular containers. Take a regular 40-foot container as an example: a regular 40-foot container costs about $5,000, whereas a reefer of the same size costs about $30,000; 6 times more expensive.

Not only is the manufacturing cost of reefers higher, but also their energy consumption costs, additional equipment, monitoring and handling costs are also more expensive. Under special circumstances, a reefer can be used as a storage unit (Rodrigue and Notteboom, 2020a, 2020c). For a reefer to work properly, several factors need to be considered, including temperature control, proper air circulation and humidity, power supply, efficient monitoring, etc., as indicated in Figure 2.5. Figure 2.6 summarises the main ways in which low

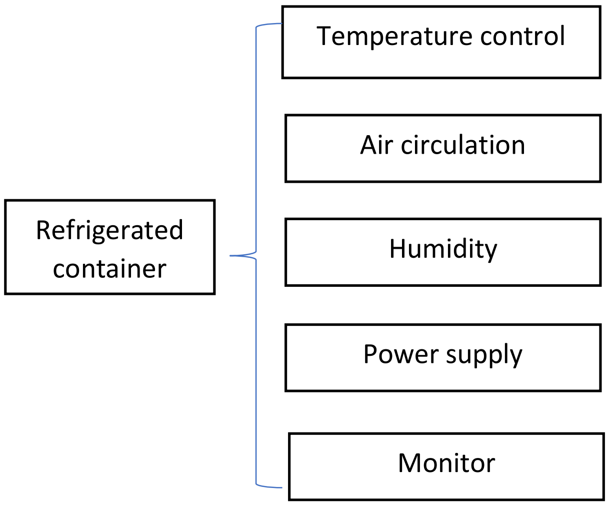


Figure 2.5: Major factors influencing performance of refrigerated containers

temperatures are produced in cold chain facilities.

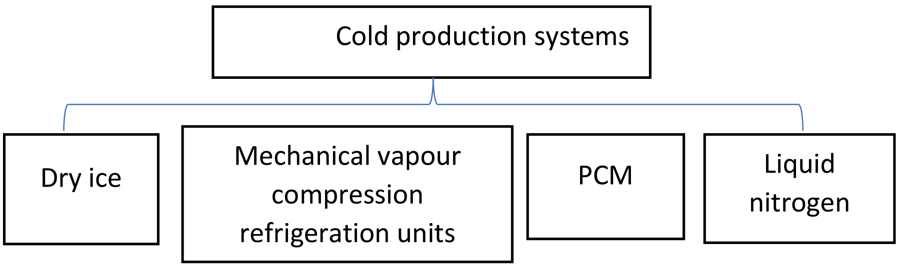


Figure 2.6: Cold production systems of refrigerated containers

2.3 COLD CHAIN MANAGEMENT (CCM)

2.3.1 AN OVERVIEW OF THE COLD CHAIN

A cold chain is a special supply chain that requires temperature control during transportation and storage. What makes the cold chain unique from other supply chains is its perishable character. Common cold chain products include fresh and frozen meat, seafood, poultry, desserts, dairy products, vaccines, medical products, blood, organs, etc. Researchers tend to discuss food and pharmaceutical cold chains separately due to their different characteristics and cold chain requirements. Food cold chains usually begin at farms and end in the hands of the consumers (Cerchione et al., 2018). Pharmaceutical cold chains begin right after the products are manufactured and normally end in clinics and hospitals. A general overview of cold chains is illustrated in Figure 2.7.

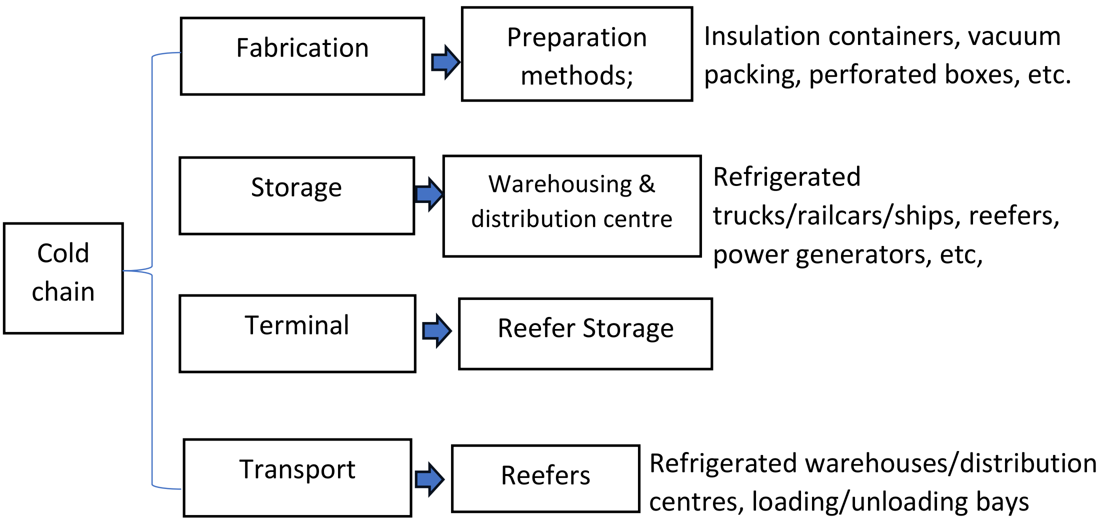


Figure 2.7: An overview of cold chains. Derived from Rodrigue (2017b)

Existing literature in cold chain management falls into three main categories: optimization, quality and safety, and sustainability, as shown in Table 2.2. Optimization focuses on how to continuously improve the planning and processing of cold chains, including cost reduction, time reduction, profit maximization, etc. (Bozorgi et al., 2014; Ali et al., 2018). Quality and safety focus on how to preserve the cold chain products so the quality will not deteriorate.

Temperature control, humidity control, air circulation control and efficient monitoring are main ways to ensure the quality and safety of cold chain products. Mataragas et al. (2019) developed a microbial time temperature indicator which continuously monitors the temperature, PH and the microorganism. Sustainability literature focuses on the impact of the cold chain on the environment, which has gained more and more attention in the past few years. Goellner and Sparrow (2014) found that the use of reusable shipping containers that require thermal control is environmentally preferable.

Table 2.2: Cold chain literature concentration and influencing factors

Concentration	What affects it?	Sources
Optimization	Vehicles routings, Cost, Time, Vehicle's capacity and total number of vehicles available, Transportation mode selection	(Bozorgi et al., 2014; Ali et al., 2018)
Quality and safety	Temperature(chilled, frozen), freshness, shelf life, fluctuations (continuous or non continuous), humidity, vibration. product type	(Hoel et al., 2017; de Frias et al., 2018; Fu et al., 2019; Briggs et al., 2020)
Sustainability	Energy consumption, carbon emission	(Chandel and Agarwal, 2017; Gao et al., 2021; Rahman et al.)

Cold chain logistics can be broadly divided into three segments: cold processing, cold storage and cold transportation and distribution (Singh et al., 2017). Table 2.3 lists the cold chain logistics units, which include processing, storage, transportation and monitoring. Some companies have their own logistics services, while others tend to outsource the logistics to third-party logistics providers. Especially for pharmaceutical cold chains, third-party pharmaceutical specialists are often in charge of transportation and storage.

Table 2.3: Cold chain logistics units (Gao et al., 2021; Han et al., 2021)

Cold chain logistic unit	Details	Research concentration
Processing	Pre-cooling, quick freezing	Heat and mass transfer
Storage	Freezers, warehousing, cold rooms, Refrigerated display cabinet, domestic refrigerators	Balance between power consumption and product quality, new technologies, refrigeration or cooling, impact of packaging on cooling
Transportation	Refrigerated container, refrigorator	Energy and environmental impact, optimization of cooling performance, digitalization and visualization
Monitoring	Data tag, temperature indicating materials	Traceability, information sharing

The environmental factor that affects product freshness the most is the temperature (Badia-Melis et al., 2018). Temperature disruptions can cause bacteria growth in food products and can cause loss of potency in pharmaceutical products, so temperature control plays an essential role in cold chain management. Temperature preservation ranges vary for different cold chain products, e.g. chilled, frozen, etc., and types of refrigeration include cold storage, refrigerated transport, ultra-low storage, etc.

Besides temperature control, other factors like humidity and air circulation also have an impact on the performance of the cold chain. Inappropriate humidity or air circulation control can lead to package decay due to high moisture content or high compression forces. The next few sections will discuss cold chain air circulation and humidity management, and corresponding cooling systems and monitoring systems in detail.

2.3.2 AIR CIRCULATION AND HUMIDITY MANAGEMENT

A summary of literature on design of packaging, air circulation and heat transfer analysis is listed in Table 2.4. Proper air circulation must be maintained to reduce temperature fluctuation and maintain proper compression force in the package. Refrigerated containers have a bottom air delivery system, where air mainly flows from the bottom to the top through packed cold chain products (Getahun et al., 2017). A clearance of 15cm must be kept between the cargo and ceiling and all reefers are painted white to lower the solar energy absorbed by the surface and consequently decrease the temperature fluctuation inside the containers (Rodrigue and Notteboom, 2020a). An improper rate of air flow can also cause a high compression force on the package, therefore damaging it. A stable humidity level also needs to be kept during cold chains to prevent the products from drying if humidity is too low and to prevent the package from soaking due to high humidity.

Table 2.4: Summary of literature with concentration on design of packaging, air circulation and heat transfer analysis

Concentration	*Sources*
The design of packaging on cooling	*(Ngcobo et al., 2012b; Berry et al., 2016; Ambaw et al., 2017; Fadiji et al., 2018)*
Air circulation and heat transfer analysis	*(Ngcobo et al., 2012a; Zhao et al., 2016, 2021; Getahun et al., 2017, 2018; Kayansayan et al., 2017; Cao et al., 2020)*
Humidity	*(Berry et al., 2019; Ikegaya et al., 2020)*

The design of the refrigerated container impacts its ventilation and heat transfer performance. Ceiling-slot-ventilated enclosures are frequently used, in which a turbulent air jet supplies cold air into the enclosure (Kayansayan et al., 2017). Getahun et al. (2017) found through numerical analysis that having vent holes on the bottom of the packaging boxes can reduce vertical airflow resistance, reducing cooling time and creating potential energy saving opportunities. Zhao et al. (2021) also conducted numerical analysis on an air-refrigerated container and found that when the air is supplied from the side, the heat transfer and flow are better when the cargo is small but the inlet will be blocked when the cargo is large.

Refrigerated containers have different floor design structures, such as T-bar, castellated plate, perforated floor and flat floor (Getahun et al., 2018). Getahun et al. (2018) found that a T-bar floor has a reduced air recirculation zone and enhanced vertical air movement compared with a flat floor. Other influencing factors include the efficient use of space/volume, stacking arrangements of cartons on pallets, proper packaging and pallet dimensions (Louw and Nel, 2019).

Humidity is another important factor besides temperature that can cause quality decay of cold chain products, especially for fresh produce. Humidity can lead to extensive damage, including corrosion, power cracking, peeling of labels, mould, microorganisms, warping of cardboard, and packaging deterioration. Ventilated corrugated fibreboard boxes, also called cartons, are often used to transport fresh produce (more than 90%), with the benefits of being completely recyclable and biodegradable, highly rigid, dense, lightweight. However, under cold chain conditions, these boxes need to endure high relative humidity, which may damage the boxes, and large compression forces which could lead to creep, a slow deforming process due to constant compression (Berry et al., 2019); the way cartons are stacked together has an impact on the moisture content. For fresh produce, drying can be an issue for long transportation times, and needs to be prevented. Ikegaya et al. (2020) found that long-term storage of strawberries requires the use of film packaging to prevent drying.

2.3.3 COLD CHAIN COOLING SYSTEMS

Cooling systems or refrigeration systems are key elements in cold chains, and about 31% of the world's food supply chain requires refrigerated transport (Fitzgerald et al., 2011). Cold chains normally incorporate cold production systems to control the temperature (Sepe et al., 2015). Common temperature control approaches for cold chains are listed in Table 2.5, including dry ice, liquid nitrogen, gel packs, eutectic plates, refrigerators and quilts. Gel packs and eutectic plates are made of PCMs. PCMs refrigerated containers have advantages in low cost, low energy consumption, simple maintenance, and extensive available transport volume, but their drawbacks include difficulties in maintaining uniform cooling, and limited cold storage capacity (Sepe et al., 2015).

Table 2.5: Major approaches to control temperatures for cold chains (Rodrigue, 2017a; Gao et al., 2021)

Temperature control	Details
Dry ice	Solid carbon dioxide can keep the temperature at -80°C; it does not melt and can sublimates in contact of air
Gel packs	Use phase changing substances to control the temperature; commonly used for pharmaceutical and medical shipments
Eutectic plates	Similar to gel packs, fill plates with liquid and can be reused many times. Can be used in delivery vehicles.
Liquid nitrogen	Liquid nitrogen can reach to -196°C and is used for long term frozen goods. It is used for biological product transportation such as tissues and organs.
Quilts	Insulated pieces, can act as a buffer to provide a contant temperature control. Low cost.
Refrigerators	Domestic refrigerators or display cabinets and freezers

The cooling systems in cold chains can be categorized into two groups: active and passive cooling systems. Active cooling applications include refrigerators and reefers, which need a power input, while passive cooling approaches, such as gel packs, dry ice, eutectic plates, liquid nitrogen and quilts, do not require any power input. Common refrigerated equipment in retail includes display cabinets and freezers, all-in-one display cabinets and red wine cabinets. Display cabinets and freezers are commonly used in large supermarkets, while all-in-one cabinets are more frequently used in small stores.

There are mainly 2 types of red wine cabinets: semiconductor and compression wine cabinets. Different regions have different regulations on refrigeration or refrigerants. For example, Europe has strict F-gas regulations and therefore prefers natural refrigerants. Gao et al. (2021) summarized the trend of refrigerants used in the past few years in China. Other refrigeration includes domestic refrigerators and ultra-low temperature refrigerators, cold rooms, reefers, etc. Reefers are temperature-controlled units, which can be vans, trucks, trailers or ISO containers and have a refrigeration plant attached.

A power supply is needed to keep the cooling system of a refrigerated container working. For a single refrigerated container, about 19% of the energy consumption is used for refrigeration. Fossil fuels are still the main sources of electricity power supply for refrigerated containers (Fitzgerald et al., 2011), so it is important for the environment to manage their energy use; Fitzgerald et al. (2011) calculated the greenhouse emission rate for apples exported from New Zealand to the UK in 2007. Li et al. (2022) proposed a method using liquefied natural gas (LNG) powered refrigerated containers which can promote energy saving and reduce emissions. New forms of energy for powering containers are also studied.

For passive cooling systems, no power is needed. Gel packs and eutectic plates use phase change materials (PCM) to control the temperature. Gel packs are often used with pharmaceutical and medical products due to their superior temperature control performance. Common temperature control ranges of gel packs are 2-8°C, which aligns with requirements of common pharmaceutical cold chain ranges. They can also provide homogeneous temperature maintenance. Eutectic plates have the advantages of low cost and reusability and are suitable for delivery vehicles for short periods.

Dry ice, or solid carbon dioxide, can maintain a temperature of -80°C and its main applications are for shipping of pharmaceuticals, dangerous products and food in refrigerated units for air cargo. Liquid nitrogen can maintain the temperature at -196°C, which is suitable for long-term cold storage. Liquid nitrogen is used for the low-temperature maintenance of the live parasites concurrently injected with East Coast fever vaccines (Atuhaire et al., 2020). Older insulation approaches include quilts, ice, etc., with the advantages of low cost and easy availability (Rodrigue, 2017a; Gao et al., 2021). Combinations of cooling approaches can be used together to provide efficient refrigeration for specific cold chains.

Technological advancement has always been a key driving force for the development of many industries, and cold chains are no exception. There have been many innovations for cold chain cooling in the past few years, and a list of cold chain cooling system innovations is given in Tables 2.6 and 2.7. Refrigerators with innovative designs can lower temperature excursions, but they may not perform well in other risky events, for which further studies are needed.

Table 2.6: Cold chain active cooling system innovations

Innovation description	Temperature maintained	Reference
Design of a thermal ballast using watering bottles in domestic refrigeration	2 - 8°C for 4 to 6h during power outages	(Chojnacky and Rodriguez, 2020)
Design of automatic temperature controlled portable cooling cabinet	Achieves 2°C within 30 mins	(Hassaan-Younis and Ur-Rashid, 2018)
The use of a separate refrigerator for cooling packs	-	(Goldwood and Diesburg, 2018)
Replacement refrigerants in the Chinese cold chain industry	--	(Gao et al., 2021)

Key active cooling innovations include replacement refrigerator component, like refrigerants, thermal ballast or absorbents, or applications of solar energy usage. Chojnacky and Rodriguez (2020) found that water bottles can be used in domestic refrigerators as a thermal ballast replacement to reduce temperature excursion risks. They also found that 15% of the total refrigerator volume can maintain vaccine temperature at 2°C to 8°C for 4 to 6h during power outage events.

Absorption cooling is a cooling technique that uses zeolite as the absorbent and heat energy to maintain a temperature of 2°C to 8°C., and solar energy can be used as the source to heat zeolite. Nasruddin et al. (2018) studied the behaviour of solar heaters for use as portable vaccine coolers. These portable vaccine coolers can be folded and carried easily, suitable for use in rural areas or during emergencies. Another portable cooling device, designed by Hassaan-Younis and Ur-Rashid (2018), uses the Peltier module, a solid-state device based on semiconductor conjunctions, to design an automatic temperature-controlled portable cooling cabinet. This cabinet is cost-efficient and environmentally friendly compared to conventional vapor compression cooling refrigeration systems.

One of the important things for active refrigeration is power usage. Because of the risk of poor performance by active cooling systems during power outages, the use of combining active refrigeration and suitable passive cooling systems, such as PCM packaging, is one good solution, for which more detailed case studies are needed.

Passive cold storage systems have received an increasing amount of attention in the past few years. Innovative passive cooling packages increase the number of possible alternatives for the packaging/containers used in cold chain management. These innovative passive cold storage systems have pros of low cost and low energy usage compared to traditionally powered refrigerators. Also, it is easy to carry, making it suitable for vaccine distribution in rural areas where power is lacking and choices of transportation are limited (Yin et al., 2020; Zhao et al., 2020b).

Table 2.7: Cold chain passive cooling system innovations

Innovation description	Temperature maintained	Reference
Use of dry ice replacing liquid nitrogen in cold chain	80°C for 30 days	(Atuhaire et al., 2020)
Development of PCM based on Tetradecane and lauryl alcohol, coupled with expanded graphite	2 - 8°C for 50.02h	(Zhao et al., 2020b)
Development of PCM based on paraffin/SiO2 aerogel, coupled with polystyrene board	Maintain time increased by 99 times compared to with only insulation board.	(Yin et al., 2020)
Development of a passive cooling device, 'Zeepot Clay'	Maintain below 26°C at an ambient temperature of 42°C.	(Lugelo et al., 2020)
Design of solar heater for the regeneration of adsorbent (zeolite) chamber	-	(Nasruddin et al., 2018)

The PCM-based packaging system is one popular topic. Zhao et al. (2020) and Yin et al. (2020) both developed cold storage systems for transporting vaccines by using PCM coupled with other insulation materials, which are usually polymer materials or card boards. The combined use of PCM and other insulation materials can increase the temperature maintenance property compared with simple insulation material. Dao et al. (2016) used N-Tetradecane as the PCM material for vaccine cold chain PCM packaging boxes, which showed better temperature maintaining behaviour than water.

In addition to PCM, other materials are considered for use as passive packaging boxes for vaccines during the cold chain. (Lugelo et al.(2020) designed several locally-made passive cooling devices, one of which, called 'Zeepot Clay', had a cost of $11 per unit, showing great temperature maintenance behaviour. A field test (12-month phases) indicated this 'Zeepot

Clay' device can maintain a temperature below 26°C when the ambient temperature is 42°C. The low cost and easy manufacture make it a promising alternative passive cooling packaging choice for the vaccine cold chain. More suitable materials are to be explored, and their performances in all dimensions (technically, economically, environmentally, etc.) should be further assessed.

Cold chain cooling systems can only maintain the temperature within specific ranges but cannot decrease the temperature of the goods. Before the transportation of these goods, sometimes pre-cooling and processing is necessary to reduce the temperature and prepare them ready for transportation and storage. For food cold chains, pre-cooling is often conducted, which aims to remove field heat right after harvest or slaughtering. Pre-cooling can slow down bacteria growth, and takes many forms, such as heat conduction cooling, phase-transition cooling and vacuum pre-cooling (Gao et al., 2021; Han et al., 2021).

Research attention has focused on ways to conduct rapid and uniform cooling of cold chain produce in the past few years. Quick freezing aims to reduce the food temperature below its freezing point in the shortest possible time, and examples are air-forced circulation freezing, indirect contact freezing, and spraying or dipping freezing (Gao et al., 2021). The design of the packaging plays an important role in this, since packages impact the process of airflow, and heat- and mass- transfer. Many studies have been carried out on simulations of heat transfer during pre-cooling.

2.3.3.1 Phase change materials (PCMs)

Much has been written on thermal regulating materials (TRM) and technologies for cold chains, and phase change materials have received a great amount of attention. The global PCM market is estimated to have a value of $3.1 billion by 2026 (NASDAQ, 2022). The application of PCM in packaging can improve thermal energy storage efficiency, contributing to sustainable development (Chatterjee and Sasidharan, 2019). TRMs are essential parts of cold chain packaging which have received increasing research attention. Singh et al. (2018b) summarized the applications of PCMs in food packaging and proposed criteria for choosing the right PCM materials. PCM changes its phase when the ambient temperature changes. The mechanism behind this involves latent heat, in which heat is released or absorbed by a system without a change in temperature (Mishra et al., 2015). This unique phase-changing property makes PCM a great candidate for cold chain packaging.

Some common PCMs are fatty acids, paraffin waxes, eutectics, etc. The applications of PCM in refrigeration aim at alleviating the cooling load and maintaining a constant temperature at the same time. This can save energy costs and contribute to sustainable development (Capps, 2021). To select suitable PCM, factors like costs, durability, corrosion, safety, sustainability and temperature maintaining ranges need to be considered.

The effectiveness of PCMs depends on factors like the size of the transporting vehicle, desired temperature, product location on the vehicle, air distribution, the composition of the PCM, etc. Four common PCM applications are PCM pallets, PCM cold plates, PCM insulated thermal shells and PCM insulated boxes (Chatterjee and Sasidharan, 2019). To evaluate the performance of PCMs, thermal performance, system cost, freight optimization, payload optimization, pack-out simplicity, physical performance and environmental impact can be considered (Singh et al., 2018b).

There have been many real-life applications of PCM in cold chain packaging. For instance, for perishable groceries ordered online, there will often be some ice bags or coolants within the packages. The earliest commercialized PCM product was PureTemp which was introduced in 2007 and was also the first 100% renewable, commercially available PCM. Its applications involve warm blankets, cooling vests, thermal and refrigerator energy storage tanks, passive thermal packaging, etc. (PureTemp, 2024). In the same year, the Greenbox thermal container was introduced, which contained PureTemp and vacuum insulation panels (VIPs) (Sonoco ThermoSafe, 2022a).. This container can keep the product temperature for about 5 days with no electrical power (Singh et al., 2018b). Today, many companies have launched cold chain shipping solutions for a diverse range of applications.

The ongoing COVID-19 pandemic has also boosted the fast development of cold chain packaging, since its vaccines mostly have rigid temperature requirements, and some COVID-19 vaccines even require an ultra-low temperature environment during transportation and storage. KoolTemp EcoFlex 96 COVID-19 vaccine shipping parcel solutions have been used for air and land transportation/storage of the Pfizer, Moderna, Johnson & Johnson and AstraZeneca COVID-19 vaccines.

To maintain an ultra-low temperature during cold chain transportation/storage, dry ice is sometimes used within the packaging to reach and maintain an extremely low temperature. For example, the Pfizer COVID-19 vaccines use dry ice to maintain a temperature of −70 °C during cold chains. Also, companies have launched programs to further study PCM-based cold chain packaging solutions. For instance, Efficiency Vermont's R&D project investigating refrigeration applications of PCM showed that these packaging solutions can be beneficial in many ways, including saving energy cost, improving cold chain efficiency, extending equipment life and reducing maintenance costs, allowing flexible load management and minimizing damage during power outages (Capps, 2021).

2.3.4 COLD CHAIN MONITORING

In addition to cold chain cooling systems, temperature monitoring is also essential for keeping a cold chain working efficiently. A list of cold chain monitoring and indication innovations is listed in Table 2.8. Common cold chain monitoring devices include indicators, remote management systems, sensors, barcodes and radio frequency identification (RFID) tags (Ahmed et al., 2018). Common indicators include time-temperature indicators (TTIs), freshness indicators, integrity indicators, etc. Sensors contain electronics to monitor chemical, physical and biological conditions of the cold chain. Barcodes and RFID tags can store and communicate information about the cold chain products, making information traceable.

All of these technologies can effectively monitor and manage the conditions of cold chain packaging during transportation and storage and should be non-toxic, stable and sensible. Packaging incorporating these technologies is sometimes called "Smart packaging" (Biji et al., 2015; Ahmed et al., 2018; Schaefer and Cheung, 2018; Ziv, 2018; Lydekaityte and Tambo, 2020; Pal and Kant, 2020).

Table 2.8: Cold chain monitoring and detection innovations

Innovation description	*Cold chain Monitor/ Detection*	*Characteristic*	*Reference*
Water proton transverse relaxation rate by Nuclear Magnetic Resonance relaxometry (wNMR relaxometry)	*Freezing variability test*	*Experiments on freeze/thaw on three freeze-sensitive adjuvants*	*(Briggs et al., 2020)*
Design of an accurate and low-cost thermochromism temperature indicator.	*Temperature indicating material*	*The designed indicator has critical phase-change temperature of 8°C.*	*(Gao et al., 2020)*
Feasibility of remote temperature monitoring devices (RTMDs) in Haiti	*Temperature Monitor*	*Remote temperature monitoring devices (RTMDs)*	*(Cavallaro et al., 2018)*
Development of a self-powered sensor monitoring time-temperature without external powering	*Temperature Monitor*	*Self-powered time-temperature monitor*	*(Zhou and Chakrabartty, 2017)*

Temperature-indicating materials, which change colours at temperature excursions, are important for temperature maintenance because they offer a way of telling whether the cooling system has worked during cold chains. Yin et al. (2020) developed a new temperature excursion indicator material based on a solution of photochromic spirogyra compounds dissolved in a mixed solvent with a critical phase-change temperature of 8°C, suitable for vaccine transportation, since 2°C to 8°C is the WHO-recommended cold chain temperature range for many vaccines. Since the requirements of different vaccines vary, materials with different phase-change temperatures can be tested and used for suitable vaccines as indicators during cold chains.

New temperature monitoring techniques, such as self-powered sensors and remote monitoring, show promising potential for use in vaccine cold chains. Temperature monitoring devices usually require a continuous power supply during cold chains and can be designed integrally on transportation packages. Self-powered sensors can alleviate the power supply burden greatly. Zhou and Chakrabartty (2017) and Cavallaro et al. (2018) both designed temperature monitoring devices for vaccine cold chains. Most monitoring devices are attached to packaging containers, but Zhou et al. (2017) proposed a self-powered sensor that can be embedded with passive RFID tags and can be integrated with packages. The temperature sensitivity of this sensor was tested as 1.5mV/°C over a monitoring duration of 100 hours, suitable for use in cold chain transportation. A study by Cavallaro et al. (2018) proved the feasibility of implementing remote temperature monitoring devices (RTMDs) in Haiti, and suggested RTMDs could be a good refrigeration option for high volumes of vaccines or when there is a shortage of conventional refrigerators.

Being able to identify temperature excursion events is important; however, not all temperature excursions lead to vaccine damage. Therefore, the detection of real harm caused is important. Both excessive heating and freezing of vaccines can cause great harm to them, and the focus before 2007was on heat damage. However, the number of freeze-sensitive vaccines, e.g., DTP-hepatitis B, liquid Hib, and influenza, has grown since then, needing more attention in this field (Hanson et al., 2017). The WHO Shake Test is often used for vaccine freeze detection, but it has several limitations, e.g. poor accuracy. An alternative Shake Test was designed by Briggs et al. (2020), using water proton Nuclear Magnetic Resonance relaxometry for aluminium adjuvanted vaccines. The conventional WHO Shake Test depends closely on visual observations, which can be hard to make when the liquid volume inside the vial is small or when there is a label on the vial.

Since variations exist among all the vials in a whole batch, the WHO Shake test may not always be accurate, and more refined methods are needed (Kartoglu and Ames, 2022). The working principle of this wNMR method is that freeze/thaw-inducing aluminium particle clusters in vaccine vials, which are different from vials that have experienced no freeze/thaw events, can be detected by wNMR signals. This wNMR measurement is quantitative, fast (10-30s per vial), not based on human judgment, and non-invasive to the vaccines, serving as a good alternative method to the WHO Shake test for vaccine freeze detection (Briggs et al., 2020).

Emerging new techniques should be further tested within integrated cold chain systems, and how each component affects others requires further research. It is also noticed that some research has been done in the area of vaccine formulations, e.g. nano-vaccines or solvent-free vaccines (Christopher and Peck, 2004; Chen and Kristensen, 2009). As the nature and properties of vaccines change, the way that cold chains work will be influenced. Therefore, the design of cold chains needs to improve to meet the requirements of emerging new types of vaccines.

2.3.5 PERFORMANCE METRICS OF THE COLD CHAIN

A number of supply chain reference models have been developed, which include: Global Supply Chain Forum framework, Supply Chain Operation Reference (SCOR) model , Gross Industry Process Classification Framework, Supply Chain Best Practices Framework, shown in Table 2.9.

Table 2.9: Supply chain reference models

Model	*Details*
Global Supply Chain Forum framework	***Aims to strategically integrate companies into a supply chain through relationship management.***
Supply Chain Operation Reference (SCOR) model	***Covers both operational design and performance measurement of the supply chain process, which include process specifications, performance metrics and best practice recommendations.***
Gross Industry Process Classification Framework	***Provides a hierarchical business process framework***
Supply Chain Best Practices Framework	***Provides structured information on world class supply chains as a benchmarking reference for different indsutries.***

The SCOR has been used for some studies in cold chain management. Sastra et al. (2019) mapped out the supply chain activities into 'plan', 'source', 'make' and 'deliver' using the SCOR model before constructing a risk management plan for the frozen tuna cold chain. Ridwan et al. (2019) mapped out the cold chain activities of the Karangantu Fisheries Port before identifying, analysing and evaluating risks and mitigation strategies for the fish cold chain. Some cold chain literature focuses on providing a reference model or performance metric for cold chains. A summary of performance metrics for cold chains is listed in Table 2.10.

Table 2.10: Performance metrics for the cold chain

Source	*Research concentration*	*Performance metrics*

Source	*Research concentration*	*Performance metrics*
(Cerchione et al., 2018)	*Performance metrics for food cold chain management*	*Carbon emission reduction, energy consumption reduction, water consumption reduction, food waste reduction, reduction of solid waste, reduction in hazardous/harmful/toxic material use, shelf life, cooling rate, shipping accuracy rate, lead time, green packaging, traceability, product quality & safety, recycling rate, machine breakdown, passive food cold chain rate, temperature monitoring errors, total cost, inventory levels, inventory holding days, customer satisfaction, total cost reduction, growth in market share, empty running, fuel efficiency*
(Bremer, 2018)	*Reference model for the cold chain*	*Product, information technology, infrastructure and equipment, regulations and standards*
(Latha and Samanchuen, 2023)	*Reference model for pharmaceutical cold chain*	*The mode include four lays: Business, Data, application Technology based on cold chain process of pack, load, transport, unload, unpack, transfer, keep, inspect, audit*
(Sun and Karia, 2023)	*Assessment of cold chain logistics in B2C E-commerce environments*	*Professionalism, reliability, immediacy, convenience, supportability in key segments such as order picking, storage and delivery, returning and signing, etc.*
(Yadav et al., 2021)	*Performance indicators in an IoT based traceability system for agricultural supply chain*	*Certification, tracking of agricultural products, implementing sustainable practices, improved the information qualities, improved global distribution networks, agri-production scheduling with optimization, understanding stakeholder's behaviour, monitoring the ongoing auditing practices, quick response to agro-terrorism, effective information sharing.*
(Nha Trang et al., 2022)	*Impacts of collaborative partnership on cold chain performance*	*Performance dimensions of cold chains include: profit oriented, profit and client-oriented, client and environment-oriented, profit, client and environment-oriented*
(Joshi et al., 2012)	*Performance attributes of a cold chain*	*Cost, quality and safety, traceability, service level, return to assets, innovations, relationship*
(Burgess et al., 2022)	*Optimization of PCM storage system for cold chain delivery*	*Threshold time, temperature inhomogeneity coefficient, discharge efficiency*
(Chen et al., 2022)	*Influencing factors of thermal performance of small-size vaccine cold storage*	*Number of cold storage units, area of cold storage, inside dimension of cold storage, air cooler direction, length to width ratio, service population, air velocity of the air cooler*
(Martínez-Martínez et al., 2023)	*Refrigerated preservation performance indicator for refrigerators in the cold chain*	*Ambient temperature, refrigerator compressor mode, relative humidity, fresh food compartment load, and product staying in the refrigerator or being removed during simulated mealtime*

Cerchione et al. (2018) proposed some performance metrics for food cold chain management, including cost, environmental impact, packaging, inventory level, lead time, cooling time, etc. Bremer (2018) constructed a reference model for the cold chain which is structured into four domains: product, information technology, infrastructure and equipment, regulations and standards, and the process of "DELIVER through cold chain" was added. Joshi et al. (2012) proposed factors like cost, quality and safety, traceability, service level, return to assets, innovations, and relationship as the performance attributes of a cold chain. Latha and Samanchuen (2023) proposed a reference model for the pharmaceutical cold chain including four different layers, each with specific data and technology requirements.

The thermal performance of cold chains is essential, and relative evaluation is needed for the thermal performance system. Chen et al. (2022) analysed the factors influencing the thermal performance of small-scale vaccine cold storage, which include indicators like the number of cold storage units, the area of cold storage, inside dimensions of cold storage, air cooler direction, length-to-width ratio, service population, air velocity of the air cooler. Active and passive storage systems in cold chains both play important roles in cold chain temperature preservation and the cooling system needs to be evaluated.

Burgess et al. (2022) proposed a performance metric for a portable PCM storage system which includes threshold time, temperature inhomogeneity coefficient and discharge efficiency. Martínez-Martínez et al. (2023) proposed a refrigerated preservation performance indicator system based on predictive microbiology and product time-temperature data, where the indicator factors used include ambient temperature, refrigerator compressor mode, relative humidity, fresh food compartment load, and whether the product stays in the refrigerator or is removed during simulated mealtime.

As well as refrigeration of the cold chain, there has been increasing application of cold chain traceability systems, especially due to the increasing use of information technologies. Yadav et al. (2021) propose a model of performance indicators for an IoT-based traceability system for agricultural supply chains, and the indicators proposed include certification, tracking of agricultural products, implementing sustainable practices, improved quality of information, etc.

Other cold chain evaluation studies focus on aspects like e-commerce, company orientation, etc. Different organisations may have different outcome focuses for the performance of the cold chain, and companies can be profit- or client-oriented. Nha Trang et al. (2022) assess the impacts of collaborative partnership on cold chain performance with different company orientations. Sun and Karia (2023) constructed an indicator system for evaluating the quality of e-commerce fresh cold chain logistics services in China, which included indicators like professionalism, reliability, immediacy, convenience, and supportability.

2.4 COLD CHAIN RISK MANAGEMENT (CCRM)

2.4.1 TERMS USED IN CCRM LITERATURE

In the field of cold chain disruption and risk management, most literature uses 'risk' or 'hazard' as the term describing unexpected disruption, while some use other terms like 'risk index', 'risk event', 'risk agent', 'risk level' or 'vulnerability', depending on the specific research concentration. Cold chain risks or hazards refer to the unexpected macro- or micro-level events or activities that have a negative impact on the cold chain, causing operational, financial, strategic or tactical failures (Ho et al., 2015). Some studies use the term 'risk level' to specify the degree or extent of the risks, leading to a hieratical risk structure with an indication of the causal relationship of the risks (Zhao et al., 2020a). 'Risk index' refers to the size of the risk, reflecting the levels of the risk, and can indicate the key risk factors in the cold chain. Risk events are adverse activities/incidents, and risk agents are triggers or causes of the risk events (Zhang et al., 2017). Cold chain vulnerability refers to the factors causing fragility in the cold chain (Yang and Liu, 2018). Cold chain inhibitors refer to factors that may hinder the performance of cold chains (Sharma et al., 2021).

2.4.2 METHODOLOGIES USED IN CCRM

CCRM literature can be categorized into theoretical and empirical studies. Theoretical CCRM studies often identify risk factors from literature review and expert opinions and then propose a conceptual framework or model, while empirical studies conduct risk identification and assessment directly on a specific scenario, e.g. in a company or a specific region. Most CCRM studies use the theoretical methodology, and the models are sometimes further validated by case studies, numerical modelling or, in some cases, comparisons. Lists of theoretical and empirical studies in CCRM literature are given in Table 2.11.

Table 2.11: Theoretical and empirical studies in CCRM literature

Theoretical studies	*Empirical studies*
(Zheng et al., 2021) (Dagsuyu et al., 2021) (Zhang et al., 2017) (Sastra et al., 2019) (Zhang et al., 2020a) (Ali and Gurd, 2020) (Beker et al., 2015) (Khan et al., 2022) (Joshi et al., 2011) (Zhao et al., 2020a) (Sharma et al., 2021) (Ali et al., 2018) (Chen et al., 2021) (Zhang et al., 2019) (Sharma and Pai, 2015) (Yang and Liu, 2018) (Soon and Abdul Wahab, 2022) (Zhang et al., 2020b) (Soon, 2020) (Bai et al., 2018) (Tsang et al., 2018) (Singh et al., 2017) (Sun, 2010) (Ndraha et al., 2019)	*(Zhang and Han, 2020) (Nakandala et al., 2017) (Wu and Hsiao, 2021) (Ridwan et al., 2019)*

Theoretical CCRM models are mainly based on expert opinions and historical data. Dagsuyu et al. (2021) applied the proposed risk assessment model to a third-party cold chain logistics company, in which the hazards are identified by company occupational health and safety specialists. Zhang et al. (2017) compared historical data of fresh agricultural cold chain logistics from Shuanghui Group and Beijing Xinfadi using the constructed risk assessment model. The results were proven to be consistent with the recent company ranking in the industry and other reality factors. Apart from the risk model being applied to specific companies or locations, some models are applied on macro-level scenarios. Sharma and Pai's (2015) model analysing the effectiveness of cold chains was validated by a case study comparing cold chain performance in a developed nation with that of a developing nation.

Besides validation by empirical studies, benchmarking is also sometimes used in the risk management process. Joshi et al. (2011) proposed a food cold chain risk management model that compares companies with the benchmarking data of the market leader. Studies utilizing empirical methodology can conduct risk identification directly from real life observations, e.g. in a specific port, company, etc. Ridwan et al. (2019) constructed a risk management model for the fish cold chain at the Karangantu fisheries port in Serang, Indonesia, based on direct observations, interviews and local expert opinions. Zhang and Han (2020) analysed risk control factors in the RK pharmaceutical Co. Ltd in Shandong, China.

Cold chain risk management consists of 3 main segments: risk identification, risk assessment and risk mitigation. The risk management segments, coverage and methodology used in CCRM literature are summarized and shown in Table 2.12. The identification of risk factors and risk mitigation strategies is usually done through literature review and expert opinions, and then the identified risk factors are further assessed. The results of the assessment depend on the decision-making method used in the risk management model.

Table 2.12: Risk management coverage and decision-making methods used in CCRM literature

Source	*Decision-making methods*	*Risk identification*	*Risk assessment*	*Risk mitigation*
(Zheng et al., 2021)	*Bayesian network (BN)*	✓	✓	
(Zhang and Han, 2020)	*Interpretative structure modelling (ISM)*	✓	✓	✓
(Dagsuyu et al., 2021)	*Failure mode and effect*	✓	✓	✓

Source	*Decision-making methods*	*Risk identification*	*Risk assessment*	*Risk mitigation*
	analysis (FMEA), Analytic Hierarchy Process(AHP)			
(Zhang et al., 2017)	*Catastrophe progression, max deviation*	✓	✓	
(Sastra et al., 2019)	*House of risk (HOR), fuzzy inference system (FIS)*	✓	✓	✓
(Nakandala et al., 2017)	*Fuzzy logic, hierarchical holographic modelling*	✓	✓	
(Zhang et al., 2020a)	*Support vector machine*	✓	✓	
(Ali and Gurd, 2020)	\	✓		✓
(Beker et al., 2015)	\			✓
(Khan et al., 2022)	*Fuzzy AHP*	✓	✓	
(Wu and Hsiao, 2021)	*FMEA*			
(Ridwan et al., 2019)	*HOR*	✓	✓	✓
(Joshi et al., 2011)	*AHP, Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS)*	✓	✓	
(Zhao et al., 2020a)	*Fuzzy MICMAC*	✓	✓	
(Sharma et al., 2021)	*FIS, fuzzy MICMAC*	✓		
(Ali et al., 2018)	*Contingency theory, resource based theory*	✓		✓
(Chen et al., 2021)	*Bayesian network*	✓	✓	✓
(Zhang et al., 2019)	*Fault tree, Bayesian network, fuzzy evaluation*	✓	✓	

Source	Decision-making methods	Risk identification	Risk assessment	Risk mitigation
(Sharma and Pai, 2015)	*BN*	✓	✓	
(Yang and Liu, 2018)	*Bow-tie, fault tree, BN*	✓	✓	
(Soon and Abdul Wahab, 2022)	*BN*		✓	
(Zhang et al., 2020b)	*BN*	✓	✓	
(Soon, 2020)	*BN*		✓	
(Bai et al., 2018)	*Fuzzy comprehension evaluation, FMEA*	✓	✓	
(Tsang et al., 2018)	*Fuzzy logic*	✓	✓	

Popular decision-making techniques used in cold chain risk management are Bayesian Network (BN), Failure mode and effect analysis (FMEA), analytical hierarchical process (AHP), fuzzy inference system (FIS), etc. The decision-making techniques used will have an impact on the way the risks are categorized. Risk models using AHP will conduct pairwise comparisons of risk factors and end up having a hierarchical structure (Khan et al., 2022).Risk models using BN will indicate the causal relationships between the risk factors, as well as the occurrence probabilities of the risk factors (Zhang et al., 2020b). The Technique for Order Preference by Similarity to Ideal Solution (TOPSIS) is good for risk mitigation since it can rank the mitigation strategies based on the given criteria, and the best strategy is the one that is closest to the positive ideal solution and furthest away from negative ideal solution (Singh et al., 2017). FMEA identifies all possible failures in a system and can prioritize factors based on their risk priority numbers (Bai, 2018; Dagsuyu et al., 2021).

For studies focusing on supply chain risks, the house of risk (HOR) is often used, and pareto diagrams are drawn to prioritize the risk agents. The method of supply chain operation system (SCOR) is also used in these studies to map out supply chain activities (Sastra et al., 2019; Ridwan et al., 2019). For studies on fraud risk management, BNs are often used as the decision-making techniques for the model and "food fraud types" are used as the targeted/child nodes. The parent nodes include food categories, year, hazards, notified by, point of adulterants, point of detection, origin or distributed via, action, etc (Soon and Abdul Wahab, 2022; Soon, 2020).

Most of the CCRM literature focuses on risk identification and assessment(Nakandala et al., 2017; Zhang et al., 2020a; Khan et al., 2022; Joshi et al., 2011; Zhao et al., 2020a; Zhang et al., 2019; Sharma and Pai, 2015; Yang and Liu, 2018; Zhang et al., 2020b; Bai et al., 2018; Tsang et al., 2018). Zheng et al. (2021) identified risk factors of cold chain logistics operations and then assessed them using a Bayesian Network. Nakandala et al. (2017) developed a risk assessment model for a fresh food supply chain. Khan et al. (2022) identified and assessed risk elements in the Halal food supply chain, based on Fuzzy AHP. Bai et al. (2018) analysed risk factors in the food supply chain using a fuzzy comprehensive evaluation model and failure mode, effects and criticality analysis. Sharma and Pai (2015) conducted an analysis of operation effectiveness of cold chains based on a Bayesian network.

A few studies cover all three segments of supply chain risk management (Chen et al., 2021; Ridwan et al., 2019; Sastra et al., 2019; Dagsuyu et al., 2021; Zhang and Han, 2020). Chen et al. (2021) identified and assessed interruption risk factors in the Chinese fresh cold chain and made some risk mitigation suggestions for China's fresh cold chain network. Ridwan et al. (2019) and Sastra et al. (2019) identified risk events and some mitigation actions based on the House of Risk method. An integrated mathematical model with analytical hierarchy method and failure mode and effect analysis was proposed by Dagsuyu et al. (2021) to prioritize risk factors and risk mitigation actions for selection of third-party logistics providers. Zhang and

Han (2020) developed a multi-level ladder interpretation structure model to analyse risk factors and risk mitigation strategies for medical cold chain logistics.

Types of cold chain products in CCRM literature are listed in table 2.13. Food products and fresh produce are the most popular cold chain products in the fields of cold chain disruption and risk management. Some studies concentrate on specific types of food; for example, Sastra et al. (2019) focused on frozen tuna and Zhang et al. (2020a) focused on strawberries, while both analysed quality risks, including contamination, moisture content, mechanical damage, etc. Ridwan et al. (2019) constructed a risk management system for fish at Banten fish port. Ali and Gurd (2020) assessed risks for the Australian horticultural industry. Zhang and Han (2020) focused on risk management of pharmaceutical products and analysed the risk control factors in a medical service provider. Some studies do not specify specific cold chain products but analyse cold chain risks in general; these include Dagsuyu et al. (2021), Sharma et al. (2021), Ali et al. (2018), and Tsang et al. (2018). Tsang et al. (2018) focused on the occupational safety risk of the cold chain, and therefore did not need to distinguish between specific cold chain products.

Table 2.13: Types of cold chain products in CCRM literature

Type of product	*Sources*
Fresh produce	*(Zheng et al., 2021) (Nakandala et al., 2017) (Zhang et al., 2020a) (Zhao et al., 2020a) (Chen et al., 2021) (Zhang et al., 2019) (Yang and Liu, 2018) (Zhang et al., 2020b) (Zhang et al., 2017)*
Food	*(Sastra et al., 2019) (Beker et al., 2015) (Beker et al., 2015) (Wu and Hsiao, 2021) (Joshi et al., 2011) (Sharma and Pai, 2015) (Soon and Abdul Wahab, 2022) (Soon, 2020) (Bai et al., 2018) (Tsang et al., 2018) (Singh et al., 2017) (Sun, 2010) (Ndraha et al., 2019)*
Fish	*(Ridwan et al., 2019)*

Medical products	*(Zhang and Han, 2020)*
Horticultural products	*(Ali and Gurd, 2020)*
Not specified	*(Dagsuyu et al., 2021) (Sharma et al., 2021) (Ali et al., 2018) (Singh et al., 2017) (Tsang et al., 2018)*

2.4.3 RISK FACTORS IN CCRM

The performance of the cold chain is impacted by factors including product quality & safety, overall efficiency of the cold chain, cost, customer satisfaction, company development & image, shelf life of the products, temperature disruptions, occupational safety, etc (Zheng et al., 2021). In the field of CCRM, due to its low-temperature characteristics, the concentrations of the risks differ from general-purpose SCRM. SCRM literature tends to focus on risks on an intra-organisational level, while CCRM literature tends to pay more attention to operational and quality-related risks. Different CCRM studies tend to focus on different types of risks, such as operational, quality, safety or fraud risks of the cold chain, the technologies used in the cold chain, the risk factors during different cold chain links, the information and financial flow, etc.

Table 2.14 summarises the ways to categorise risk factors in the CCRM literature. Categorising risk according to logistical links is common in CCRM, and some studies categorise packaging as a separate link of the cold chain (Zhang et al., 2020b, Zhang et al., 2019, Dagsuyu et al., 2021, Zheng et al., 2021). Another way to classify cold chain risks is to divide them into external, internal and network risks, with external risks referring to environmental disruptions, internal risks referring to risks that occur inside the company/provider, and network risks focusing on the supply chain or market perspectives. Chen et al. (2021) categorised risks of fresh cold chains into external, internal and network risks, with external risks further subcategorised into social, political, natural and market risks; internal risks are further subcategorised into management, financial and technical risks; network risks are further subcategorised into credit, logistics and information risks.

The decision-making tool chosen for risk assessment tends to affect the terms used for describing risks and hazards. For example, the term "risk level" is sometimes used to form a hierarchical structure, with an indication of the causal relationship of the risks. Zhang et al. (2019) use 9 risk levels to model the risk of the food supply chain, in which risk levels 1 to 4 include all market-related risks; level 7 risks relate to lack of information management; level 8 risks relate to poor infrastructure; level 9 risks include all external risks.

Zhao et al. (2020) constructed a reliability analysis model using 3 risk levels: delivery delay, quantity and variety inadequacy, and unqualified products. For studies concentrating on fraud risk management, Bayesian Network approaches are often used as the decision-making techniques for the model and 'food fraud types' are used as the targeted/child nodes. The parent nodes include food categories, year, hazards, notified by, point of adulterants, point of detection, origin or distributed via, action, etc (Soon and Abdul Wahab, 2022).

Table 2.14: Summary of cold chain risk category methods

Sources	*Cold chain products*	*Risk category methods*
(Zheng et al., 2021)	*Fresh produce*	*1. processing and packaging links 2. transportation and distribution links 3. warehousing links 4. information links*
(Zhang and Han, 2020)	*A medical provider in Shandong, China*	*1. Facilities and equipment 2. Transportation risk 3. Operational risk 4. External environment*
(Dagsuyu et al., 2021)	*Cold chain*	*1. Supply hazards 2. Storage hazards 3. Packaging hazards 4. Transportation hazards*
(Ridwan et al., 2019)	*Agri- food*	*1. Technology applications 2. Organisation and management 3.Facilities and equipment 4. External environment*

Sources	*Cold chain products*	*Risk category methods*
(Sastra et al., 2019)	*Frozen tuna*	*1. Plan 2. Source 3. Make 4. Deliver*
(Nakandala et al., 2017)	*Fresh food and vegetables*	*Fresh food and vegetable supply chain: agro-supplier-producers-processors-wholesales-retailers; partners include: knowledge, logistics, financial, regulatory bodies. 1. Internal risk (process, control risk) 2. Operational risk external to the firm (demand, supply risk) 3. Macro-level risk (environmental risk)*
(Zhang et al., 2020a)	*Strawberries*	*1. Technological 2. Biological 3. Sustainability 4. Environmental 5. Emergency*
(Beker et al., 2015)	*Food*	*1.Expert/Scientific 2.Public*
(Khan et al., 2022)	*Halal food supply chain*	*1. Supply-related risks 2. Demand-related risks 3. Production-related risks 4. Outsourcing 5. Government and organisation*
(Wu and Hsiao, 2021)	*Food (quality and safety)*	*1. Receipt 2. Storage 3. Dispatch 4. Delivery*
(Ridwan et al., 2019)	*Fish*	*Priority risk agent is very important*
(Zhao et al., 2020a)	*Agri-food*	*Risk levels*
(Ali et al., 2018)	*Food*	*1. Cold chain logistics risk, 2. Supply chain risk, 3. Firm performance*
(Chen et al., 2021)	*Perishable products (fruit and vegetable, flowers, milk, meat)*	*1. External risk (social, political, natural, market) 2. Internal risk (management, financial, technical) 3. Network collaboration risk (credit, logistics, information)*
(Zhang et al., 2019)	*Agri-products*	*Logistics functions: transportation, storage, packaging, loading and unloading, logistics information management; Hierarchy structure of 3 levels (here first 2 levels): 1. delivery delay 2, quantity and variety inadequacy 3. unqualified products*
(Yang and Liu, 2018)	*Agri-food*	*Financial, information flow in short-term and long-term from upstream, mid-stream and downstream.*
(Soon and Abdul Wahab, 2022)	*Food, safety*	*Types of food fraud: 1. food categories, 2. year, 3. adulterants,4. reporting 5. country, 6. point of adulteration, 7. point of detection.*
(Zhang et al., 2020b)	*Food*	*Logistics links: 1. transportation 2. storage 3. loading and unloading 4. packaging 5. distribution process 6. information process*

Sources	Cold chain products	Risk category methods
(Soon, 2020)	*Food safety*	*Food Fraud type: 1. year 2. food categories 3. hazards/others 4. notified by 5. origin or distributed via 6. action*

Table 2.15 lists the main risk factors identified from the literature review in CCRM, which are categorized into environmental risk, supply chain risk, logistic risk, information risk, quality risk, packaging and processing risk. Details of the risk factors will be discussed in the following paragraphs.

Table 2.15: Categories of risk based on literature review on cold chain disruptions and risk management.

Risk category	Risk factors	Sources
Environmental	*Natural disasters, climate instability, traffic instability, political instability (government regulations, strikes), emergency events (power blackouts)*	*(Cerchione et al., 2018) (Zhang et al., 2017) (Sastra et al., 2019) (Nakandala et al., 2017) (Zhang et al., 2020a) (Beker et al., 2015) (Khan et al., 2022) (Zhao et al., 2020) (Ali et al., 2018) (Chen et al., 2021) (Zhang et al., 2019) (Sharma and Pai, 2015) (Zhang et al., 2020b) (Bai et al., 2018)*
Intra organisational	*Supply failure, supply delay, market/demand instability, bullwhip effect, lack of supply chain integration, unable to meet required quality, forecasting errors, economic instability (lack of investment), payment delay, high capital cost, lack of standardisation, lack of customer knowledge, reliability of third-party logistics*	*(Zhang and Han, 2020) (Dagsuyu et al., 2021) (Cerchione et al., 2018) (Zhang et al., 2017) (Sastra et al., 2019) (Nakandala et al., 2017) (Ali and Gurd, 2020) (Khan et al., 2022) (Wu and Hsiao, 2021) (Ridwan et al., 2019) (Zhao et al., 2020) (Sharma et al., 2021) (Chen et al., 2021) (Zhang et al., 2019) (Yang and Liu, 2018) (Bai et al., 2018) (Singh et al., 2017)*
Logistic	*Improper loading/unloading/ handling, poor or shortage of infrastructure/ facilities/equipment (vehicle breakdowns, cold room breakdown, counting mistakes, improper/failed temperature control equipment, improper/failed monitor devices, GPS broken, unqualified technology), insufficient temperature control, unavailability of power, inefficient detection equipment, cold storage capacity, improper humidity, temperature uniformity, vibration errors, human errors (counting errors, poor driving, wrong storage location)*	*(Zheng et al., 2021) (Zhang and Han, 2020) (Dagsuyu et al., 2021) (Cerchione et al., 2018) (Zhang et al., 2017) (Sastra et al., 2019) (Zhang et al., 2020a) (Khan et al., 2022) (Wu and Hsiao, 2021) (Ridwan et al., 2019) (Zhao et al., 2020) (Sharma et al., 2021) (Chen et al., 2021) (Zhang et al., 2019) (Sharma and Pai, 2015) (Yang and Liu, 2018) (Zhang et al., 2020b) (Bai et al., 2018) (Tsang et al., 2018) (Singh et al., 2017) (Mercier et al., 2017)*
Information	*Lack of awareness of using IT, improper traceability, insufficient supply chain information sharing, lack of product temperature information, inadequate information system infrastructure, hidden*	*(Zheng et al., 2021) (Zheng et al., 2021) (Khan et al., 2022) (Wu and Hsiao, 2021) (Joshi et al., 2011) (Zhao et al., 2020) (Sharma et al., 2021) (Chen et al., 2021) (Zhang et al., 2019) (Sharma and Pai, 2015) (Yang and*

Risk category	*Risk factors*	*Sources*
	information of transmission or storage dangers	*Liu, 2018) (Zhang et al., 2020b)*
Quality	*Contaminated with other substances, presence of bacteria, mechanical damage and integrity*	*(Sastra et al., 2019) (Zhang et al., 2020a) (Beker et al., 2015) (Joshi et al., 2011) (Ali et al., 2018) (Sharma and Pai, 2015) (Soon and Abdul Wahab, 2022) (Soon, 2020) (Bai et al., 2018) (Tsang et al., 2018) (Mercier et al., 2017) (Ndraha et al., 2018)*
Packaging/ processing	*Unsuitable packaging material/effect, lack of sanitation, improper processing and packing, unsafe packaging materials, packaging lacks sustainability, damaged packaging, poor quality after processing*	*(Zheng et al., 2021) (Zhang and Han, 2020) (Dagsuyu et al., 2021) (Cerchione et al., 2018) (Sastra et al., 2019) (Nakandala et al., 2017) (Khan et al., 2022) (Ali et al., 2018) (Zhang et al., 2019) (Zhang et al., 2020b) (Bai et al., 2018)*

2.4.3.1 Quality risks

Failure of the cold chain can lead to quality decay of the cold chain products. Quality decay of food and pharmaceutical products is usually caused by temperature disruption, leading to damage that is detrimental to human health and safety. Many studies have identified quality-related risks of the cold chain. Zhang et al. (2020a) analysed the biological risks of the food cold chain, of which common examples identified include ‘contamination’, ‘presence of bacteria’, etc. All studies of cold chain quality risks focus on food cold chains (Sastra et al., 2019; Zhang et al., 2020a; Beker et al., 2015; Joshi et al., 2011; Ali et al., 2018; Sharma and Pai, 2015; Soon and Abdul Wahab, 2022; Soon, 2020; Bai et al., 2018; Tsang et al., 2018; Mercier et al., 2017; Ndraha et al., 2018).

There are very few studies concerning quality decay of pharmaceutical products so far. However, it has been found that not all temperature disruption leads to vaccine damage (Ren et al., 2021). Therefore, it is important to study the quality decay process of pharmaceutical products to alleviate false alarms from cold chain monitoring devices and to improve overall cold chain efficiency.

2.4.3.2 Intra organisational risks

Like all other SCRM studies, the cold chain is not immune to external, supply chain, logistical, or information risks. Most studies in CCRM focus on supply chain and logistical risks. Supply chain risk refers to unforeseen market fluctuations, e.g. sudden increase in demand, supplier failure, etc. Most common supply chain risks in the cold chain include supply delay, market instability, quality not meeting requirements, lack of integration, forecasting errors, etc.

Zhao et al. (2020), studying agricultural food supply chain risk, categorise supply chain related risks into 4 levels: market fluctuations; lack of investment and high energy costs; delay in payment; and imbalance of supply and demand. Zhang and Han (2022), Dagsuyu et al. (2021), Sastra et al. (2019), Nakandala et al. (2017), Ali and Gurd (2020), Khan et al. (2022), Joshi et al. (2011), Chen et al. (2021) and Zhao et al. (2020) all identify demand instability or market fluctuation risk in the cold chain. Supply-related risks are also identified by many studies (Zhang and Han, 2020; Dagsuyu et al., 2021; Zhang et al., 2017; Nakandala et al., 2017; Khan et al., 2022, Wu and Hsiao, 2021; Chen et al., 2021). Khan et al. (2022) found supply-related risks to be the major risk for the Halal food cold chain. Other supply-related risk concerns with payment delay and the high capital cost (Ali and Guard, 2020; Sharma et al., 2021). Lack of integration and collaboration is another risk factor indicated by Zheng et al. (2021), Zhao et al. (2020), Sharma et al. (2021) and Zhang et al. (2019).

Lack of consumer awareness was found to be one of the key risks leading to temperature disruption in the cold chain (Sharma et al., 2021). Mercier et al. (2017) also found that domestic refrigeration was when temperature disruption occurred the most. Also, sometimes different cold chain products are transported and stored in the same logistical containers due to convenience and cost considerations. Since different temperature requirements exist for different cold chain products, e.g. dairy, fruit, vegetables, meat, seafood, medical and pharmaceutical products, etc., it is challenging to manage and standardize the temperature requirements. Therefore, it is important to comply with regulations that specify a standard for cold chain temperature managements for different products. Other risks include 'unable to meet required quality', 'skill shortage', etc.

2.4.3.3 Logistical risks

Logistical risk refers to hazards that may occur during transportation and storage, of which 'poor loading/unloading/handling' and 'insufficient temperature control' are the most common in CCRM. This type of risk has received great attention in CCRM due to the perishable nature of cold chain products, which have stricter requirements during transportation and storage. Poor quality or shortage of cold chain infrastructure and related devices are the most common risk factors causing cold chain logistical failures (Zheng et al., 2021 Zhang et al., 2017; Sastra et al., 2019; Zhang et al., 2020a; Wu and Hsiao, 2021; Zhao et al., 2020; Sharma et al., 2021; Ridwan et al., 2019; Zhang et al., 2019).

In addition to the cold chain transportation vehicles and storage rooms, monitoring of the cold chain is also important to detect any temperature disruption. Insufficient numbers of detection or monitoring devices can lead to temperature abuse (Zhang et al., 2017). Moreover, lack of awareness or related skills among personnel may lead to improper handling of the packaged products, causing potential risks of product quality decay (Dagsuyu et al., 2021; Zheng et al., 2021; Sharma et al., 2021; Khan et al., 2022).

Many companies choose to use third-party logistics for the transportation and storage of their cold chain products, which can also have potential risks. Sharma et al. (2021) identified the reliability of third-party logistics as one of the inhibitors of the cold chain, and Khan et al. (2022) identified the risks of outsourcing. Singh et al. (2018) analysed how to select third-party logistics for cold chain products, considering logistical infrastructure and warehousing facilities, quality control and inspection, tracking, customer service, etc.

2.4.3.4 Information risks

Since cold chains require constant temperature monitoring throughout transportation and storage, information and data management are of equal importance. Information-related risk concerns managing the information flow of the entire cold chain. Yang and Liu (2018) modelled the information and financial flow of cold chain vulnerabilities in the short term and long term for upstream, midstream and downstream links. Information system process-related risks are identified by some studies (Zheng et al., 2021; Khan et al., 2022; Sharma et al., 2021; Sharma and Pai, 2015; Joshi et al., 2011). Lack of awareness of information technology and management systems is another risk identified (Shashi et al., 2018).

Furthermore, the product temperature data is sometimes not sufficient due to improper monitoring or lack of related devices (Wu and Hsiao, 2021). Mismatched, missed or damaged product information has also been found to be present during the cold chain and has the potential to damage cold chain product quality (Chen et al., 2021; Zhang et al., 2020b).

2.4.3.5 Environmental risks

In addition to logistics, supply chain management and information risks, unexpected disruptive activities can also have dramatic negative effects on the cold chain. Therefore, it is crucial to analyse the external risks, which refer to events or activities not within the control of companies and individuals, such as natural disasters, pandemic, political instability and all other emergent events. Emergency-related risk factors identified by Zhang et al. (2020a) involve equipment maintenance capacity, emergency plan management, etc. Other natural disaster risks include earthquakes, extreme weather, etc. (Nakandala et al., 2017; Sastra et al., 2019; Ali et al., 2018). Zheng et al. (2020) identified ‘extreme weather’ as the riskiest event of the cold chain.

As well as natural disasters, other unforeseen risks also have great impact on the cold chain. Beker et al. (2016) found ‘intentional contamination’ risk in the food cold chain, and food fraud risks are analysed by several studies (Soon, 2020; Soon et al., 2021). Political instability, such as changes in government regulations, and labour strikes also affect the overall effectiveness of the cold chain (Shashi et al., 2018; Nakandala et al., 2017; Khan et al., 2022; Zhao et al., 2020a; Chen et al., 2021; Sharma and Pai, 2015). Also, power outage or unavailability of power may lead to vehicle and cold room breakdowns, damaging the temperature control of the cold chain (Shashi et al., 2018; Sastra et al., 2019; Zhang et al., 2019 a).

2.4.3.6 Packaging risks

Packaging and processing risk concerns the original quality of the products, pre-treatment methods, packaging, etc. In SCRM studies, packaging-related risks are often grouped under the manufacturing risk category, along with other production risks. In CCRM, some studies make packaging a separate risk category (Zheng et al., 2020; Dagsuyu et al., 2021; Zhang et al., 2020a), and ‘packaging material’ and ‘packaging processing’ are common risk factors listed within the packaging risk category.

Apart from the materials and processing of the packaging, other packaging-related risk factors are also identified. Dagsuyu et al. (2021) identified packaging-related risks, including ‘occupational accidents during packaging’ and ‘lack of sanitation’. Zhang et al. (2020b) presented several packaging-related risk factors under the ‘sustainability’ category, such as ‘safety of packaging materials’, ‘packaging reliability and strength’ and ‘packaging sustainability’. Khan et al. (2019) put the ‘packaging issues’ risk under the risk category of outsourcing. All packaging-related risk factors are general terms. Therefore, risk management that focuses on cold chain packaging is needed, while packaging-related risk factors need to be specific and fit the overall function and purpose of the packaging.

Cold chain shipping solutions are often used by companies for their cold chain products. The selection of suitable shipping solutions is important and can be subject to some risks. There are many cold chain shipping solutions available, with various temperature ranges, sizes, capacities and other services, but inappropriate selections may lead to cold chain packaging failure. The selection of phase-change material is essential since it regulates the temperature range of the cold chain packaging.

For logistical shipping containers, besides the parcel and the pallet, accessories such as pallet covers, vacuum insulation, etc., are often available to provide additional temperature maintenance or physical protection (Cold Chain Technologies, 2022a). Choosing suitable accessories affects the performance of the packaging. Apart from PCM and accessory selections, choosing a suitable size and capacity can minimise waste and increase overall cold chain sustainability. Also, add-on services are sometimes provided with shipping containers. For example, Cold Chain Technologies, a cold chain shipping solution company, provides services such as reusable/return service programs, thermal modelling, thermal packaging design, logistic management assistance, training sessions, etc (Cold Chain Technologies, 2022). Selecting appropriate services that fit the overall cold chain goal is important for the cold chain packaging performance and effectiveness.

2.4.3.7 Technology, third party logistic and sustainability risks

Besides the above-mentioned risk factors, other risk factors like technology risk, third party logistic risk and sustainability related risks also received some research attention. Digitalization and decarbonation have been identified as major challenges for container shipping supply chains (Song, 2021). Technologies have great impact on the overall effectiveness and efficiency of cold chains. The risk management model for the strawberry cold chain by Zhang et al. (2020a) groups all technology-related risks into a separate risk category which includes factors like temperature, humidity, pre-cooling time, vibration, etc.

Depending on each company's supply chain and logistical strategies, many choose third-party logistics providers for their cold chain products. Many factors can affect the selection of third-party logistics providers, including specialty, cost, availability, etc. Singh et al. (2017) proposed a third-party logistics selection model considering cost, facilities, network management, etc. Sustainability-related risks have received more and more attention in CCRM literature. Zhang et al. (2020a) identified packaging-related risks, carbon dioxide concentration, preservations, oxygen concentration as sustainability risks of the cold chain.

2.4.4 RISK MITIGATION STRATEGIES IN CCRM

Risk mitigation strategies are identified and assessed by several studies: Zhang and Han (2020), Dagsuyu et al. (2021), Sastra et al. (2019), Ali and Gurd (2020), Beker et al. (2015), Ridwan et al. (2019), Ali et al. (2018) and Chen et al. (2019). Some risk mitigations are at the strategic level; for example, Zhang and Han (2020) conducted risk management in medical cold chains and proposed mitigation strategies such as encouraging marketization, learning from more advanced logistical information systems and developing logistical information platforms using new technologies. Other strategic suggestions include changing suppliers, improving inventory systems, providing more personnel training, increasing knowledge sharing, improving integrity of supply chains, improving related technologies and management systems, etc (Ali and Gurd, 2020; Zhang and Han, 2020; Chen et al., 2021; Dagsuyu et al., 2021).

Operational-level strategies are also provided by some models that involve making banners in rooms, giving penalties to fishermen who do not handle catch results properly, unloading the results of fishing on the dock, etc (Ridwan et al., 2019; Sastra et al., 2019). Ali and Gurd (2020) propose knowledge-sharing risk mitigation strategies to manage the operational risks for food cold chains; such strategies include supply chain partners sharing integrated knowledge, information and data regularly, jointly developing R&D, etc.

Also. time and cost constraints are sometimes considered when conducting risk mitigation strategies and actions (Dagsuyu et al., 2021; Ridwan et al., 2019). A scale effect is hard to achieve because the transportation and storage of refrigerated medicines has “multi batch, small batch, high aging” characteristics (Zhang and Han, 2020).

Table 2.16: Risk mitigation studies

Sources	*Research concentration*	*Risk mitigation strategies identified*
Zhang and Han (2020)	*Risk management of medical cold chains in China*	*Design a refrigerated car with multi-temperature control system, build a more efficient information platform of medical cold chain logistics incorporating technical forces, adopt marketization under the guidance and promotion of the government*
(Dagsuyu et al., 2021)	*Risk management of a third-party logistics company, with constraints of time and budget*	*Change supplier, revise inventory management system, hygiene training, job training, occupational health and safety training*
(Sastra et al., 2019)	*Risk management of frozen tuna*	*Choosing suppliers based on the good quality of staple ingredients (analyze the strengths and weakness of suppliers, make an absolute work contract), supplier must use vehicles that are appropriate to the fish shipping standard (use pick up cars where ice is included, use motorcycle or becak that is equipped with insulation).*
(Ali and Gurd, 2020)	*Managing operational risks through knowledge sharing in food cold chains*	*Firms and supply chain partners have integrated knowledge base and know-hoe, frequently share scientific knowledge and jointly invest in R&D, frequently share data on production, distribution and sale, jointly develop business b=plans and solve problems, have cross organisational teams for process improvement*
(Ridwan et al., 2019)	*Risk mitigation for a fish port*	*Consult on how to handle good catch results, give penalties for fishermen who do not handle catching results properly, add the port operational section in the field of fish demolition inspection, propose the procurement of fishing*

Sources	Research concentration	Risk mitigation strategies identified
		aids to the ministry of Maritime affairs and fisheries, prepare of fishing when the ship is on the dock
(Ali et al., 2018)	Resilience model for cold chain logistics	Business certifications, cross trained workplace, quality management system, multi-sourcing
(Chen et al., 2021)	Risk management of Chinese fresh cold chains	Improve the integrity of supply chain network members, improve the distribution efficiency and quality of logistics, improve cold chain storage technology and the quality of cold chain technology, adopt information management technology

2.5 RESEARCH GAPS IDENTIFIED

Despite the existence of a fair number of existing studies in cold chain management and cold chain risk management, there is still a lack of focus on the cold chain packaging system. Many studies in cold chain management discuss forms or components of cold chain packaging but there is a shortage of research with packaging as its focus. Packaging in the cold chain is a broad term and needs further comprehensive analysis. Most of the literature in cold chain risk management relies on empirical studies or is limited to one specific industry or product. Thus, conceptual frameworks and non-industry-specific models are still lacking.

Packaging-related risks are often overlooked in cold chain risk management studies. Although many studies in cold chain risk management have identified packaging as a main risk factor, general terms are often used for packing risks. No studies have delved deeper into the issue of what is making packaging a potential risk for the cold chain and what is causing packaging-related risks. However, packaging plays an essential role in cold chain management since it involves most of the links of the cold chain and is critical in preserving the temperature during transportation and storage.

Monitoring or indicator devices (e.g. for temperature, humidity, etc.) are often incorporated in the packaging, and the passive cooling mechanisms of the packaging can maintain its temperature during loading and unloading when refrigeration is not present. The packaging used along the cold chain has a significant impact on the overall cold chain performance and its overall sustainability, but there are still many uncertainties in cold chain packaging which need more research attention. It is essential that the risk of cold chain packaging should be assessed and managed.

However, cold chain packaging studies mainly focus on material and technology innovations. Moreover, the terms used for cold chain packaging are still vague; therefore, it is important to have clear definitions of the terms and scope of the topic. Furthermore, most of the studies in the field of cold chain risk management concentrate on one specific risk type. Supply risks have received much research attention in the past few years due to the high uncertainty levels caused by the COVID-19 pandemic and geopolitical tensions. Supply risks have a huge impact on cold chain performance; however, other risks also play critical roles during cold chain transportation and storage, such as information-flow-related risk, infrastructural risk and operational risk.

To fill the above-mentioned gaps, this research aims to provide a comprehensive framework for cold chain packaging, which includes a framework model consisting of key performance metrics of the cold chain packaging system and a risk management model comprising risk identification, risk assessment and risk mitigation. This research can fill the knowledge gaps by adding to the knowledge of the cold chain packaging sector, which can serve as a guideline for definitions of important terms in cold chain packaging and the scope of the topic. The risk factors identified, causal relationships and probabilities of the risk factors, together with risk mitigation strategies, can provide some insights and guidelines for professionals in cold chain packaging. The overall effectiveness and efficiency of cold chain packaging systems can be improved through this proposed risk management model, improving product quality and occupational safety.

2.6 CONCLUSION OF THE CHAPTER

This chapter has reported a literature review in cold chain management and cold chain risk management, and research gaps have been identified. Cold chain management studies focus on technologies and innovations for regulating and monitoring the internal environment. Many cold chain risk management studies focus on a specific aspect of the cold chain or a single risk type.

Packaging has been identified as a main influencing factor in causing cold chain disruption. The temperature-sensitive nature of cold chains makes packaging a critical element, since packaging is the primary contact of the cold chain products. However, the definition and scope of cold chain packaging are still vague. What factors influence the performance of the cold chain packaging needs to be explored, and there is a need for analysis of risk and uncertainties in cold chain packaging. Therefore, this study aims to address the above gaps and to propose an integrated risk management model for cold chain packaging. The research methodologies used and conceptual framework of the research will be illustrated in the following two chapters.

CHAPTER 3 RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter explains how this study is conducted and aims to address the research questions proposed in the previous chapter. The overall structure of the study is presented (see Figure 3.2) to illustrate the philosophical, theoretical and methodological links. Since the scope of the study covers the three steps of the risk management process, i.e., risk identification, assessment and mitigation, a selection of methods are chosen for each phase.

3.2 RESEARCH DESIGN

Research aims at using scientific methods to explore and find solutions for problems, test existing theories or develop new theories. The research onion was developed by Al-Ababneh (2020), and serves as an overview framework for conducting research. The research onion has many layers, and each layer considers a different aspect of the research process (Saunders et al., 2000), shown in figure 3.1. Starting from the outer layer, it has research philosophies, research approaches, research strategies, research choices, time horizons, research techniques, and procedures.

In the outermost layer, the research philosophies deal with knowledge development, and the four main types of research philosophy are positivism, realism, pragmatism and interpretivism. The next layer concerns the research approaches, which are principally deductive and inductive approaches. The third layer deals with research strategies, and examples of research strategies are experiments, surveys, grounded theory, etc. The fourth layer of the research onion concerns research choices, where researchers can choose to use a mono-method, multi-method or mixed method. The fifth layer is about the time horizons. The time horizon of the research can be cross-sectional or longitudinal. The sixth layer, or the innermost layer, concerns research techniques and procedures: these deal with the data collection and analysis methods used in conducting the research.

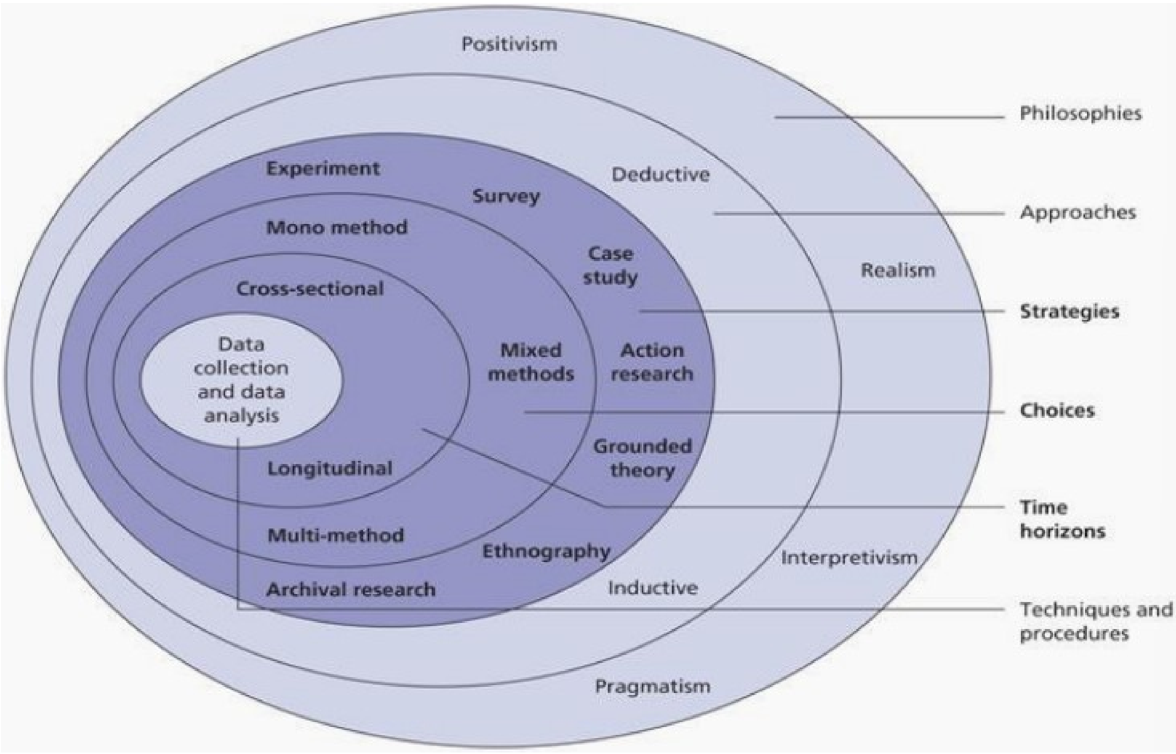


Figure 3.1: Research onion, derived from Saunders et al. (2000)

3.3 RESEARCH PHILOSOPHY

The first step for researchers is always to look at the research philosophy concerning knowledge development and assessment. Different people have different opinions and views on the same event. So the research choice made by the researcher really depends on how the researcher views the world. There are two main research philosophies: positivist and interpretivist research philosophies. The positivist research philosophy views reality as stable, and positivists think that if they observe things from a distance with minimal contact, they can find 'reality', or can assume the findings to be true. Common research methodologies under the positivist philosophy include experiments and surveys. The results are often quantitative.

On the other hand, the interpretivist research philosophy views the world in a different way. Interpretivists do not believe objective truth exists; reality can be multiple or can be created by people. Common research methodologies under interpretivism include hermeneutical and dialectical. Babbie (2014) believes there are two types of interpretivist philosophies: phenomenology and interactionism. Phenomenology is about how humans can assign meanings to the external world, while interactionism is the process by which humans interpret the social world through their interactions with other humans.

3.4 RESEARCH APPROACH

There are two research approaches, i.e., inductive and deductive, according to Brennan(1998). A deductive approach is about the development of a theory continuously tested by a researcher, while an inductive approach is about developing a theory based on observations or empirical data. A deductive approach focuses on scientific principles or theories, and empirical studies can be conducted to test those theories. An inductive approach tends to turn data into a theory. This study utilizes a deductive approach, where an existing method will be used in the context of the research topic, and both qualitative and quantitative data will be collected.

3.5 RESEARCH STRATEGIES AND CHOICES

When only a limited amount of knowledge about the research topic can be found or the subject is of high uncertainty, an exploratory study is usually conducted. Exploratory studies have high flexibility and aim to identify the boundaries of the issues. On the other hand, explanatory studies aim to analyse a particular problem and find causal links between factors. Explanatory studies are very structured in nature, compared to exploratory studies where strict structures are often lacking. In this study, both strategies are used; it follows a mixed-method approach using a combination of quantitative and qualitative methods to conduct research on a specific topic.

A conceptual framework for an industry solution is proposed, using an exploratory study as well as the risk factors and mitigation strategies identified for the risk management model. The data used for this framework is derived from commercially available shipping solutions in the industry, therefore increasing the practical implications of this research. Both qualitative and quantitative data are collected in this study. Details of the data collection and analysis used in this research will be further explained in the next section.

3.6 METHODOLOGY FOR DATA COLLECTION AND ANALYSIS

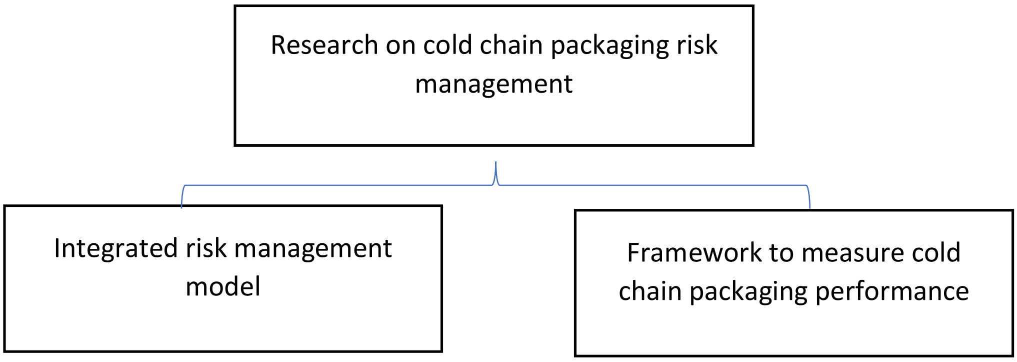


Figure 3.2: Methodology propsoed for research on cold chain packaging packaging research

Figure 3.2 illustrates the proposed research methodology for the thesis. It consists of 2 parts: a framework consisting of key performance metrics and risk management of cold chain packaging. A framework consisting of key performance metrics of the cold chain packaging system will be developed based on literature review. Then an integrated risk management model of the cold chain packaging system will be constructed based on literature review, expert opinions, Fuzzy Bayesian network and TOPSIS inferences.

For the part 1 the conceptual framework to measure the cold chain packaging performance, key performance metrics of the cold chain packaging system can be identified, as shown in Figure 3.3. And not only they are based on literature review but also from industry cold chain shipping solutions. An overview of the industry cold chain shipping solutions will be given based on company websites in the cold chain shipping solution industry. Characteristics of the shipping solutions will be discussed. Also, the scope of cold chain packaging and definitions of key terms used in the field will be defined. At the end key performance metrics can be found based on both academic literature and industry shipping solutions. This can increase the practical applications of the study.

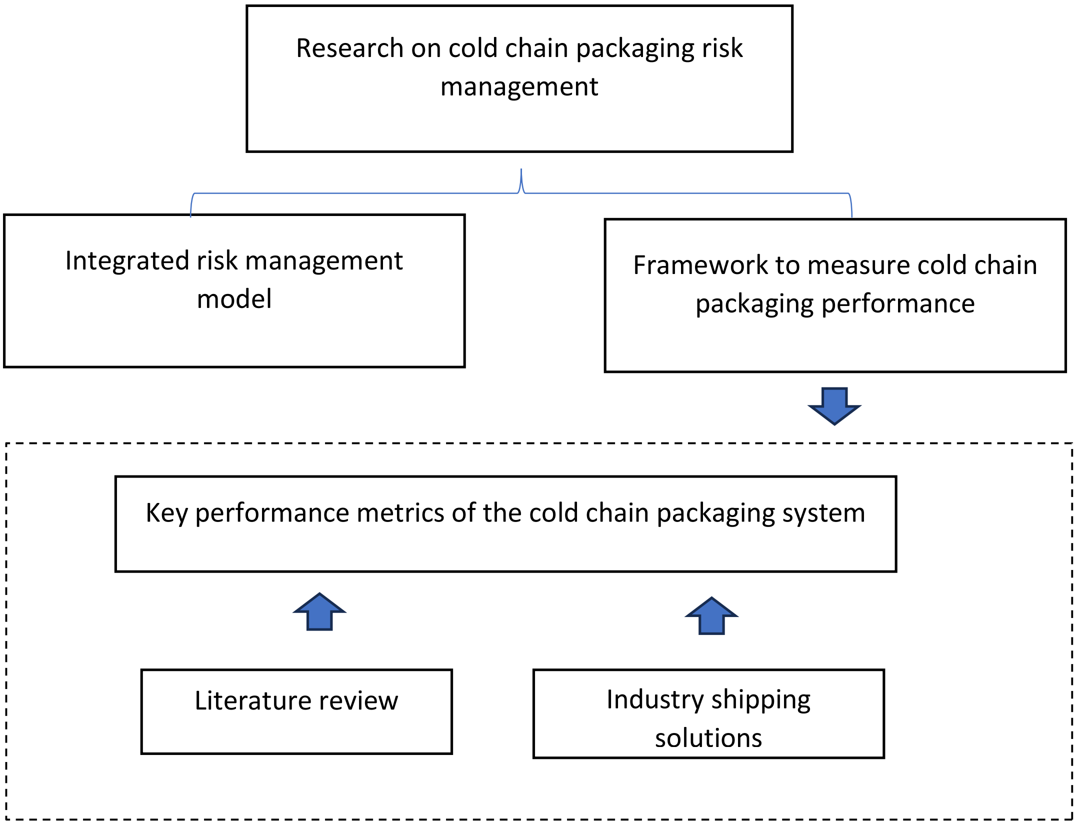


Figure 3.3: Part 1 of the methodology propsoed for research on cold chain packaging: Framework to measure cold chain packaging performance

Part 2 involves the development of an integrated risk management model for cold chain packaging. To capture risk factors as much as possible, both qualitative and quantitative approaches are used, as well as carrying out further expert validation due to the scarcity of existing studies. There are a few risk management steps that involve data collection. Questionnaire are sent out for the purpose of validating the risk factors and risk mitigation strategies identified as well as the assessment of them. The questionnaire used for the study are included in Appendix 1 and 2.

A fuzzy Bayesian network is used to assess risk factors, and fuzzy TOPSIS is used to rank the identified risk mitigation strategies. An case study is conducted on the risk management of vaccine cold chain shipping containers utilizing the proposed integrated risk management model. Table 3.1 details the data collection and analysis methodologies, while the risk management includes three stages: risk identification, risk assessment and risk mitigation. The approaches used at each stage are described in the table. The details of the methods used for the risk management model is shown in Figure 3.4.

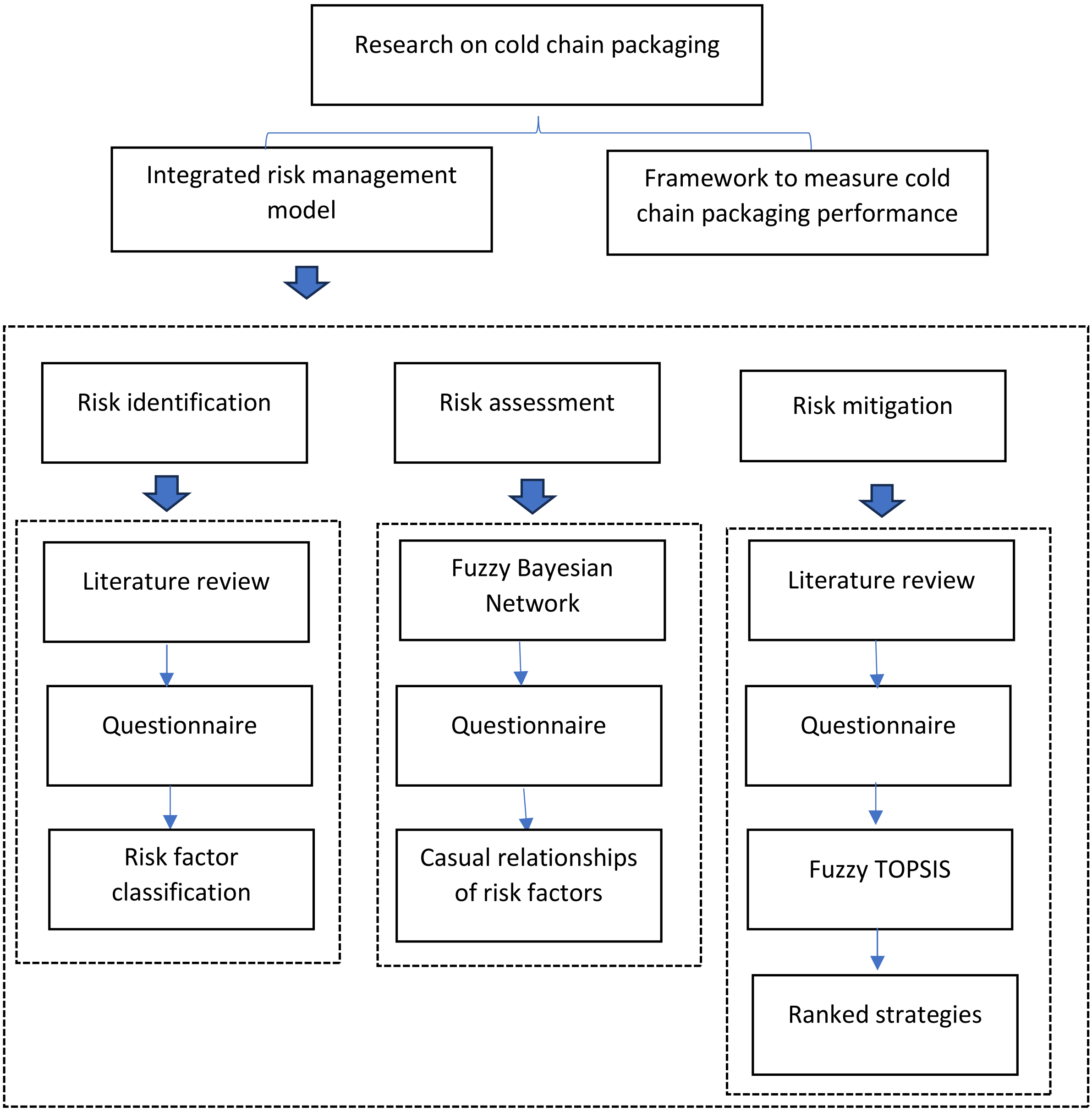


Figure 3.4: Part 2 of the methodology propsoed for research on cold chain packaging: Risk management model

Table 3.1: Summary of the research methods for data analysis

Stage	*Approach*	*Rationale*
Risk factor and mitigation strategy identification	*Literature review*	*To identify relative risk factors and risk mitigation strategies in cold chain shipping containers from academic and industry articles*

Stage	*Approach*	*Rationale*
	Questionnaire	*To validate the identified risk factors, the causal relationships of risk factors, risk mitigation strategies and include any more factors not identified.*
	Interview	*To further investigate the reliability of factors and interrelationship identified.*
Risk factor assessment	*Fuzzy Bayesian Network*	*To assess the causal relationships of the risk factors.*
Risk mitigation strategies evaluation	*Fuzzy TOPSIS*	*To evaluate the risk mitigation strategy factors and determining the priorities.*

The risk management model consists of three parts: risk identification, risk assessment and risk mitigation. First, risk factors will be identified through literature review. Then the results will be verified by experts. Phase two is the assessment of the risk factors identified, and Fuzzy Bayesian Network will be used which the casual relationships and probabilities of the risk factors will be found. Questionnaire will be sent out to experts to verify the casual relationships and assign the probabilities of each risk factor identified. Prior and conditional probabilities of the risk factors are determined by experts, and a seven point Likert scale rating is used since it is recommended by the experts and by the International Maritime Organization (IMO).

For the risk mitigation phase, risk mitigation strategies will be first identified from the literature review. Then the results will be verified by experts using questionnaire and will be further assessed by the Fuzzy TOPSIS approach. The experts are asked the rate the level of importance of each risk mitigation strategy identified. In the case study, a five point Likert scale rating is used since it is suggested by the experts. After the assessment, the ranking of the risk mitigation strategies will be determined. Fuzzy number sets are used for both Bayesian network and TOPSIS methods to convert linguistic terms into fuzzy number sets.

Questionnaire are used for the validation of the identified risk factors and risk mitigation strategies. includes the risk factor and mitigation strategies identified from the literature review, and experts are asked to validate all those factors and suggest removals or additions. The causal relationship of the risk factors and ranking of the risk mitigation strategies are also included in the questionnaire, for validation by experts.

Fuzzy BN and fuzzy TOPSIS are used for the assessment of risk factors and evaluation of the mitigation strategies identified. Fuzzy BN is selected due to its high flexibility, the ability to take multiple forms of data inputs, the incorporation of both qualitative and quantitative data analysis. Fuzzy TOPSIS is selected due to its ability to rank the variables based on multi criteria and to assign the level of importance to each variable. Fuzzy logic reasoning can compensate the limitation of subjectivity of BN and TOPSIS. A seven Likert scale and a five Likert scale of rating tables have been used for the fuzzy BN and fuzzy TOPSIS analysis, as suggested by domain experts. To further validate the results, sensitivity tests are conducted. Sensitivity tests are good to see if the model is sensitive or robust regarding input changes. After the sensitivity tests, we can see how sensitive the fuzzy BN and fuzzy TOPSIS models are towards input changes.

3.7 CONCLUSION OF THE CHAPTER

In this chapter, the research onion research methodologies have been reviewed and different layers have been explained. How the methods used for this research correspond to the research onion is also discussed. Both qualitative and quantitative data are collected. Methodologies used for the research are discussed. This research consists of 2 main parts:

part 1 a conceptual framework to measure the cold chain packaging performance and part 2 an integrated risk management model for cold chain packaging. For part 1 the framework to measure cold chain packaging performance, review of the exiting literature and available industry cold chain shipping solutions are done to identify the key performance metrics of the cold chain packaging system. Key terms used in cold chain packaging and the scope will also be defined.

For part 2 the risk management model, there are three stages: risk identification, assessment and mitigation. During the first stage, risk identification, risk factors are identified and assessed through the literature review, and then these are validated through questionnaire surveys and interviews with experts. Next, in the risk assessment phase, risk factors are assessed using a Fuzzy Bayesian Network, where linguistic terms are turned into quantitative data and fed into the model. The causal relationships between risk factors are further validated by experts, and the probability of each risk factor is calculated from the linguistic terms provided by the experts using fuzzy set theory. Finally, in the risk mitigation phase, the risk mitigation strategies are first identified by reviewing literature and documents, which are then verified by experts using questionnaire. A fuzzy TOPSIS method is used for this phase, in which the risk mitigation strategies are ranked based on expert opinions.

CHAPTER 4 CONCEPTUAL FRAMEWORK FOR RESEARCH INTO COLD CHAIN PACKAGING

4.1 INTRODUCTION TO THE CHAPTER

The goal of this chapter is to propose a conceptual framework for research into cold chain packaging to be used as a foundation and guideline to assist with decision-making in the field. The proposed conceptual model comprises two main parts: a conceptual framework consisting of the performance metrics of cold chain packaging and an integrated risk management model for cold chain packaging. An overview of the current cold chain packaging industry will be given, followed by the key performance metrics for cold chain packaging. Next, the development of an integrated risk management model for cold chain packaging will be presented, which includes three steps: risk identification, risk assessment and risk mitigation. Each step is explained in detail in this chapter.

4.2 THE DEVELOPMENT OF A CONCEPTUAL FRAMEWORK FOR RESEARCH INTO COLD CHAIN PACKAGING

A conceptual framework for this research into cold chain packaging, focusing on managing risks, is shown in Figure 4.1. This conceptual model consists of a conceptual framework with key performance metrics and an integrated risk management model. Continuous improvement can be achieved with a closed loop of risk identification, risk assessment, risk mitigation and performance outcomes of cold chain packaging. The performance outcomes of the cold chain packaging system need to be measured by identifying key performance metrics or indicators of the system. This part will be linked to the risk identification and risk mitigation steps. Risk factors will be identified from the performance outcomes of the cold chain packaging system. Also, the implementation of risk mitigation strategies will have an impact on the performance outcome of the cold chain packaging system.

Therefore, measuring the performance outcomes of the system is important. Thus, the conceptual model comprises of the key performance metrics of the cold chain packaging system will be given. Since many companies in the industry have developed cold chain packaging solutions for transporting various products. An overview of the cold chain packaging industry is covered, and the performance metrics identified will be based on results from both literature review and industry solutions to improve the practicality of the model.

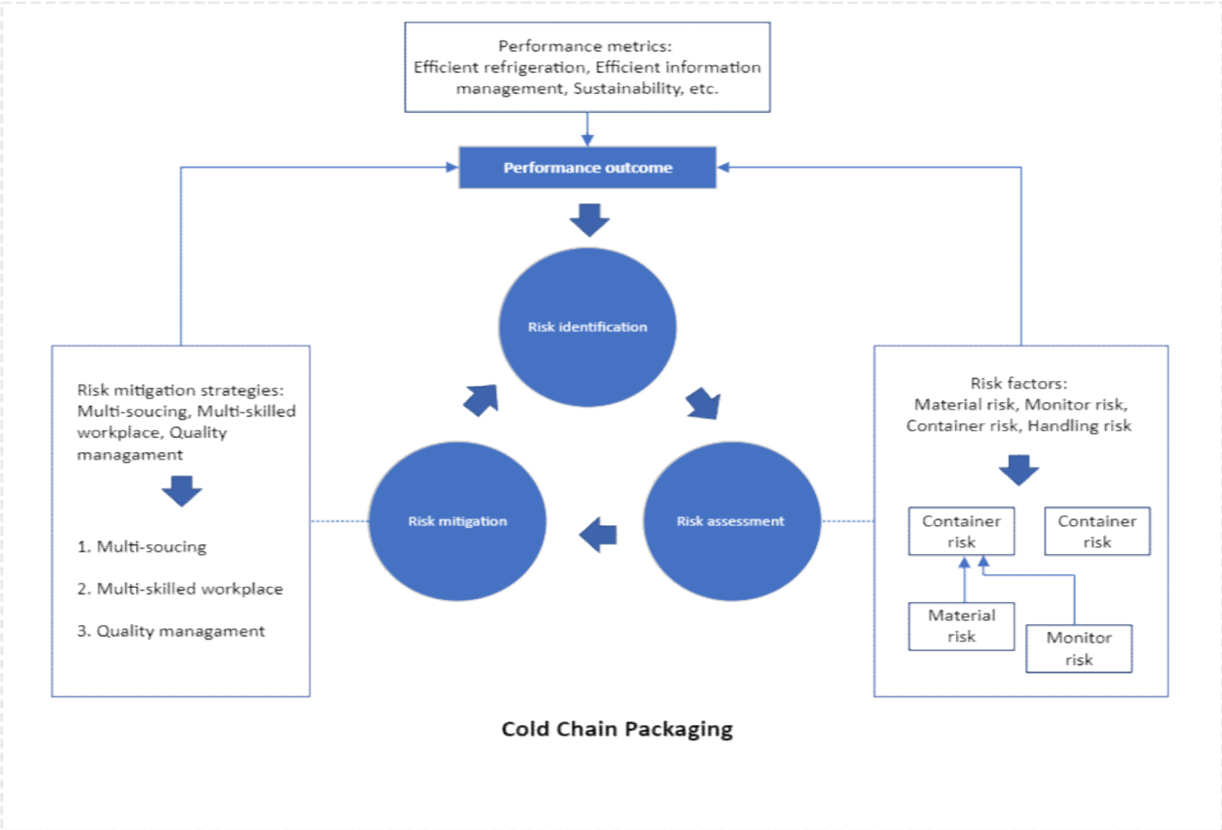


Figure 4.1: Conceptual framework for research into cold chain packaging

4.2.1 PERFORMANCE METRICS OF THE COLD CHAIN PACKAGING SYSTEM

To solve a problem, the first requirement is to understand what the problem is, instead of jumping straight into the problem-solving stage. The factors that may affect the performance of cold chain packaging need to be analysed. Also, the implementation of the risk management system will have an impact on the performance outcome; the performance outcome is not a static condition and can be changed by the implemented risk mitigation strategies. Therefore, it is important to assess what factors will influence the performance of cold chain packaging.

An overview of the cold chain packaging industry is carried out to provide the context for the conceptual model. A pallet-parcel-coolant-PCM hierarchical structure model for cold chain refrigeration systems is also developed to help better understand the structure of cold chain packaging. Based on the overview, key performance metrics are proposed, and details will be discussed in Chapter 5.

4.2.2 DEVELOPMENT OF AN INTEGRATED CCP RISK MANAGEMENT MODEL

Risk management is a decision-making process identifying and assessing risks related to the scenario and proposing appropriate risk mitigation strategies. It is an efficient approach for analysing the supply chain network and supply chain disruption. Supply chain risk management is a risk management process regarding how disruption affects the supply chain activities and aims to detect and explain the whole process of turbulence during supply chain planning and processing. Decision-making is essential for risk management and supply chain risk management. Therefore, suitable decision-making approaches need to be chosen for each step of the risk management model.

There are three main components of risk management: risk identification, risk assessment and risk mitigation. A good risk management process should be able to detect and analyse risks, which paves the way for risk mitigation strategies. This is an iterative process, since after the implementation of the risk mitigation strategies, the dynamic of the system may change, which may cause some unforeseen events or new disruptions. The same risk management may not be as effective for all scenarios, so it is necessary to continuously monitor the system's performance so as to construct a continuous improvement loop. This can help the model to continuously learn from mistakes and past experiences.

Since the public and private sectors are both involved in the cold chain packaging industry, the process needs to be integrated and transparent. This continuous improvement process is beneficial for companies and other stakeholders for the cold chain packaging industry. Therefore, the integrated risk management framework proposed for cold chain packaging contains three main supply chain risk management steps. Th proposed risk management model consists of three steps, so one methodology will not fit all of the steps; the methodologies used for each step are explained in the following sections.

The existing literature in cold chain risk management has identified ‘packaging’ as a main impact factor in cold chain disruption, since packaging is involved in the logistics, supply chain and temperature control of cold chain management. Therefore, it is essential to assess the risk factors associated with the cold chain packaging system.

Cold chain packaging involves many stakeholders, including both the public and private sectors. It is important to critically detect and assess the potential risks in the planning and processing of cold chain packaging, so that the overall effectiveness and efficiency of the cold chain can be improved for the benefit of all the providers and practitioners in the cold chain industry. To achieve this goal, an integrated risk management model is proposed for cold chain packaging comprising risk identification, assessment and mitigation, as shown in Figure 4.7.

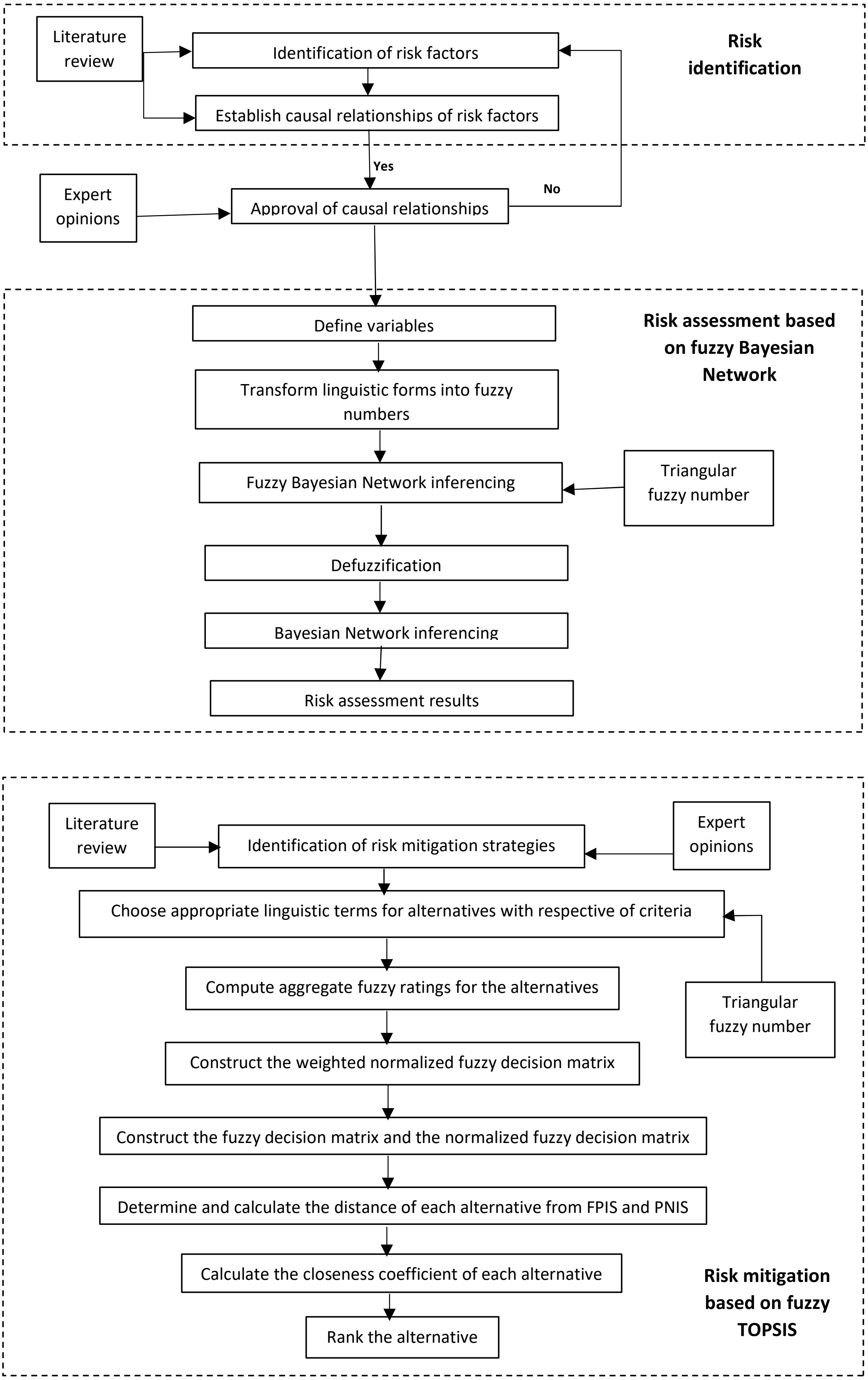


Figure 4.7: Proposed integrated risk management model for cold chain packaging

First, risk factors and causal relationships are identified through literature review, and they are verified by experts. The risk assessment component involves analysing the causal relationships and probability of the risk factors identified based on the fuzzy Bayesian network method. The risk of the upstream organisations will have an impact on the downstream organisations and vice versa. Therefore, it is important to understand the supply chain network of an industry when conducting risk analysis, due to the interdependencies of supply chain activities.

The risk mitigation component is about the implementation of supply chain risk mitigation strategies to reduce cold chain packaging risks. The risk mitigation strategies are identified from the literature review (Chapter Two) and then verified by experts. The implementation of risk mitigation strategies can continuously improve cold chain packaging performance outcomes; risk management is not a static condition, and continuous monitoring is needed. Therefore, a risk management system with continuous improvement loops can be formed. Each step of the risk management model will be explained in detail in the following sections.

4.2.2.1 CCP RISK IDENTIFICATION

The first step is the identification of risk factors: this step is critical since it gives a basic understanding of what factors may lead to unfavourable consequences. It also impacts the subsequent risk assessment and mitigation steps. Literature review and questionnaires are good risk identification methods. In this thesis, a literature review is conducted first, allowing a preliminary causal relationship model of cold chain risk to be formed. Then the risk factors and causal relationships are verified by experts; This can provide a primary overview of the causal relationships of risk factors in cold chain packaging.

However, this cannot guarantee that all of the risk factors can be found in this way, so a feedback loop needs to be developed to continuously modify the model. Questionnaire surveys are used to get **feedback from experts about the risk factors and causal relationships identified from the literature. Thus, the risk factors identified can be**

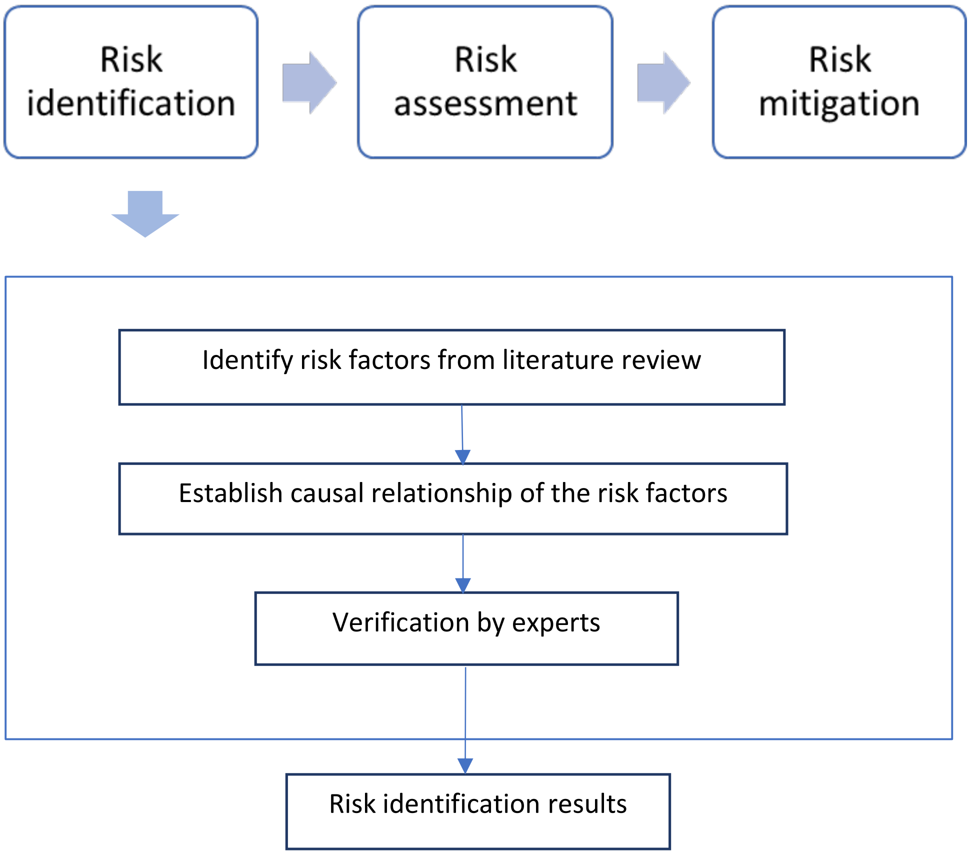


Figure 4.8: Flow diagram of the risk identification process

further analysed so that their comprehensiveness and causal relationships can be verified.

4.2.2.2 CCP RISK ASSESSMENT

Risk assessment is the second step in the risk management model. Many decision-making techniques have been selected for risk assessment in cold chain risk management studies, such as Bayesian Network (BN), Analytical hierarchical process (AHP), fuzzy inference system (FIS), Interpretive structure modelling (ISM), Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS), machine learning algorithms, etc. For studies concentrating on supply chain risks, the supply chain operation system (SCOR) method is sometimes used to map out the activities of the supply chain before risk assessment, while the house of risk (HOR) and pareto diagrams are often used to prioritize the risk factors.

AHP consists of a goal, several options or alternatives and a group of criteria with respect of the alternatives. Pairwise comparison is done of the alternatives based on the criteria (Joshi et al., 2011; Singh et al., 2017; Dagsuyu et al., 2021; Khan et al., 2022)**.** ISM is an interactive learning process that fragmented information are structured into a comprehensive system model based on adjacency and reachability matrixes (Zhang and Han, 2020). Both AHP and ISM have hierarchical structures. Support vector machine is a machine learning algorithm that uses supervised learning models to solve complex classification, regression and outlier detection problems (Zhang et al., 2020a)**.** BN is commonly used for accessing uncertainties and representing links between variables and has been used widely in the field of risk management (Sastra et al., 2019).

There are pros and cons of each method. AHP and BN have advantages of being able to analyze multiple forms of data input, like datasets and expert opinions. Inputs based on expert opinions are variables assigned by experts instead of being derived directly from experiments, observations or datasets. BN also has pros of assigning probabilities to its variables. BN is also proven to be more robust and flexible and thus has many applications, e.g., risk modelling, engineering safety and reliability management, medical diagnosis, etc. (Nguyen et al., 2019). Machine learning algorithms can assess large data sets but may not work well when there is not enough data. BN is selected as the decision-making method for the risk assessment due to their high flexibility and the ability to demonstrate interconnections among risk factors.

BN originates from statistics and artificial intelligence and aims to study the uncertainty in knowledge-based systems. BN is a probabilistic graphical model for uncertainty modelling that contains nodes and directional arcs between nodes. The directional arcs represent the causal relationships of different nodes. When two nodes are not directly linked to each other, they are assumed to be conditionally independent. The degree of dependence between nodes is represented by conditional probabilities, which is usually determined by historical data and expert opinions. The conditional probabilities of the BN nodes are calculated based on the formula below:

$$\boldsymbol{P(A|B) = \frac{P(B|A)P(A)}{P(B)}} \qquad (4.1)$$

P(A) is the prior probability of event A, and P(A|B) is the posterior probability. P(B) is the probability of event B, and P(B|A) indicates the probability of A when B has already happened. Conditional probability tables (CPT) are needed for all the non-root nodes. Then the probability value of each node is determined based on the data derived from expert opinions and practitioners in the field. A triangular fuzzy number will be used to account for any linguistic ambiguity to expand the BN model to a fuzzy BN model.

BN can also take multiple forms of information, e.g., datasets and expert opinions, which makes it a good option for cold chain risk analysis because perfect data is hard to obtain for cold chains. BN also has the merit of being able to update the system with new information. This is particularly useful for complex systems, since interdependencies between risk factors have a significant impact on the overall performance, which issue can be solved by BN (Ren et al., 2009). Both forward and backward inference can be achieved using BN models.

GeNie is graphical editor for interactive model building and learning. It can build dynamic Bayesian networks of any order and also has flexible data handling features which can include import from external databases. Figure 4.9 demonstrates an example BN model developed by GeNie, which we can see that the casual relationships and probabilities are shown in the figure. As we can see from the figure, the states of nodes can be probabilities or numbers. In this research, GeNie is used for the Bayesian network inferencing for the risk management model.

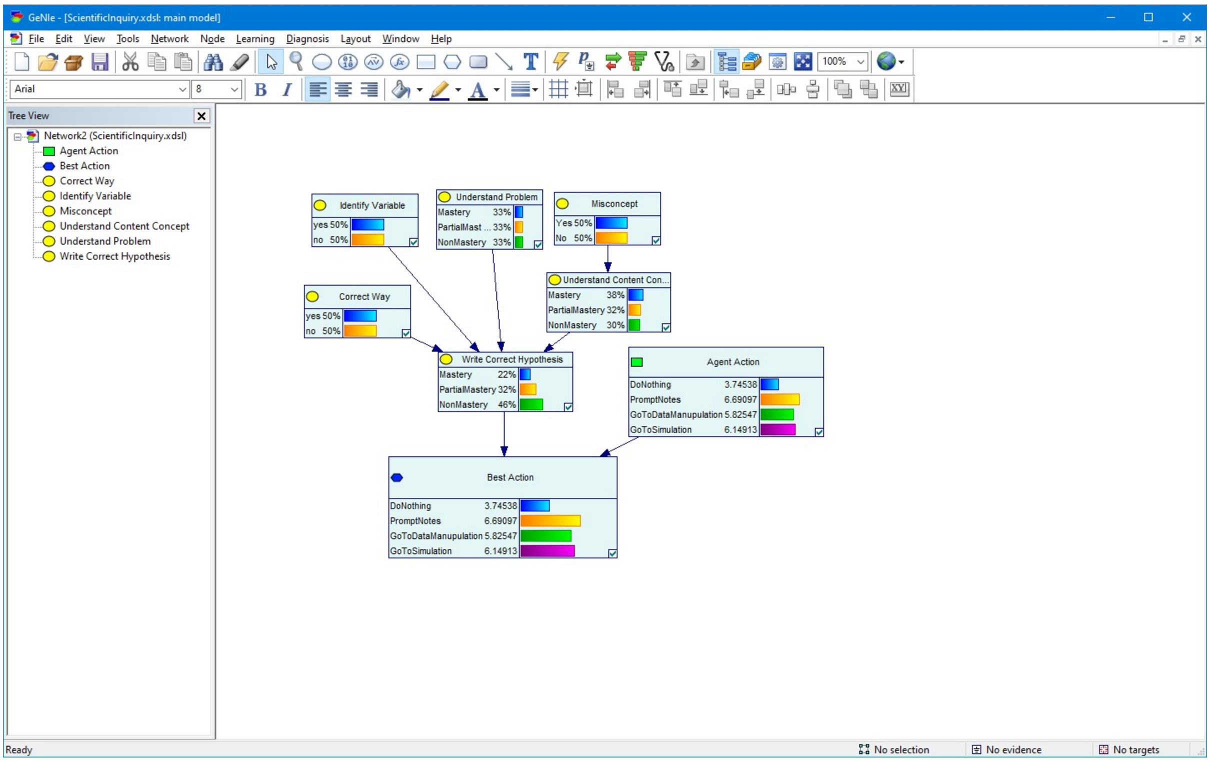


Figure 4.9 GeNie interface demonstration from BayesFusion (2023)

Despite all of BN's advantages, it is still subject to some limitations. Only crisp numbers, or numerical probabilities, can be input into BN-based models. Sometimes it is hard to obtain complete data. Expert feedback and opinions can be subjective and vague, and some people may not be very comfortable with assigning numerical levels for probabilities. In this way, fuzzy logic reasoning can be incorporated to deal with system uncertainties and vagueness. Fuzzy logic theories are often used to deal with issues with a high level of vagueness and have been used widely in decision analysis, classification, approximation, etc.

Fuzzy number sets were first conceptualised in the 1960s by Zadeh (1965) and aim to represent the degree of truth. Fuzzy logic models use mathematical methods to represent vagueness and imprecise data and information. It is very flexible but depends heavily on specific scenarios. Fuzzy logic defines what linguistic terms are suitable to describe a variable and convert them into numerical values. A fuzzy membership function defines the associated reliability of the values. A fuzzy membership function maps input numbers into a range from 0 to 1, based on their possibility of being a member of the set. A combination of fuzzy logic reasoning and Bayesian Network modelling methods can be used to deal with the high uncertainty and complex causal relationships due to the complicated interdependence of risk factors and insufficient data from cold chain packaging systems.

Fuzzy logic methods often include fuzzification, inference and defuzzification. Through fuzzification, experts can use linguistic terms like "high" and "low" to determine how likely a particular risk factor is to occur or lead to the occurrence of other risk factors. Rather than using linear expressions, fuzzy membership functions and fuzzy-based rules are often used for the inference of models. Membership functions are often used to describe the fuzziness of the number based on the degree of truth. Common forms include triangular, trapezoidal, Gaussian membership functions, etc. Fuzzy inference has the advantages of providing flexibility and levels of probabilities when assessing experts' opinions. Then, in the stage of defuzzification, fuzzy numbers are converted back to crisp values. Common defuzzification methods include bisector and centroid defuzzification (Ren et al., 2009)**.**

Many cold chain risk management studies have incorporated fuzzy logic into their risk assessment systems (Nakandala et al., 2017; Bai et al., 2018; Sastra et al., 2019; Zhang et al., 2019; Zhao et al., 2020a; Dagsuyu et al., 2021; Sharma et al., 2021; Wu and Hsiao, 2021). Tsang et al. (2018) proposed a dynamic fuzzy occupational safety risk assessment model including input parameters like body mass index, age, average heart rate, average calories burnt and work experience. Experts' judgements are needed to decide what fuzzy membership shapes and rules are used. Trapezoidal and triangular membership functions are the most used methods due to their simplicity. Rule-based fuzzy inference is often used to determine the correlation probabilities between parameters. Therefore, a fuzzy BN method is used for the assessment of the risk factors. The flow diagram of the proposed BN-based risk management model is shown in Figure 4.9.

Triangular fuzzy membership functions are used for the fuzzy BN-based risk assessment. The first step is to define the problem and identify all the risk factors and causal relationships through past data and expert opinions. Then, main variables can be defined and input into the fuzzy BN-based risk management model. Next, sensitivity analysis will be conducted to test the sensitivity of the parameters by changing their values to see how this affects the outcomes. Defuzzification is done through transforming fuzzy number sets back into crisp numbers, which can then be input into BN modelling.

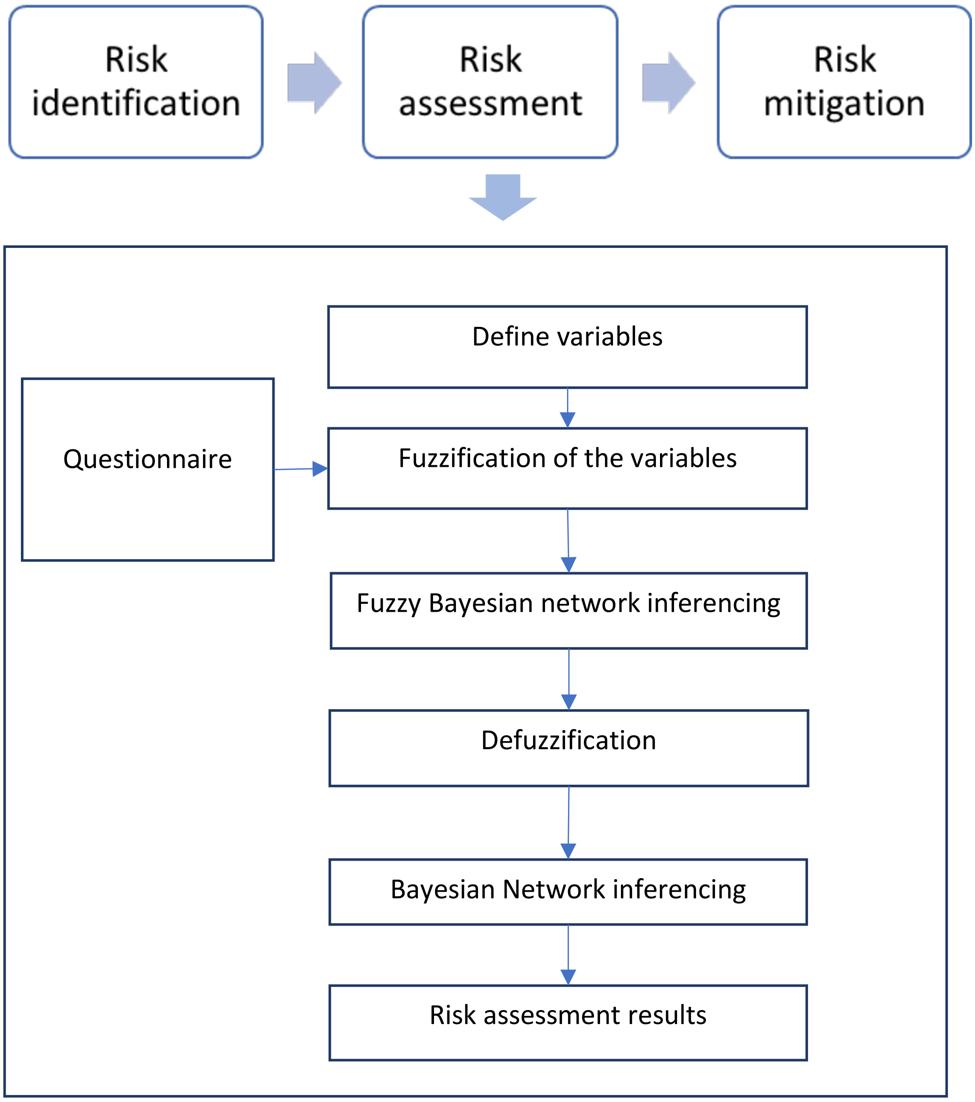


Figure 4.10: Flow diagram of the BN based risk identification and assessment process

4.2.2.3 CCP RISK MITIGATION

After risk identification and assessment, the final step focuses on the identification and assessment of the risk mitigation strategies. Risk mitigation strategies are actions or solutions that can be implemented to reduce the adverse impacts caused by the risks. Many multi-criteria decision-making methods have been used to reduce cold chain risks, including TOPSIS, House of risk (HOR), Mixed integer programming, Fuzzy inference system (FIS), Mamdani fuzzy logic, etc. Among these methods, TOPSIS has the advantage of being able to rank and choose the best alternative that is closest to the positive ideal exposition and farthest from the negative exposition, i.e., the one that has the shortest distance to the positive ideal solution and the longest distance to the negative ideal solution (Hwang and Yoon, 1981). TOPSIS can locate the option that considers the best- and worst-case scenario of the alternatives simultaneously. It is a good method for evaluating risk mitigation strategies, since it can deal with various weight estimation systems. It also has the advantage of having no limit to the number of criteria and attributes (Rashidi and Cullinane, 2019). Liu et al. (2016) integrated TOPSIS with a consistency-based linear programming model.

However, TOPSIS is subject to some limitations. It is not able to handle vagueness and imprecision on the part of decision-makers, though this can be compensated for by the fuzzy set theory. Similar to Bayesian Networks and AHP, TOPSIS relies on the input of expert opinions, which are likely to be vague and imprecise. Therefore, it is necessary to incorporate fuzzy set theory with TOPSIS, and fuzzy TOPSIS is good at systematic and objective evaluation of multiple alternative criteria. Fuzzy TOPSIS aims to find an alternative that is close to the Fuzzy Positive Ideal Solution (FPIS) and far from the Fuzzy Negative Ideal Solution (FNIS).

There have been many applications of fuzzy TOPSIS. Chen (2000) proposed a TOPSIS for group decision-making under a fuzzy environment. Many scholars have proposed TOPSIS with fuzzy set theories. Rashidi and Cullinane (2019) utilized fuzzy TOPSIS for selecting suitable sustainable suppliers. A generalized fuzzy linguistic weight average operator was introduced to assess the linguistic information by Xian and Guo (2020). Fuzzy TOPSIS is often used to select the best alternatives for aggregate scores based on proposed criteria and linguistic terms. step. Therefore, fuzzy TOPSIS is selected as the decision-making technique for the risk mitigation step. Figure 4.11 illustrate the flow chart of the risk mitigation process. The specific steps of the fuzzy TOPSIS process are indicated in Figure 4.12.

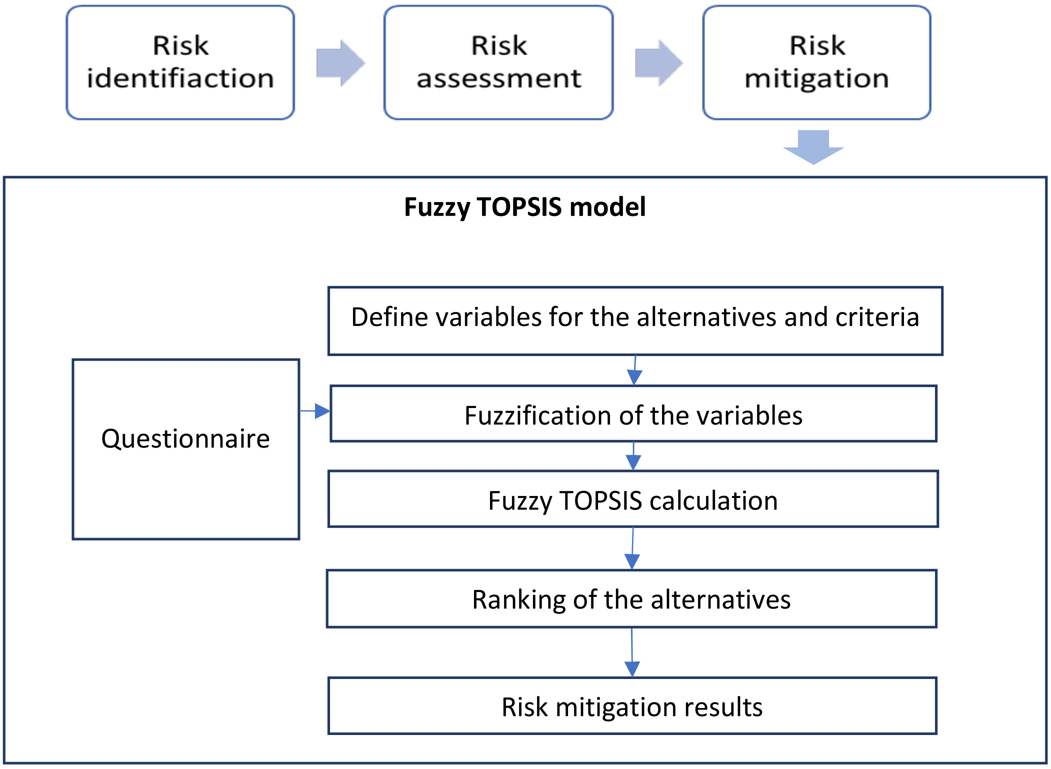


Figure 4.9: Flow diagram of the risk mitigation process

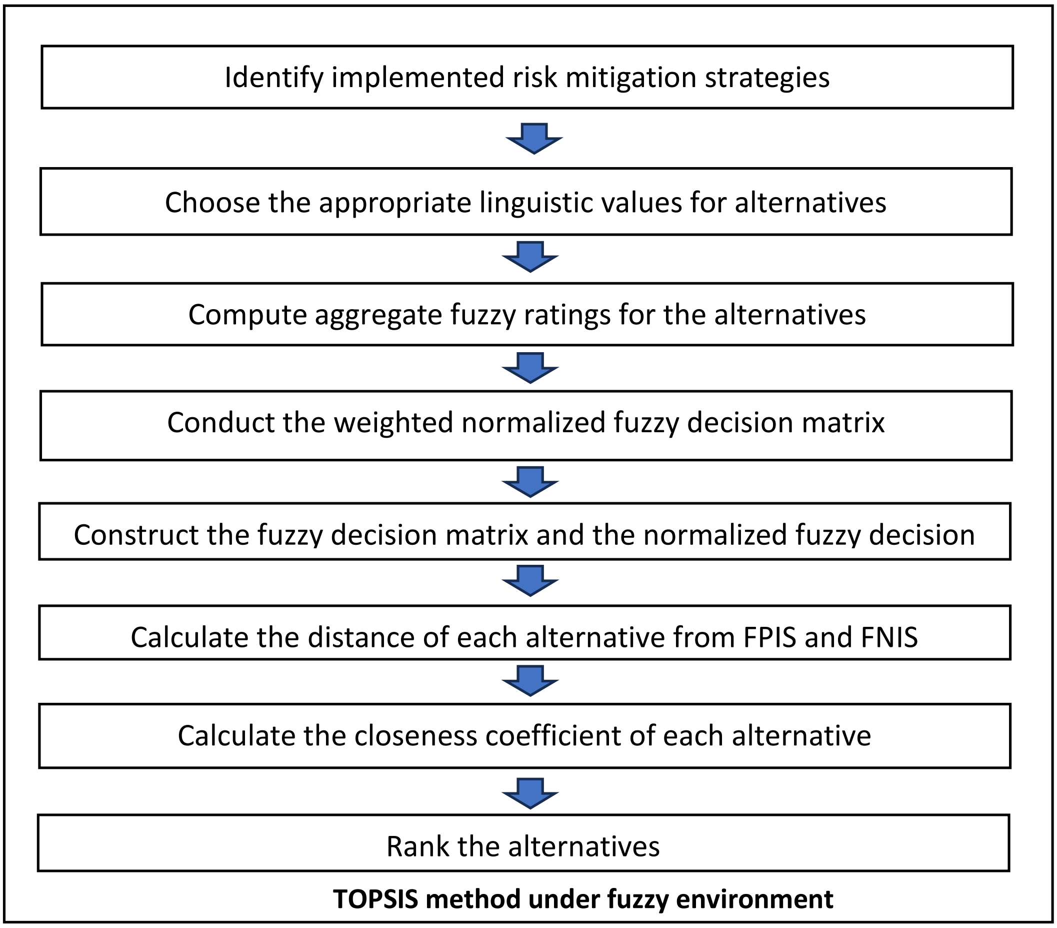


Figure 4.10: Flow diagram of the Fuzzy TOPSIS-based risk mitigation process

4.3 CONCLUSION OF THE CHAPTER

This chapter develops a conceptual framework for research into cold chain packaging, which can be used as guidance to assist with decision-making in the industry. Based on this framework, key performance metrics of the cold chain packaging system can be determined, and an integrated risk management model is proposed which includes risk identification, assessment and mitigation. The development of an integrated risk management model is important since many risk factors are interdependent, which means that one event may lead to other events, and most supply chain failures are complex in nature. The risk management model first identifies risk factors from a literature review, and these are then further validated by experts. Then the risk factors are identified using a Fuzzy Bayesian Network method. Risk mitigation strategies are then identified and assessed using the Fuzzy TOPSIS method. The utilization of the proposed risk management model will be followed in the next chapters to identify, assess and mitigate risk factors in cold chain packaging.

CHAPTER 5 THE DEVELOPMENT OF A CONCEPTUAL FRAMEWORK TO MEASURE THE COLD CHAIN PACKAGING SYSTEM PERFORAMNCE

5.1 INTRODUCTION TO THE CHAPTER

Many researchers and companies have investigated and reviewed the topics of PCMs and cold chain shipping solutions, most papers have focused on the PCMs or individual shipping solutions. However, there is still no comprehensive review of cold chain shipping solutions, and the structure and components of shipping solutions are not specified or standardized by any studies. Many companies have launched comprehensive cold chain shipping packaging solutions for various cold chain products. But these industry solutions are often overlooked in cold chain packaging studies. Therefore, this section aims to propose a conceptual framework to measure the cold chain packaging system performance that incorporates both academic literature and industry shipping solutions.

A hierarchical model detailing the structure of cold chain shipping solutions is proposed, along with a conceptual framework developed with key performance metrics of the system. This can contribute new concepts and ideas to the literature on cold chain packaging, and by incorporating the industry's perspective, the overall practicality of the study can be improved. This can be beneficial for stakeholders and provide them with practical guidelines. The scope of cold chain packaging and some key definitions are given first to help better understand the concept.

5.2 THE SCOPE OF COLD CHAIN PACKAGING

Cold chain packaging is a complex system, and the term "Cold chain packaging" have been used to refer to different things in literature and industry. Cold chain packaging can refer to cartoons for fresh produce (Berry et al., 2016, 2019), or insulation materials or cooling approaches used in packages, shipping containers (Ge et al., 2013; Singh et al., 2013), sensors, indicators or approaches to monitoring the cold chain (Fuertes et al., 2016; Singh et al., 2018a; Abu-Thabit et al., 2020; Baek et al., 2020). . In most studies, a specific device, material or technology of the packaging used in the cold chain is discussed, and they are all called “cold chain packaging”. Therefore, it is important to first clarify the definition and scope of the it. Different terms have been used to describe cold chain packaging in academia and industry. It is necessary to summarize the common terms often used in cold chain packaging studies and clarify the scope of the term.

Terms like “refrigerated container”, “cold storage box”, “passive cooling box”, “packaging film”, “shipping container” are used in cold chain studies. These terms are all forms of cold chain packaging, and cold chain packaging can include PCMs, refrigerators, sensors, indicators, insulation, active substances, stacking of cartons, etc., as illustrated in Figure 5.1. The design or selection of cold chain packaging should consider all of these features, which have all been discussed in previous sections of this thesis. Other factors that need to be considered during the design of cold chain packaging include infrastructure conditions,

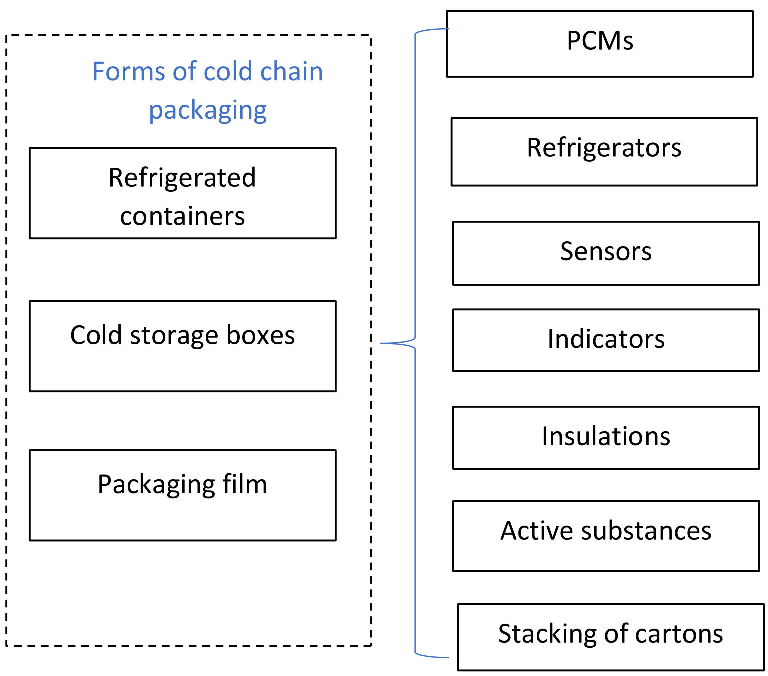


Figure 5.1: Main forms and components of cold chain packaging

compliance requirements, resources available, cost, time, etc.

To better understand the scope of cold chain packaging, some previously mentioned concepts need to be revisited first. In previous sections, terms like 'cold chains', 'packaging', 'container', 'refrigerated container', 'cold chain cooling system' and 'monitoring system' have been used and discussed. They are all related to cold chain packaging in various ways and there is some overlap among these concepts. Table 5.1 summarizes definitions of these terms. 'Packaging' and 'cold chain' are both very broad concepts: 'cold chain packaging' is the overlapping of cold chain' and 'packaging', as illustrated in Figure 5.2.

Table 5.1: Summary of definitions of some key terms

Term	*Definition*	*Sources*
Packaging	***All of the devices and approaches that provide containment and protection for the goods, interaction and communication for different stakeholders, and incorporate design features that are ergonomic and meet logistical requirements***	***(Lydekaityte and Tambo, 2020)***
Cold chain	***All activities from when products are harvested or manufactured all the way to when they are consumed or used***	***(Ren et al., 2021)***
Container	***Large standardized containers used to store goods during shipment***	***(Rodrigue and Notteboom, 2020a).***
Refrigerated container	***Containers with refrigeration units in them***	***(Rodrigue and Notteboom, 2020c)***
Cold chain monitoring system	***The incorporation of sensors, indicators and relative technologies to achieve monitoring of cold chain conditions***	***(Ren et al., 2021)***
Cold chain cooling system	***Refrigeration units used in the cold chain for temperature control***	***(Ren et al., 2021)***

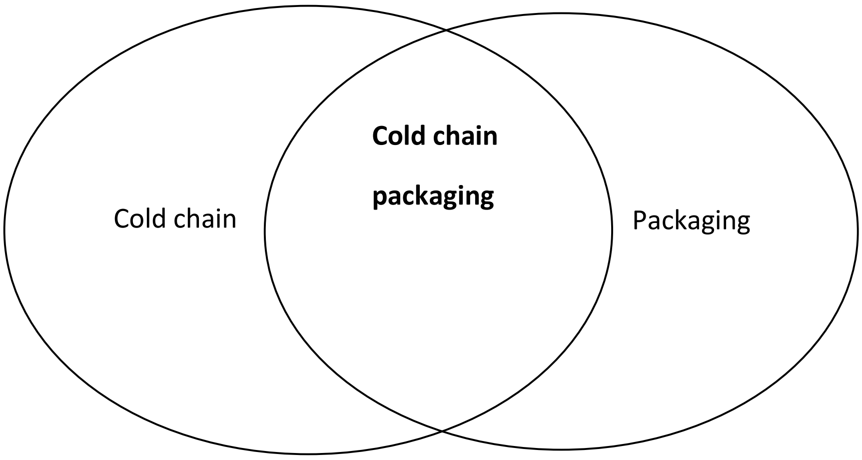


Figure 5.2: The correlations among cold chain, packaging and cold chain packaging

Containers are special forms of packaging, and therefore fall under the category of packaging. Refrigerated containers are containers with refrigeration units. Refrigerated containers are special forms of cold chain packaging, and therefore fall under the category of cold chain packaging. Figure 5.3 details the correlations among packaging, cold chain, cold chain packaging, container and refrigerated container. Cold chain cooling systems are the refrigeration units of cold chains and fall under the categories of cold chain and packaging. Cold chain monitoring systems are used to monitor the internal and external environments of cold chain packaging. Monitoring systems are not cold-chain-exclusive and can be used in any form of package. Figure 5.4 indicates the correlations among cold chains, packaging, cold chain packaging, cold chain cooling systems, and monitoring systems.

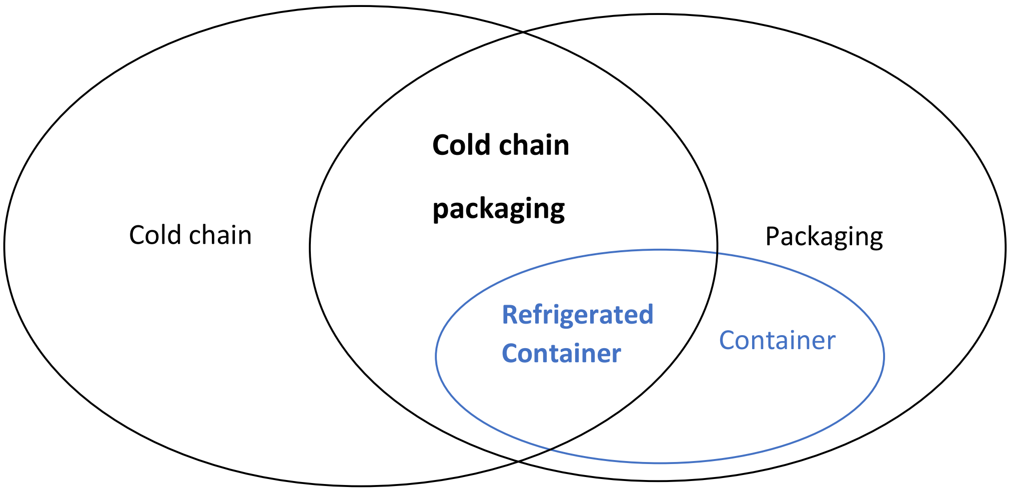


Figure 5.3: The correlations among cold chain, packaging, cold chain packaging, container and refrigerated container

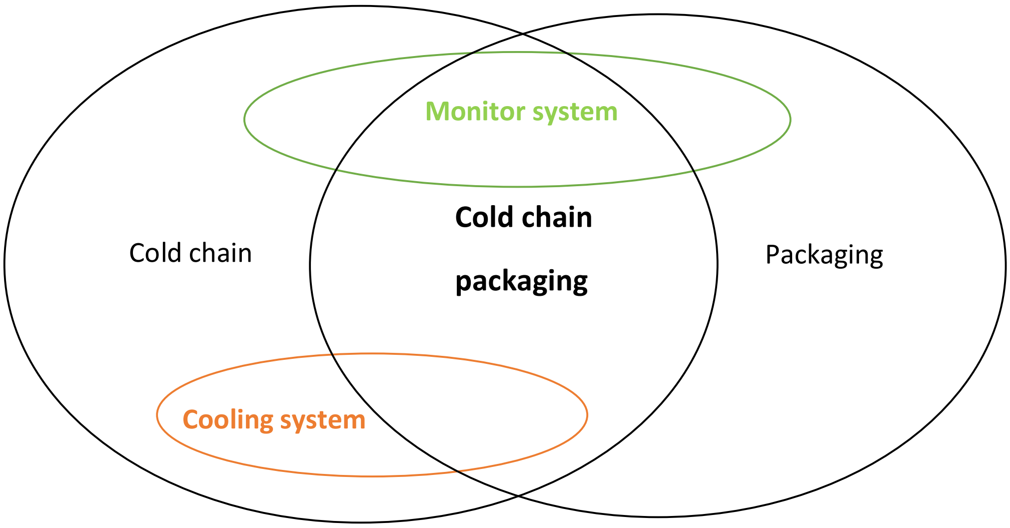


Figure 5.4: The correlations among cold chain, packaging, cold chain packaging, cooling system and monitoring system

The term ‘cold chain packaging’ in different contexts tends to concentrate on different aspects. Table 5.2 summarizes the role of cold chain packaging in the context of packaging, packaging level, supply chain and cold chain.

Table 5.1: The role of cold chain packaging in context of packaging, packaging level, supply chain and cold chain

Context	***The role of packaging in cold chain packaging***
Packaging	***Concerns all the packaging features of containment, convenience, communication and interaction.***
Packaging level	***Concerns all packaging levels of primary, secondary, tertiary and quaternary packaging.***
Supply chain	***Concerns the planning and processing of the entire supply chain***
Cold chain	***Plays an important role in regulating the internal environment and monitoring relative data along the cold chain***

From a packaging perspective, cold chain packaging concerns all the packaging features: containment, convenience, communication and interaction, and cold chain packaging concerns all packaging levels. Primary packaging contains and protects cold chain products from the external environment and is in direct contact with the products. Temperature indicators can be placed inside the packaging to indicate temperature changes through colour changes (Lu et al., 2013). Active materials can be used to release chemicals from the packages to the products (Adobati et al., 2015). Secondary packaging offers additional protection and optimizes handling during transportation and storage. Tertiary and quaternary packaging refer to the logistical or shipping unit of packaging. From a supply chain perspective, cold chain packaging involves the planning and processing of the entire supply chain.

The design of all packages should take the supply chain into account during the design phase, so that it is ergonomic and easy to handle the packages during transportation and storage and can provide the best protection for cold chain products. Since data like temperatures, humidity, and time are strictly monitored along the cold chain, data loggers are often used to monitor such data. It is important to plan the monitoring of the supply chain beforehand. From a cold chain perspective, cold chain packaging plays an important role in regulating the environment inside the package and monitoring related data along the cold chain. Phase-change materials are the most popular temperature regulating materials in cold chain packaging. Air circulation and humidity level should be regulated to ensure product quality and safety. Active substances can be released from the cold chain packaging to regulate humidity or pH (Arvanitoyannis, 2012).

Cold chain packaging concerns all of the features and functions of packaging and all of the steps of the cold chain, as shown in Figure 5.5. The main functions of cold chain packaging include containment & protection, ergonomic design, interaction, ergonomic design, refrigeration, monitoring and regulation of inside conditions.

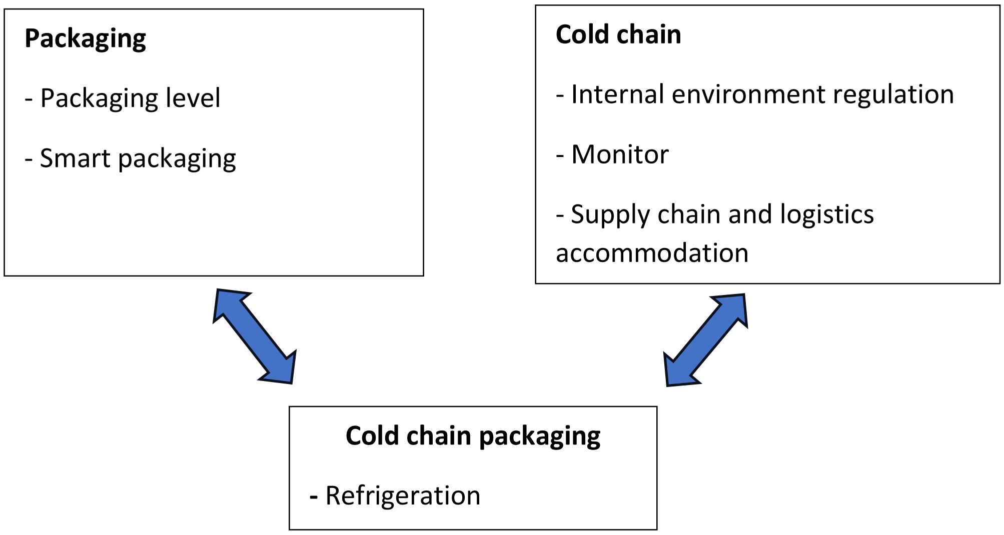


Figure 5.5: Cold chain packaging with respect to packaging and cold chain

The primary function of cold chain packaging is to contain cold chain products and protect them from the external environment. Second, since low temperature preservation during transportation and storage is always needed for cold chains, conventional packaging alone is not enough for the preservation of cold chain food and pharmaceutical products, so cold chain packaging can provide refrigeration for the products inside. Cold chain packaging can incorporate both active and passive cooling systems. Monitoring can also be achieved by cold chain packaging. Monitoring devices can be placed inside or outside the packaging, or sometimes even integrated with the packaging.

The design of cold chain packaging also needs to be ergonomic, so it is easy for handling throughout the logistics. Cold chain packaging also has the function of regulating the environment inside the packaging. Apart from the temperature regulation function of cold chain packaging, other factors like air flow rate, moisture level and compression force can be regulated. The air circulation and humidity level should be regulated to ensure product quality and safety. Active substances can be released from the cold chain packaging to regulate humidity or pH (Arvanitoyannis, 2012). The way the packages are stacked and placed together has an impact on the levels of compression force, humidity and air circulation.

Therefore, cold chain packaging can be defined as comprehensive cold chain shipping solutions which consider all packaging features and levels, supply chain planning and processing, and cold chain temperature control and monitoring. The purpose of cold chain packaging is to protect products from spoilage and damage, maintain temperatures within the required range, show robust performance during transportation and storage and to provide other value-added services, such as enhancing the convenience of handling and providing communication between the products and operators or consumers (Cerchione et al., 2018; Chatterjee and Sasidharan, 2019; Lydekaityte and Tambo, 2020).

5.3 OVERVIEW OF EXISTING COLD CHAIN SHIPPING SOLUTIONS

5.3.1 HIERARCHICAL STRUCTURE OF COLD CHAIN SHIPPING SOLUTIONS

Packaging used in the cold chain not only has to consider the traditional protection features but must also take into consideration the low temperature and logistical nature of the cold chain. From the packaging level perspective, commercial cold chain shipping solutions are mainly concerned with secondary, tertiary and quaternary packaging and concentrate on shipment and distribution. From the packaging function perspective, shipping solutions are concerned with all the functions of packaging, including protection, communication, convenience and interaction, but mainly focus on the protection and convenience functions. The interaction function normally happens at the primary packaging level, since active substances are released directly to the products inside the packages. From the cold chain perspective, shipping solutions are concerned with transportation, storage, temperature regulation and monitoring, loading and unloading, etc., involving all the links across the entire cold chain.

Since different companies offer various products and services, many terms have been used regarding packaging solutions in cold chain transportation and storage, such as 'pre-qualified cold chain shipping solutions', 'thermal systems', 'parcel shippers', 'cooling bags', 'passive cold storage systems', 'temperature control packaging system', etc. In this paper, the term 'cold chain shipping solution' is used to describe comprehensive cold chain shipping solutions. In order to systematically review these solutions, a hierarchical structure is proposed in Figure 5.6 to demonstrate their structure, components and categories.

Cold chain shipping solutions usually have a packaging system, a monitoring system and some add-on services. The overall cold chain packaging system has a Pallet–Parcel–Coolant–PCM hierarchy structure, and the coolant usually employs PCMs. Accessories and other technologies are often used to provide additional protection or enhance particular performance. The monitoring system contains temperature/humidity indicators, data loggers and related management systems and software. The services that come with the shipping solution include programmes for reuse, recycling, training, testing, etc. Many companies have launched different cold chain shipping solution products to suit various end needs, and both pre-qualified and customized cold chain shipping solution products and services are available, providing clients with the flexibility to choose solutions that meet their needs. Of all the components above, the PCM coolant is the core of the shipping solution since it is the main source of temperature regulation.

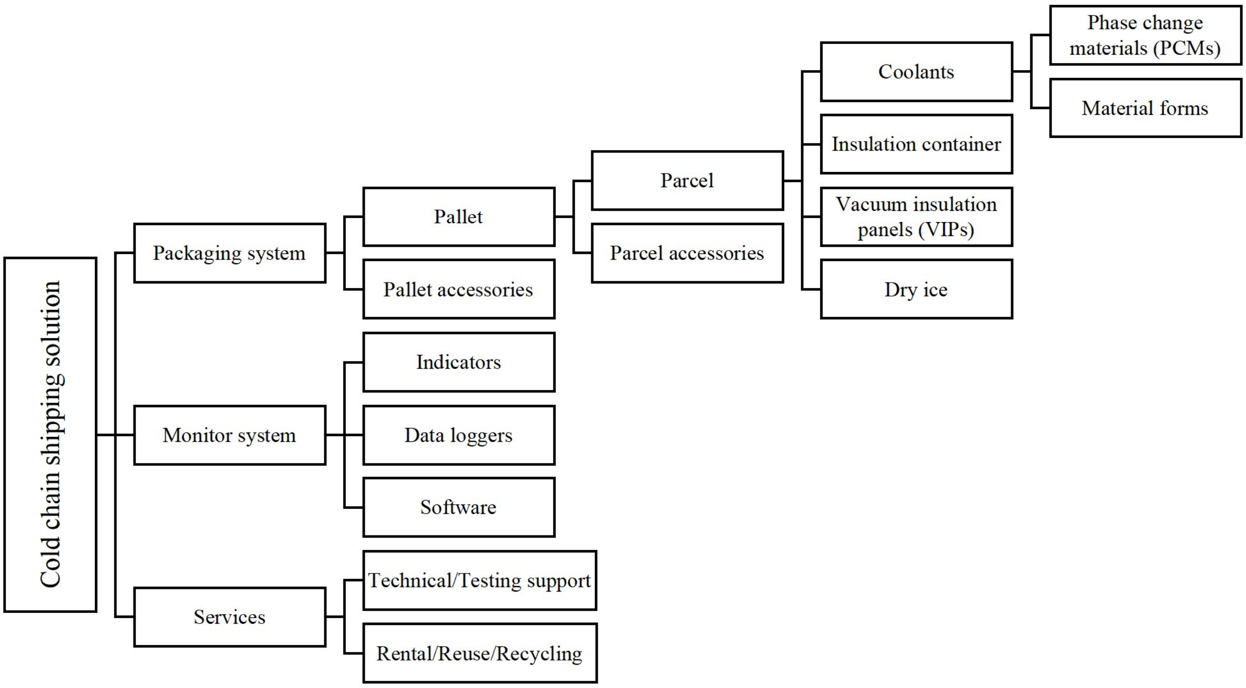


Figure 5.6: The conceptual model of the structure, categories and components of the industry cold chain shipping solutions.

5.3.1.1 Coolants

The term 'Coolant' is often used in industrial cold chain shipping solutions. Coolants refer to phase-change materials in different forms, such as solid, liquid, gel, etc., which can be stored in packs, bottles or foams. Coolants originate from using ice for passive cooling of cold chain products, and water-based cool packs are used in some shipping solutions with the advantage of freezing at a lower temperature than regular ice and taking more time to warm up (Capps, 2021). Some current cold chain shipping solutions use water coolants that show good temperature-maintaining properties. For instance, the AmbiTherm parcel solution uses water-based cool packs and can maintain a temperature of 15 to 25°C for up to 48 h (Sonoco ThermoSafe, 2024c) .

Today, many non-water PCM coolants are produced and used to achieve superior thermal performance. Some coolants are renewable, which can significantly reduce greenhouse gas emissions and enhance sustainability. For example, the Biochill coolant is made from 100% biobased feedstock, and PureTemp is made from palm, coconut and soybean oils (BioChill, 2023; Rolland et al., 2012; Singh et al., 2018b). PCM coolants have a wide range of temperature maintenance ranges from −26°C to 25°C to suit different product and transportation requirements (Rolland et al., 2012). A list of commercial coolants is shown in Table 5.3. The available materials or storage forms and temperature ranges of the coolants are also listed.

Table 5.3: Commercial cold chain shipping coolants

Coolant Name	*Available Storage Forms*	*Temperature Range (°C)*	*Source/Manufacturer*
PureTemp	*Gel pack, foam brick, two-cell pillow panel*	*−25 to 23*	*(Rolland et al., 2012; Singh et al., 2018b)*
FreezeTech	*EPS box*	*−25 to −15*	*(Sonoco ThermoSafe, 2024a)*
Evercold	*Foam brick*	-	*(Avantor, 2024)*
PolarPack	*Gel, bottle pack, moisture guard*	*0*	*(Avantor, 2024)*
U-tek	*Pack, mat, tray*	*−23*	*(Avantor, 2024)*
Koolit	*Gel, foam brick, pack, gel bottle*	*3,5,7,17*	*(Cold Chain Technologies, 2022)*
Polarchill	*Gel, bottle pack*	*2 to 8, −26, 5*	*(Polar Thermal, 2024)*
Easi-chill	*Gel*	*2 to 8*	*(Icertech, 2024a)*
Sofrigam PCM	*Bottle pack*	*−21 to 25*	*(Sofrigam, 2022)*
Tempack	*Bottle pack, gel*	*2−8*	*(Tempack, 2024a)*
Nordic ice	*Gel, foam brick, wrap*	*−21 to 25*	*(Nordic cold chain solutions, 2023a)*
Nordic drain safe	*Gel*	-	*(Nordic Cold Chain Solutions, 2023b)*

Coolant Name	*Available Storage Forms*	*Temperature Range (°C)*	*Source/Manufacturer*
Icer pack coolants	*Gel, water ice mats*	-	*(Icerteh, n.d.)*
Pharmachill	*Bottled pack*	*2 to 8, 15 to 25*	*(Intelsius, 2024c)*
Cold Cell	*Gel*	*2 to 8, 15 to 25*	*(Intelsius, n.d.)*
BioChill	*Semi foam*	*2 to 8, 15 to 25*	*(Intelsius, n.d.)*

While the properties of cold chain shipping solutions depend heavily on the coolant used, the PCM used inside the coolant and its storage form are the main factors affecting their temperature maintenance ranges. In fact, there are different forms of PCM: liquid, gel, solid, foam, semi-foam, etc., which are stored and packed in different forms (Lydekaityte and Tambo, 2020). Liquid PCM is usually stored in rigid bottles, while solid or gel PCM is often stored in plastic packages.

Gel coolants are often used for ambient or chilled temperature ranges. They have the benefits of saving space due to the flexibility of their shape and have received increasing attention in the past few years. Bottled coolants have the benefits of low cost but risk leakage of the liquid during transportation. Some coolants are ready for use by themselves, while others are incorporated within the parcel or pallet solutions. Companies like Sonoco ThermoSafe, Cold Chain Technologies, Softbox, etc., have all launched cold chain shipping solutions incorporating PCM coolants.

Depending on the specific requirements, different versions of coolants are available to accommodate different temperature ranges, durations, payload sizes, etc. However, there are still some challenges with regards to these commercial PCM coolants. Leakage is one of the main issues, which is also addressed in the literature concerning the developing phases of PCMs.

Therefore, it is important to concentrate more on the refinement of the PCM. Researchers have studied how to improve the thermal performance of phase-change materials. Various techniques have been applied to improve PCM properties, such as novel encapsulation, including the addition of nano particles, micro encapsulation, electrospinning, vacuum impregnation, etc. The addition of nanoparticles increases thermal conductivity in an efficient and cost-effective way. Therefore, industry practitioners should cooperate with academic researchers to increase knowledge sharing and work together to increase the overall performance of PCMs and speed up the commercialization process.

Apart from coolants, other accessories are also often used for better performance. Expanded polystyrene (EPS), polyurethane (PUR) and vacuum-insulated panels (VIP) are some examples of the extra insulation used for both life sciences & healthcare products and food & perishables. EPS, along with corrugate and foam, can prevent chemicals leaching during use and disposal, improving overall safety and reducing cost. Compared to EPS, PUR performs even better as insulation, while VIP offers superior heat damage protection during shipment (Melone et al., 2012). Cardboard or plastic outer containers are also often used for outer protection. For blood transportation and temporary storage, portable bags and boxes are used, mostly for ambient temperature maintenance.

The packaging itself may sometimes still fail due to unexpected disruption during the cold chain. Therefore, monitoring technologies and management systems are often used inside the shipping solutions. Cryopak has launched a data logger the Q-Pak TimeSaver to monitor and store temperature data (Cryopak, n.d.). Console Plus data management software is also available with data loggers. Monitoring systems can be categorized into temperature indicators, data loggers, management software and other advanced technologies, like the Internet of Things (IoT). Cold chain monitoring system solutions are often integrated with parcel or pallet solutions, and customizable products are available for manufacturers and end users to choose from. For data loggers, there are single-use, multi-use, real time monitoring software, and accessories.

5.3.1.2 Cold chain shipping solutions

With the integration of insulation, coolants, other accessories and monitoring devices or system (e.g., data loggers, indicators), a parcel solution is designed. Both prequalified and customized parcel systems are available. Pallet solutions are also available that can be shipped in bulk by truck and plane, minimizing handling and making it easier to ship large volumes. For example, Sonoco ThermoSafe has US- and European-based pallet shippers that can transport pharmaceuticals with durations up to 7 days. Some pallet accessories are also used to protect the pallet. SilverSkin pallet covers by Softbox are manufactured from flexible and strong materials to provide extra protection under challenging transportation, packing and warehousing conditions. Other accessories are also available from many companies.

The shipping solutions for vaccines or other pharmaceutical products differ from food shipping solutions due to their stricter temperature requirements. Many companies have launched vaccine carriers for shipping vaccines, including solutions for COVID-19 vaccines. Table 5.4 lists commercial, prequalified cold chain shipping solutions and services, including parcels, pallets, indicators, data loggers, management software packages, rental and training services and programmes.

Table 5.4: Commercial pre-qualified cold chain shipping solutions/services.

Solution/Service Name	*Category*	*Temperature/°C*	*Duration/h*	*Source/Manufacturer*
Greenbox	*Parcel*	*2 to 8, 15 to 25, −15*	*144*	*(Cold Chain Technologies, n.d.)*

Solution/Service Name	*Category*	*Temperature/°C*	*Duration/h*	*Source/Manufacturer*
Envoy	*Parcel*	*2 to 8,* *15 to 25, −20*	*168*	*(Sonoco ThermoSafe, 2024b)*
Wired	*Parcel*	*2 to 8,* *15 to 25, −20*	*120*	*(Certis, 2024)*
AmbiTech	*Parcel*	*15 to 25*	*120*	*(Sonoco ThermoSafe, 2024c)*
FreezeTech	*Parcel*	*−25 to −15*	*48*	*(Sonoco ThermoSafe, 2024d)*
Orion r	*Rental Service*	-	-	*(Sonoco ThermoSafe, 2024e)*
ChillTech GC17	*Parcel*	*7 , 15 to 53*	-	*(Sonoco ThermoSafe, 2024f)*
Multipack	*Pallet*	-	-	*(Sonoco ThermoSafe, 2024g)*
KoolTemp *EcoFlex 96 family*	*Parcel*	*2 to 8,* *15 to 25, −15*	*120*	*(Cold Chain Technologies, 2024a)*
STS Frozen Parcel Family	*Parcel*	*−20,* *−15 to −25,* *−70*	*48*	*(Cold Chain Technologies, 2024d)*
KoolTemp *EndeavAir 1600 L*	*Pallet*	*−2 to 8,* *15 to 25, −20*	*144*	*(Cold Chain Technologies, 2024b)*
TransTracker	*Indicator*	*0, −1, −6, 9, 25*	-	*(Cold Chain Technologies, 2024f)*
InTemp Data Logger	*Data Logger*	-	*365*	*(Cold Chain Technologies, 2024c)*
Reusable Solutions & Return Service Programs	*Service*	-	-	*(Cold Chain Technologies, 2024e)*
Tempcell Max	*Parcel*	*2 to 8,* *15 to 25*	*96*	*(Softbox, 2018)*
Tempcell ECO	*Parcel*	-	*72*	*(Tempcell ECO, 2022)*
Frozen parcel shippers	*Parcel*	*−20, −60, −90*	-	*(CSafe Passive Systems, 2024a)*
Silver Skin	*Pallet cover*	-	-	*(CSafe Passive Systems, 2024b)*

Solution/Service Name	*Category*	*Temperature/°C*	*Duration/h*	*Source/Manufacturer*
CoolGuard Advanced	*Parcel*	*2 to 8, 15 to 25, −18*	*120*	*(Peli Biothermal, 2024a)*
Deepfreeze	*Parcel*	*−65*	*96*	*(Peli Biothermal, 2024b)*
Nanocool	*Parcel*	*2 to 8*	*96*	*(Peli Biothermal, 2024c)*
Elite Cubic	*Parcel*	*2 to 8, 15 to 25, −18 to −15, −80 to −20*	*168*	*(Sofrigam, 2024b)*
Initial	*Pallet*	*2−8, −25 to −15, −80 to −20*	*168*	*(Sofrigam, 2024c)*
Scan Online	*Data logger*	-	-	*(Sofrigam, 2024d)*
So Reuse	*Service*	-	-	*(Sofrigam, 2024e)*
PharmaTherm	*Parcel*	*2 to 8,15 to 25*	*120*	*(Intelsius, 2024d)*
ORCA	*Parcel*	*2 to 8,15 to 25*	*120*	*(Intelsius, 2024b)*
ORCA Pallet	*Pallet*	*2 to 8,15 to 25*	*96*	*(Intelsius, 2024a)*
ORCA Rental	*Service (rental)*	-	-	*(Intelsius, 2024e)*
CarryTemp	*Parcel*	*2 to 8, 15 to 25, −15*	*48*	*(Tempack, 2024a)*
Greenin SU	*Insulation*	-	*48*	*(Tempack, 2024b)*
Console Plus	*Data management software*	-	-	*(Cryopak, n.d.)*
BloodSafe 22	*Parcel*	*22 to 24*	*24*	*(Cryopak, n.d.)*
Q-pak TimeSaver	*Data logger*	*2 to 8, 15 to 25, −15*	*120*	*(Cryopak, n.d.)*
Styrofam	*Parcel*	*2 to 8, 15 to 25, −15*	*48*	*(Dupont, 2024)*
Chill-Pak	*Parcel*	-	-	*(Chill-Pak, 2023a)*

Solution/Service Name	Category	Temperature/°C	Duration/h	Source/Manufacturer
PUR container	Insulation	-	-	(Chill-Pak, 2023b)
Nordic Express	Parcel	2 to 8	24	(Nordic Express, 2022)

For parcel and pallet shippers, many parameters affect their overall performance, including size, weight, capacity and capability, and these all need to be considered during the design of the packages. The components of the parcel are sometimes integrated and also consider ergonomic features for better handling and assembly. For example, Cold Chain Technologies' KoolTemp EcoFlex 96 parcel contains the Koolit advanced PCM gel, VIPs and dry ice. The unique flexible design allows for multiple temperatures and durations (Cold Chain Technologies, 2024a).

Compared to traditional packaging, the main advantages of these cold chain shipping systems include light weight, low volume, simple packing, low cost, durability and flexibility, improving temperature regulating properties, and improving sustainability. These parcels and pallets re suitable for use with both food/perishables and pharmaceutical/medical products. Pharmaceutical/medical products are the major targeted products due to their greater temperature sensitivity and the high demand for vaccines during outbreaks of disease. Some companies launched particular shipping solutions for the COVID-19 vaccines. The pandemic and the accompanying expansion of global immunization programmes both promoted the rapid devel opment of these shipping solutions.

5.3.2 CHARACTERISTICS OF COLD CHAIN SHIPPING SOLUTIONS

The overall performance of cold chain packaging can be improved with the aid of these shipping solutions, which specifically can increase thermal performance, robustness, leak protection, duration, etc. PharmaTherm and CoolGuard Advanced solutions claim that their shipping solutions can provide superior performance without compromising other properties

(Intelsius, 2024d; Peli Biothermal, 2024a). Since some vaccines require ultra-low temperature during transportation and storage, some solutions provide deep frozen transportation and storage options, including Nordic Express, ORCA, Elite Cubic, DeepFreeze, Softbox Frozen Parcel Shippers, STS Frozen Parcel Family, etc. The majority of them (Polarthermal, 2022; Cold Chain Technologies, 2024d) use dry ice to aid with achieving ultra-low temperatures during storage and transportation. Many vaccines are freeze-sensitive to low temperatures during transportation and storage, and freezing has been found to be one main issue causing vaccines to lose their potency, posing a great threat to human health.

As well as temperature regulation, the durability of the cold chain shipping solutions matters, since a shipping solution with a longer viable duration will have more resilience to cold chain disruption. Elite Cubic and Initial Express solutions both show greatly improved performance in durations, and can achieve a duration of up to 168 h (Sofrigam, 2022a, 2024b). Besides thermal performance, the overall robustness of cold chain packaging can be increased, as indicated by the Elite Cubic solution, which incorporates anti-shock and anti-perforation technology, VIP, eutectic gels, PP or cardboard in its parcel solutions. AmbiTherm is proven to show high puncture resistance and leak protection. EOS has been shown to have increased insulation and cushioning properties (Sonoco ThermoSafe, 2024a; d). The application of these cold chain shipping solutions will greatly increase the thermal and insulation performance and prolong the shelf life of cold chain products.

Besides superior thermal performance, there are various shipping options available to choose from. Cold chain shipping solutions provide flexibility to the overall cold chain operations in terms of temperature ranges, packing and assembly options, switching between durations, etc. Globalisation has encouraged a rising amount of international trade, while different countries may have different regulations on transport, storage, temperature and packaging of perishable products, posing additional challenges for international transportation. To solve this issue, many shipping solutions, in particular the parcel solutions, offer various sizes and payload options. This flexibility can greatly ease the tension caused by different requirements and regulations.

Besides the various options of sizes and capacities, a variety of temperature maintenance ranges are provided by shipping solutions. For example, deep-frozen cold chain parcels and cold boxes for medical products are available, increasing the resilience of the cold chain in case of any unexpected disruption, such as power outages. Some parcel solutions offer alternatives to dry ice for frozen cold chains. FreezeTech, for example, uses FreezeSob, a nontoxic salt-based PCM, which can maintain a temperature range of −25 to 15 °C for 48 h. This helps alleviate the cold chain stress that complicates the high demand for COVID-19 vaccines (Sonoco ThermoSafe, 2024d). Between 2–8°C is the typically recommended storage temperature range for most vaccines, and many shipping solutions have products within this temperature range (Hanson et al., 2017). For the cold chains of blood, specimens, organs, and other medical products, specially made boxes are usually designed and used.

Besides the various temperature ranges, different load sizes and duration options are also available for shipping parcel solutions. For example, AmbiTech, the PCM-based CRT shipper, has three versions, with different durations and sizes of each version. AmbiTech Regional has a duration of 72 h and has five payload sizes ranging from 9 L to 71 L; AmbiTech has a duration of 90 h and has four payload sizes ranging from 5 L to 35 L; AmbiTech Global has a duration of 120 h+ and has seven payload sizes ranging from 4 L to 65 L. The various shipping solutions available with various temperature ranges, durations and capacities provide companies an easier and more convenient way to create and maintain a robust and smooth supply chain (Sonoco ThermoSafe, 2024c) .

In addition, the design of the shipping solutions takes ergonomics and safety into consideration. It has been found that occupational safety is a main risk of the cold chain, since working under an extraordinary environment can potentially cause harm to the working personnel (Tsang et al., 2018). Standardized components of parcels make them universally or seasonally packable, making it easier for handling and saving time. Some parcel solutions can use the same packout for refrigerated, CRT and frozen cold chains, e.g., Greenbox, Certis and Envoy parcel solutions (Cold Chain Technologies, n.d.; Sonoco ThermoSafe, 2024b ; Certis, 2024).

The PCMs inside are sometimes interchangeable to accommodate changes of temperature and duration expectations. Some parcels have off-the-shelf use convenience, such as Envoy and Chill-Pak. NanoCool parcels do not require preconditioning of the coolant gel and are portable (Peli Biothermal, 2024c). All these ergonomic features of the shipping solutions will make handling and assembling much easier and decrease the overall operational safety risks, since working with or in a cold environment can be challenging.

The light weight, low volume and reusability of some parcels increase the overall sustainability and cost-efficiency of the cold chain, and add-on services and programs can increase the knowledge sharing function of cold chain packaging. Some shipping solutions claim to be environmentally friendly and cost-efficient. Tempcell's ECO solution, for instance, claims to be 100% recyclable, and Initial Freight Forwarding and Initial Express solutions both claim to be 70% recyclable (Tempcell ECO, 2022) . Many shipping solutions can be reused or recycled, and related programs are offered by some companies. For instance, a Reuse service program is provided along with the KoolTemp EcoFlex 96 family parcel system. The Reuse program encourages re-use of the parcels, making them environmentally friendly and reducing cost burdens (Cold Chain Technologies, 2024e).

Also, most shipping solutions incorporate monitoring devices and systems. For example, ORCA parcels have multiple data loggers integrated within the parcels for monitoring temperatures. Effective temperature monitoring can save product losses during transportation and storage, saving cost and waste (Cold Chain Technologies, 2022; Tempcell, 2022). Besides reuse and recycling programs, other additional services are also available, such as training and tutorial programs, rental services, consulting, monitoring and management systems, technical support, etc., meeting various end-user needs. Add-on programmes and services can enhance knowledge sharing in the field of cold chain packaging. STS frozen Family offers some training videos and study kits, and pack-out instructions are provided by Q-pak TimeSaver parcels (Cold Chain Technologies, 2024d). Cold Chain Technologies hold regular educational seminars. Softbox and Intelsius both provide technical consultation support. Cryopak provides trouble shooting, knowledge and training support.

Despite all the advantages of cold chain shipping solutions, there are still challenges due to the complexity of the cold chain. Although many solutions claim to be cost-efficient, the commercialization of PCMs and the overall shipping solutions remain difficult and can sometimes be costly. Therefore, further studies are needed. More empirical studies are needed to further validate knowledge in this field of study. Cost and environmental considerations also add to the difficulty of commercialising PCMs and shipping solutions. Furthermore, novel materials and technologies are continuously being developed, and it is essential to study how new technologies affect the development of cold chain packaging. Tsang et al (2018) proposed an IoT-based cold chain monitoring system to manage risk along the cold chain. The application of Internet of Things (IoT) technology on cold chain packaging can have a huge impact on future trends in cold chain packaging (Tsang et al., 2018).

5.4 PERFORMANCE METRICS OF COLD CHAIN PACKAGING

A performance measurement system is a set of metrics which are used to quantify the efficiency and effectiveness of actions (Wudhikarn et al., 2018). As in other areas of study, management of cold chain packaging requires appropriate performance metrics and measures to assess how an organisation is performing. Performance measures of logistic management may focus on tangible or financial assets or some intangible capital like operational efficiency and effectiveness. There have been many performance metrics proposed for the cold chain. Cerchione et al. (2018) proposed performance metrics for food cold chains which include a metric of green packaging. Martínez-Martínez et al. (2023) proposed a refrigerated preservation performance indicator system based on predictive microbiology and product time-temperature data. Burgess et al. (2022) proposed performance metrics including threshold time, temperature inhomogeneity coefficient and discharge efficiency for a portable PCM storage system. However, key performance metrics for the cold chain packaging system is still lacking.

To better understand the performance of cold chain packaging, it is important to construct relative performance metrics. Cold chains differ from conventional supply chains due to their perishable nature. Therefore, a cold chain needs to consider many special factors when assessing its performance or behaviour, such as seasonality, traceability, refrigerated transportation and storage requirements, shorter shelf lives, etc. (Nha Trang et al., 2022). Many existing studies have proposed metrics for assessing cold chain performance. Table 5.5 lists some of the proposed cold chain performance metrics.

Table 5.5: literature review on cold chain performances

Sources	*Focus*	*Performance metrics*
(Sadeghi Asl et al.,	*Resilient supply*	*Cost, service, level, quality & safety, relationship, innovativeness, traceability, return*

Sources	*Focus*	*Performance metrics*
2021)	*chains*	*to cost*
(Cerchione et al., 2018)	*Sustainability*	*Carbon emission reduction, Energy consumption reduction, Water consumption reduction, Waste reduction, Reduction in hazardous/ harmful/toxic material use, Shelf life, Cooling rate, Shipping accuracy rate, Lead time, Green packaging, Traceability, Product quality & safety, Recycling rate*
(Yadav et al., 2021)	*Traceability*	*Certification, tracking of Agri-products, implementing sustainable practices, improved information qualities, improved global distribution networks, agri-production scheduling with optimization, understanding stakeholder's behaviours, monitoring the ongoing practices, quick response to agro-terrorism, effective information sharing*
(Nha Trang et al., 2022)	*Collaboration*	*Scope of parties (vertical, horizontal), decision function (centralized, decentralized), relationship types (level of joint commitment, dyadic relationship, integration degrees), shared components (planning. Operating, communication, incentives)*
(Aiello et al., 2012)	*Quality*	*Quality, time, temperature, deterioration*
(Laguerre et al., 2014)	*Operations*	*The influence of input variables (ambient and thermostat setting temperatures) and equipment parameters (dimension, airflow rate, insulation) on the load temperatures.*

The performances of supply chains can be measured with different focuses, e.g. profit-focused, client-focused, or environment-focused. A profit-focused supply chain will aim to minimize the cost and time to maximize profits. A client-focused supply chain will aim to maximize customer satisfaction and minimize response time. An environmentally-focused supply chain will aim to minimize waste and hazard to the environment. Other supply chain focuses include agile, lean and resilient supply chains. Agile supply chains have the ability to respond quickly in case of changes or disruptions. Lean supply chains aim to deliver products in the most efficient way with minimized waste and strive to continuously improve the process. Resilient supply chains are supply chains that can resist disruption and minimize the consequences. The performance of cold chains needs to consider all of these conventional supply chain metrics, as well as their temperature-sensitive nature.

As discussed earlier, cold chain packaging is a comprehensive cold chain shipping solution that involves all packaging levels and smart packaging features, and incorporates specific cold chain requirements, such as temperature, humidity, bacteria, air circulation regulation and monitor. The need for cold chain packaging has increased in the past few years, so performance metrics of cold chain packaging are needed. Performance metrics for cold chain packaging are proposed in Figure 5.7, which integrates aspects both from cold chain packaging studies in academia and cold chain shipping solutions in industry. Performance metrics such as efficient regulation of the internal environment, information management, sustainability, operation optimization, ensured quality and safety, profit and customer satisfaction are included.

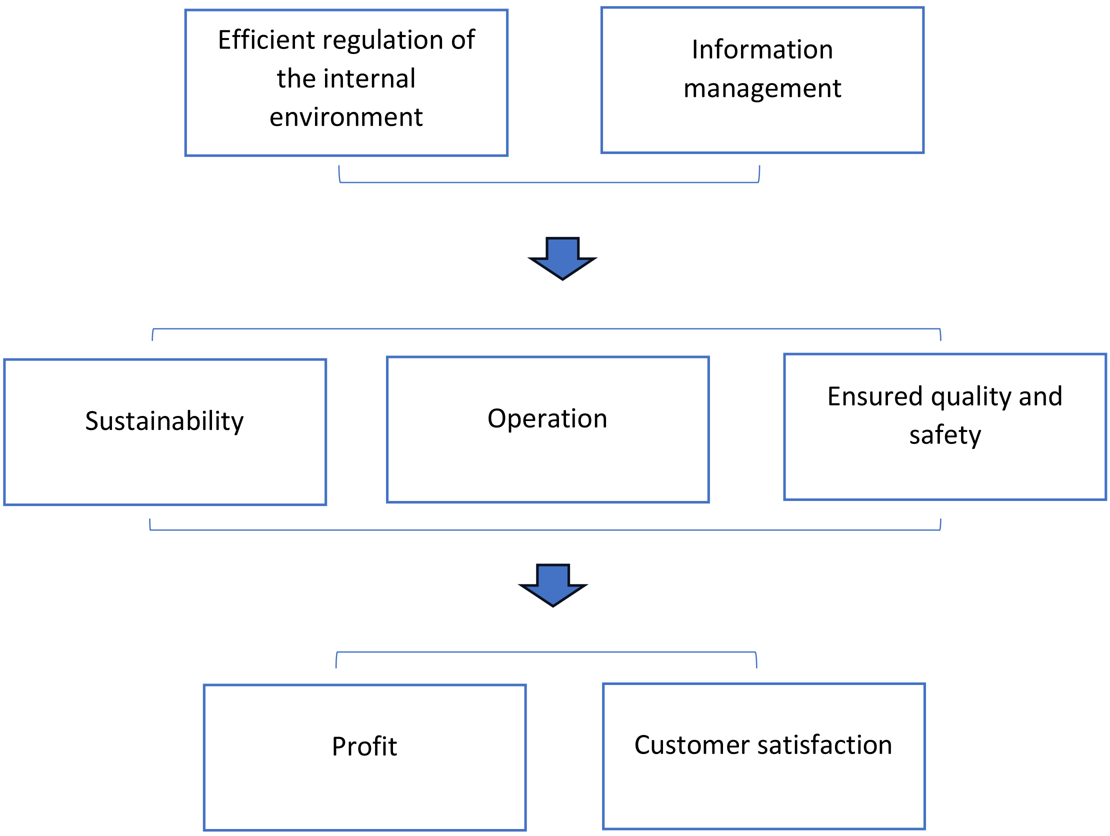


Figure 5.7: Structure of the performance metrics of cold chain packaging

Efficient regulation and monitoring of the internal environment are essential for the performance of cold chain packaging, which directly impacts the optimization of operation, sustainability and quality and safety of the products. For instance, insufficient refrigeration can lead to quality decay and potential safety hazards. Hazardous materials used can lead to negative consequences for the environment, and poor information management can impede the optimization of the operation process. All of these factors can lead to economic loss, decreased customer satisfaction or a negative impact on the environment. Details of each metric are listed in Table 5.6 and discussed in the sections below.

Table 5.6: Proposed performance metric for cold chain packaging

Metric	*Details*	*Sources*
Efficient regulation of the internal environment	*Factors like temperature, humidity, air circulation, compression forces need to be maintained within required ranges.*	*(Singh et al., 2018b; Capps, 2021)*
Information management	*The data collected along the cold chain monitoring needs to be properly stored and shared. The data needs to be traceable.*	*(Chaudhuri et al., 2018; Shen et al., 2019)*
Sustainability	*Sustainable materials need to be used to control the energy used during transportation and storage and reduce environmental hazards, Management of empty container rates.*	*(Babagolzadeh et al., 2020; Rodrigue and Notteboom, 2020b)*
Operation optimization	*Efficient planning of the cold chains considering the design of the packaging.*	*(Tsang et al., 2018; Ali and Gurd, 2020; Zheng et al., 2021).*
Ensured quality and safety	*The quality and safety of the cold chain products need to be maintained.*	*(Bai et al., 2018; Wu and Hsiao, 2021; Kartoglu and Ames, 2022)*

5.4.1 EFFICIENT REGUALTION OF THE INTERNAL ENVIRONMENT

Cold chain packaging should be able to regulate and maintain temperature, humidity, air circulation, and compression forces within the required ranges. Failure of such regulation can lead to quality and safety issues. The quality and freshness of cold chain products under lengthy transportation and storage are great challenges. Temperature disruption can cause quality decay in cold chain products; WHO reports that in 2011, about 2.8 million doses of vaccines were lost because of cold chain disruption in 5 countries (Gore et al., 2021). Therefore, keeping cold chains refrigerated is critical. Efficient refrigeration needs to be preserved throughout the cold chain to maintain product quality. Besides refrigeration, HACCP (Hazard Analysis and Critical Control Points) strategy needs to be broadly implemented in food cold chains to ensure food safety (Mercier et al., 2017). For vaccine cold chains, shake tests can be used to test freezing/thawing conditions (Hanson et al., 2017).

It is important to select the most suitable refrigeration modes for different cold chain links. Depending on the temperature range required, devices like refrigerators, freezers, cold storage systems, etc., are used for maintaining the temperature. For certain cold chain products, e.g. vaccines, ultra-low temperatures need to be maintained (Ren and Matellini, 2021). Temperature control during loading and unloading cannot be overlooked; during in-between links or during loading and unloading when active refrigeration is missing, passive cooling systems are the only source of refrigeration. Overheating can be another problem of cold chain packaging, especially during summer. The refrigeration units of refrigerated containers are based on a vapor compressor system powered by electric current which is produced by the alternators of the carrying vehicles or direct electric grid connection, which may not be available during loading and unloading (Copertaro et al., 2016). Therefore, choosing efficient cooling systems is critical.

There have been many studies conducting thermal and air flow analysis on cold chain packaging. Non-uniform cooling can lead to uneven cooling of cold chain products, harming their quality and safety. Thus, it is also important to improve the distribution of the cooling in cold chain packaging. External environment and internal air circulation are key factors impacting temperature uniformity. To protect products from the external environment, insulation of the cold chain packaging is essential. Phase-change materials, vacuum insulation panels, advanced plastic insulation materials are used for this purpose. To achieve proper air circulation, influencing factors are the design of the components of cold chain packaging, including the design of refrigerated containers and packages, packaging stacking arrangements and pallet configurations (Jiang et al., 2020).

Apart from refrigeration, other factors like humidity, ventilation, compression force, etc., need to be strictly controlled during transportation. The humidity level affects the quality of fresh produce. For example, drying of fresh produce can occur during the cold chain when the humidity level is too low, and when the humidity level is too high, it may cause damage to the packaging, especially paper-made packages like cartons. The ventilation of the cold chain packaging can affect refrigeration. Active refrigerating systems may not be able to function if the ventilation inside is not sufficient. Also, the way the packages are stacked or placed impacts the air circulation and compression forces on and between the products and packages.

5.4.2 INFORMATION MANAGEMENT

Information management is an important influencing factor in the performance of cold chain packaging. Some common causes of information management cold chain disruption were summarized by Comes et al. (2018), as shown in Table 5.7. Information management is important in supply chain management in general, but cold chain packaging differs from other supply chains due to its perishability. The factors mentioned in the last section, such as temperature, humidity, air circulation, compression force, need to be monitored. Other factors that need to be monitored include the quality of the products, locations, inventory, personnel health conditions, weather conditions, etc. Besides monitoring, efficient management of the information and data is needed, such as how the data is stored, who has access to what information, etc. Information and data should be traceable, so that if there are any problems, the records can be checked and traced back.

The cold chain packaging network needs to be integrated to improve information management, for which public-private collaboration is needed. Cold chain packaging databases can be developed to provide practitioners with useful historical or real-time datasets. For example, a web based platform called FRISBEE has been developed to collect data on temperature conditions for European chilled and frozen food cold chains, including data from industry, distributors, retailers and consumers (Gogou et al., 2015). Furthermore, information and decision-making should always be aligned (Comes et al., 2018). Thus, the capacity to collect and manage data and information is essential to support the ability to make data-based decisions.

Table 5.7: Information management cold chain disruptions (Comes et al., 2018)

Category	*Details*
Disruption of material flow	*Infrastructure failure, e.g., power outage transportation network breakdown, warehouse closedown, failure of equipment and lack of redundancy, e.g. lack of fuel, spare parts, back-up energy*
Information gaps	*Monitoring and tracking system failure, incorrect use of vaccine vial monitors, no tracking of max and min temperature, communication and information system breakdown, lack of ability to manage complex information stream, work with delayed, lacking or uncertain information*
Failure of decision making	*Deficiencies in vaccine storage and handling and lack of training, lack of information and management options for possible disruptions, lack of planning, lack of operational decision support.*

Technology advancement has been a main driver for the development of information management. Many tools and approaches have been used to support the monitoring of cold chains, such as RFID, wireless sensor network (WSN), global positioning system (GPS), cloud computing, Internet of Things (IoT), Virtual reality (VR), artificial intelligence (AI), etc., and Industry 4.0 has accelerated the application of these digital technologies. The use of technologies can improve logistic operation performance. Figure 5.8 gives an example illustrating the connections between logistics and IoT, derived from Tang et al. (2023).

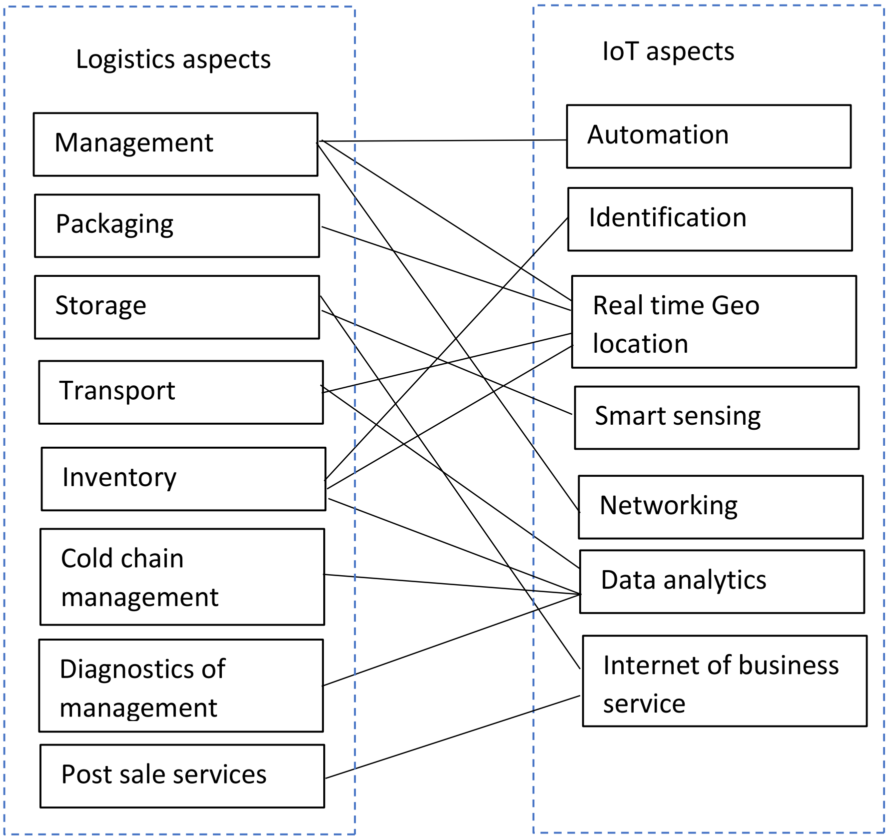


Figure 5.8: Connections between aspects of logistics and IoT (Tang et al., 2023)

The use of technologies should be easy and informative, while attention also needs to be paid to issues like security and privacy. It is essential for the measurement to be sufficiently accurate; for example, the selection of phase-change materials, sensors or indicators should have suitable temperature-changing ranges for the specific product in transport. The sensitivity of the measurement should also be suitable; for example, if an increment of 1°C can lead to quality decay for a certain cold chain product, then an indicator with a sensitivity of 3°C is not sufficient. Furthermore, the technologies should be easy to use, with comprehensive instructions, and proper training should be given to the relevant personnel.

Many information management models have been proposed that incorporate innovative technologies for supply chain management. Yadav et al. (2021) developed an IoT-based traceability system for the agricultural supply chain. Traceability is also impacted by collaboration: food cold chains are more subject to this factor than pharmaceutical cold chains, since they are more fragmented. Pharmaceutical cold chains also often have specialised logistics providers. Nha Trang et al. (2022) analysed the impact of collaborative partnerships on the performance of cold chains for agricultural products. The drivers of collaboration include quality and safety improvement, innovation development, improving sustainability, etc. Tang et al. (2023) developed an IoT-based Cold-chain Logistics Service Quality management system with four quality-scale dimensions: Customers' pleasure, return motivation, security, and privacy.

5.4.3 SUSTAINABILITY

Cold chains contribute about 2.5% of total global greenhouse gas emissions, and there are about 1 million refrigerated road vehicles and 400,000 refrigerated containers in use worldwide (Copertaro et al., 2016). Sustainability has become an important topic these days, and companies should assess the impact of their activities on energy use, CO_2 emissions and the environment. The overall sustainability of cold chain packaging is impacted by factors such as sustainable materials used, energy usage, impact on global warming, waste, recycling and reuse management. The use of sustainable and non-hazardous materials and accessories should be encouraged for cold chain packaging. Since many components of cold chain packaging are charged by energy, energy use and potential green energy alternatives should be assessed. In addition, waste management and other cold chain packaging management should receive more attention, such as the management of empty containers.

Sustainable materials need to be used to control the energy used during transportation and storage and reduce environmental hazards. The materials and devices used in cold chain packaging need to be safe and environmentally friendly. Blanc et al. (2019) found bioplastics have less environmental impact than conventional plastics. With the advancement of technologies and materials, the impact on the environment of the application of these technologies should be carefully assessed. For example, dry ice and liquid nitrogen have good temperature control properties; however, their impact on the environment needs further evaluation. Similarly, the sustainability of the use of phase-change materials and other materials or devices, needs to be assessed.

Energy use should also be evaluated. According to the International Association of Ports and Harbors, global climate change is caused by rising emissions of greenhouse gases, including carbon dioxide, methane and nitrogen dioxide in port operations (Yang, 2017). The use of refrigerated warehouses and trucks consumes a large amount of energy (Saif and Elhedhli, 2016). Reefer activities account for about 20%-35% of the total energy consumption of a terminal (Rodrigue, 2017b). Most cold chain packaging activities depend on energy, such as vessel or reefer operations, refrigerators, cold rooms, monitoring devices, etc. Some phase-change materials need to be frozen or refrigerated down to a specific temperature before use, while some cold chain products, such as food, need to be pre-cooled before transportation, which requires additional energy use.

Refrigeration should be planned after comprehensive research on the routes, to identify where and when to use which cooling approaches to minimize energy use. Due to the rise in diesel prices, stricter regulations on air pollution and increasing awareness of sustainable development, renewable energy can be good substitutes, like electricity from solar power. Cargo handling equipment with electrical power has advantages over traditional equipment in terms of energy savings and CO_2 emissions (Yang, 2017). However, the optimal configuration of quality, temperature and energy use needs to be analysed (Zanoni and Zavanella, 2012).

The active cooling systems of cold chain packaging may contribute to emissions of greenhouse gases, which have been found to be the main cause of global warming. The energy consumption of cold chain packaging is associated with CO_2 in power generating equipment. Furthermore, refrigeration systems use Hydrofluorocarbon (HFC)ESP gases which have high global warming potential; air conditioning and refrigeration contributes the largest amount of HFC emissions, while food processing also contributes. Excessive leakage of HFC can seriously pollute the environment (Saif and Elhedhli, 2016); therefore, emissions of these gases should be monitored and regulated.

Different stakeholders can take different measures to reduce GHG emissions and energy use. Manufacturers can make sure the design of cold chain packaging shipping solutions meets GHG emission reduction requirements. These shipping solutions can then be adapted by logisticians and shippers. Energy providers can add bio fuels into petrol or diesel to reduce GHG emissions. Carriers can optimize their distribution planning and routes to minimize energy use. Public policies can increase incentives for people and companies to behave in more ecofriendly ways (Rizet et al., 2012).

Waste also needs to be minimized. Reusable packaging is more sustainable than single-use packaging. Reusing or recycling schemes provided by cold chain logistic providers along with their cold chain packaging can reduce unnecessary waste and harm to the environment. Goellner and Sparrow (2014) found that using reusable shipping containers can significantly reduce environmental impact. Empty containers have been one of the complex problems in global freight transportation when the containers cannot find goods to transport for the outbound shipment. Empty containers account for about 10% of existing container assets and 20% of global port handling, mainly due to causes like trade imbalance, repositioning costs, manufacturing and leasing costs, usage preferences, etc.

The most important factor influencing the problem of empty containers is trade imbalance; a region with more imports than exports will face a systematic accumulation of empty containers, while a region with more exports than imports may face a shortage of containers. Another factor is the repositioning costs, which include both inland and international transport costs. If the costs are too high, this may lead to shortages of containers in the export markets. Similarly, if the cost of manufacturing new containers or leasing existing containers is lower than repositioning them, empty containers may accumulate. Furthermore, some companies may prefer to use large shipping lines to publicise their brand and may be reluctant to maximise the container usage rate (Rodrigue and Notteboom, 2020b).

It is also important to evaluate the waste and recycling management of materials and technologies used for cold chain packaging, like phase change materials, sensors, etc. Life cycle assessment can be conducted to evaluate these newly developed materials and technologies (Canals et al., 2006; Finnegan, 2013; Rezaei et al., 2019; Bonou et al., 2020). Also, companies need to optimise the balance between economic and environmental objectives, while policy makers should carefully evaluate the empty container situation and introduce appropriate guidelines to improve the overall sustainability of containers.

5.4.4 OPERATION OPTIMIZATION

Optimization in supply chain and logistics operations is important. Cold chain logistics requires not only more investment in infrastructure and technology but also a “no breakage chain”, since low temperatures need to be maintained (Du et al., 2022). Most of the optimization models proposed in the cold chain literature focus on route planning and the impact on the carbon footprint. Wang et al. (2017) analysed the optimization of vehicle routing problems of time windows, cost and carbon emissions. Andoh and Yu (2023) proposed a model integrating route optimization and advanced simulation for the sustainable performance of last-mile vaccine cold chain operations. Li et al. (2019) studied the optimization of cold chain integrated inventory routing considering carbon emissions. In such optimisation calculations, it is important to analyse clients' needs and propose cold chain packaging solutions accordingly, considering factors like cost, time, sustainability, etc.

The cold chain packaging system needs to be optimized to fit supply chain and logistics, refrigeration and packaging requirements. Efficient planning of the cold chain needs to consider the design of the packaging, including making the shipping solution ergonomic and easy to handle during the cold chain; tertiary packaging or logistical packaging units need to be easy to handle for logistics workers. Standardized containers are good for operation and handling, but also need to meet the requirements for reefer terminal facilities, such as stacking. For example, reefers can be stacked through wheeled storage, stacked storage or rack storage, depending on the cost and space available (Rodrigue and Notteboom, 2020c). Secondary cold chain packaging should be easy to handle for distribution, and primary packaging needs to meet consumers' requirements. All levels of cold chain packaging need to have sufficient refrigeration.

The design and configuration of the cold chain is a continuous decision-making process of optimization. Another aspect that needs more attention is stakeholders' perception of risk in cold chain packaging. Risk attitudes and perception impact people's behaviour; therefore, the risk perception of managers and practitioners has an impact on their decision-making and actions taken in a certain scenario. Guo et al. (2018) analysed the impact of socio-demographic and situational factors on a practitioner's risk perception and risk probability measurement. The risk perception of workers can also affect the performance of cold chain packaging; if the workers are not aware of the negative consequences of temperature disruptions, then they may be reluctant to follow the strict rules of low-temperature preservation and monitoring.

A further link that is often ignored in cold chain logistics is the link from purchase to home and at home. Customers are found to sometimes not follow cold chain requirements on the way home or at home, and this is due to unsatisfactory efforts in educating and informing consumers (Ovca and Jevšnik, 2009). Therefore, efficient information, instructions and training need to be given to different stakeholders in cold chain packaging to make sure the operations of cold chains are maintained.

Proper and up-to-date personnel training should be given regularly. Efficient certification and upskilling should be implemented to optimize the operational process. In this way, the process can be standardized, which can reduce the risk of human error and occupational safety hazards (Tsang et al., 2018). Occupational safety can also be improved, preventing injuries. Interactive smart packaging is good for providing instructions and information in an interactive way for workers and consumers. The impact of incorporating new technologies, like sensors and remote-control systems, also needs to be assessed. Electrically powered cargo handling equipment has higher working efficiency than conventional equipment since it has fewer parts and is therefore easier to repair and maintain (Yang, 2017). Thus, the overall operation can be optimized, saving cost and time. However, some of the infrastructure of reefer terminals can be costly, and thus further research is needed into ways of encouraging companies to adopt new technologies.

5.4.5 ENSURED QUALITY AND SAFETY

Ensuring the quality and safety of cold chain products is essential and is the ultimate goal of cold chains. Depending on the type of cold chain products, different factors need to be considered in evaluating product quality. For food products, factors that impact quality and safety include bacterial growth rate, humidity, pH and temperature (Hoel et al., 2017). For vaccines, potency can be lost due to factors like freezing, temperature disruption, etc. Besides the need to maintain product quality, cold chain packaging should also be safe, causing no potential harm to the product inside, to the workers handling it, to consumers, etc. Many applications have emerged of new technologies in cold chain packaging, such as sensors, indicators, PCMs, etc. Despite the merits they bring, they can bring new challenges at the same time.

The quality of cold chain products should be foremost since it is the foundation of other things. Disruption of temperature, humidity or air circulation can lead to quality deterioration of the product quality. Therefore, sufficient regulation and monitoring of the internal environment of cold chain packaging is essential. Efficient information management and decision-making are also important; good information management should make sure information is shared among relative stakeholders. At the same time, data storage and management should pay attention to potential cybersecurity risks.

The trend of cold chain packaging has shifted from traditional packaging to smart packaging, with more advanced materials, technologies, and management systems, which has improved overall cold chain performance. However, there are still limitations and challenges regarding current smart cold chain packaging. For example, operation under low temperatures may inhibit its performance. Also, the risks of new smart packaging forms remain unclear; there is still a lack of literature in this area of study. The complexity of the cold chain and the properties of PCMs are key factors affecting the performance of cold chain packaging, which need more research attention. Leakage of PCM has been found to be the main issue with this coolant, and many studies have been conducted of possible solutions to this problem, such as microencapsulation, the addition of nanoparticles, etc.

Cold chain packaging should be safe and not cause any harm to the product, people or environment. However, some new materials and technologies used in cold chain packaging have been found to be potentially hazardous. For example, commercial-grade PCM produces hazardous vapours when burnt. PCMs made of vegetable oils are safe but are highly flammable. Salt hydrates in general are safe but they may cause irritation and breathing problems if handled improperly (Chandel and Agarwal, 2017). Therefore, the handling of these materials still needs more research attention, and relevant guidelines are needed.

Occupational safety is another concern for cold chain packaging. Tsang et al. (2018) analysed risks related to occupational safety through IoT-based risk monitoring of the cold chain. Workers in cold chain packaging are still subject to potential hazards. For example, working in an ultralow temperature environment can lead to cold-related illnesses. Monitoring of workers' health conditions is important, which can be achieved with the aid of new wearable technologies, but data management can be an issue for this; access to the data needs to be strictly regulated and managed to protect workers' privacy.

Another area of concern is that cold chain packaging is being transported in a dynamic environment; the route, weather and season all have an impact on the performance of the packaging. Therefore, when planning the route, it is important to consider all of these factors. Furthermore, there should always be a certain level of redundancy available for cold chain packaging in case of any emergency situation, especially for added-value cold chain products or expensive medical products. In this way, the quality and safety of cold chain packaging can be subject to a lower level of risk.

5.5 CONCLUSION TO THE CHAPTER

This chapter gives an overview of the existing industry shipping solutions and proposes a conceptual framework that consists of the key performance metrics of the cold chain packaging system. A Pallet-Parcel-Coolant-PCM hierarchical structure of the refrigeration of cold chain shipping solutions is proposed, and coolants, parcels, pallets, accessories, monitoring systems and available services are discussed. The PCM coolant is the core of temperature regulation in cold chain shipping solutions due to its phase-changing nature. Parcel and pallet solutions integrate coolants with other insulation, technologies, and accessories to achieve better performance and wider temperature ranges, durations and payload sizes. **A conceptual framework consisting of the key** performance metrics for cold chain packaging is proposed, including metrics like efficient regulation of the internal environment, information management, sustainability, operational optimization and ensured quality and safety. All of these factors play important roles in the performance of cold chain packaging.

CHAPTER 6 A CASE STUDY OF RISK MANAGEMENT OF VACCINE COLD CHAIN SHIPPING SOLUTIONS

6.1 INTRODUCTION OF THE CHAPTER

This chapter includes a case study applying the use of the risk management model proposed in chapter 4. Risk identification, assessment and mitigation of risks of cold chain packaging in the vaccine industry are done. First, the description of the case study is given, including some background information about vaccine cold chains. Then the methodologies for data collection and analysis used in the case study are explained. The results of the risk management process are shown and discussed at the end.

6.2 CASE STUDY DESCRIPTION

The global expansion of immunization programs, humanitarian supply chains and the pandemic disruptions of COVID-19 have increased the demand for vaccines in the past few years. The distribution of COVID-19 vaccines has received considerable attention in the past few years due to its urgency and special temperature requirements for vaccine storage and distribution. The WHO now has humanitarian vaccines for more than 20 life-threating diseases, including diphtheria, tetanus, pertussis, influenza, measles, etc., which can prevent about 3.5 to 5 million deaths every year (Anon, 2024).

A vaccine cold chain starts from when the research and development of the vaccines begins and then through manufacturing, transportation to national and regional storage facilities, and next to health centres or to outreach, all in refrigerated environments during transportation and storage. Figure 6.1 illustrates the flowchart of the vaccine cold chain.

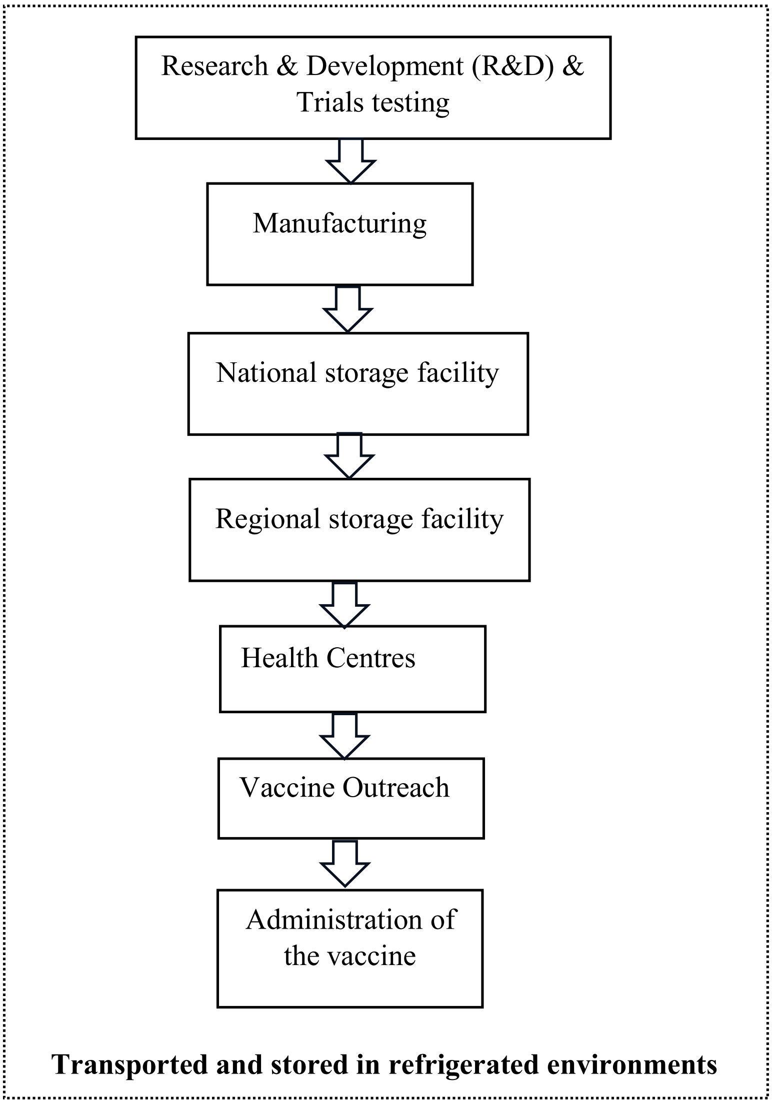


Figure 6.1: A flowchart of vaccine cold chains

Vaccine cold chains start from Research & Development (R&D), followed by several trials testing. Then they will be manufactured and transported to national or regional storage centres. After that, they will be distributed to hospitals and health centres. In some situations, vaccine outreach is needed in remote areas where there is a lack of healthcare and cold chain infrastructure. Vaccines need special low-temperature storage and distribution due to their temperature-sensitive nature, and if not properly stored, can lead to serious health and safety hazards. Ultra-low cold environments are required for some vaccines, e.g., COVID-19 vaccines.

Quality and safety of vaccines are important since quality and safety related issues can lead to adverse consequences on people's health. Occupational safety is another issue which needs more attention. The cold working environment can cause many cold diseases such as hypothermia. Frostbite, etc. Existing literature mainly focuses on quality management of the food cold chain, and occupational safety is often overlooked. Thus, it is important to delve into the safety and risk management of vaccine packaging. And how the shipping containers and handling affect quality and safety related risks need to be addressed. Therefore, this case study aims to analyse quality and occupational safety related risks and the impact of shipping containers and handling on them using the risk management model proposed in chapter 4. This study focuses on an operational level, therefore environmental and supply chain related risks are not within the scope of the study.

Therefore, this case study aims to identify, assess and mitigate the potential risks involved in vaccine cold chain packaging in Thailand, using the risk management model proposed in chapter 5. Risk factors identified in the case study include product safety risk, occupational safety risk, container risk, handling risk, packaging risk and monitoring risk. The causes and possible consequences of the risk factors are assessed. The prior and posterior probabilities of each factor are defined based on expert opinions. Risk mitigation strategies identified include multi-sourcing, a multi-skilled workplace, information management, and refrigeration management. Sensitivity analysis is conducted to assess the impact of changing one variable on other variables.

6.3 DEVELOPMENT OF INTEGRATED RM MODEL IN COLD CHAIN SHIPPING CONTAINERS

6.3.1 RISK IDENTIFICATION

In the case of vaccines, product safety risks can cause potential health hazards due to vaccine quality deterioration. Contamination, loss of vaccine potency, over-thawing or mechanical damage can lead to product safety issues, which can lead to hazards like vaccines not being effective or even causing harm.

Occupational safety risks are risks that can cause harm to cold chain workers' health and safety due to the extraordinarily cold working environment or improper training, and these can lead to injuries or cold-related illness or slipping on cold surfaces. Container risks are risks that can damage the shipping containers, which can lead to temperature disruption, quality decay and safety hazards. Potential causes of container risk include poor packaging or monitoring of the cold chain.

Handling risks are risks that can lead to product or occupational safety issues due to wrong handling, which can lead to safety hazards, damage to products, injuries or waste. Factors that can lead to handling risk include insufficient personnel training, vague instructions, lack of sanitation, etc. Monitoring risk refers to risks that cause monitoring disruption and have the potential to cause over-thawing, lack of traceability, temperature disruption, etc. Insufficient or poor monitoring devices, and poor traceability can cause monitoring-related risks.

Packaging risk refers to risks that can cause damage to the packages, resulting in packages not being able to provide sufficient temperature control or harming the environment. Potential causes of packaging-related risk include inappropriate materials, inappropriate capacity, unsafe packages and lack of packaging sustainability. Figure 6.2 details the construction of the risk management model topology for the vaccine cold chain shipping container risk management model.

6.3.1.1 Product safety risk

Several factors can potentially lead to product safety-related risks for vaccines, which include temperature disruption, insufficient monitoring, fraud, poor handling, supply chain and environmental risks. For vaccines, exposure to temperatures outside the recommended temperature range can cause great damage. Temperature disruption above or below the recommended range can both lead to negative impact on the safety of the vaccine; the quality of the vaccine will be harmed, which can have an adverse impact on people's health. Also, fraud can be an issue for the safety of vaccines since fraudulent vaccines do not follow strict guidelines during manufacturing and insufficient refrigeration and monitoring are used in the shipping solutions. Poor handling of the shipping containers can also cause damage to vaccines.

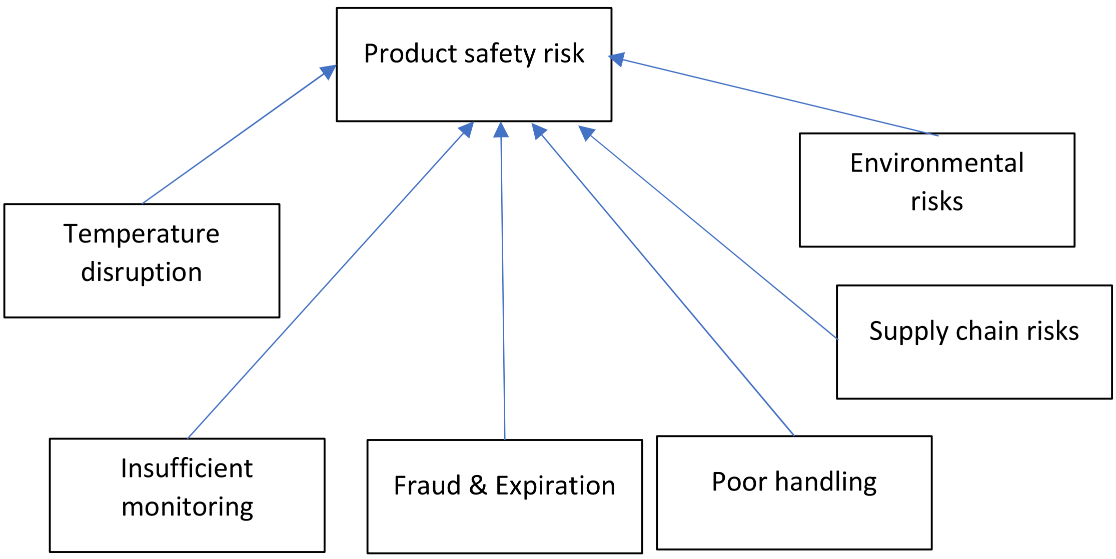


Figure 6.3: Factors leading to vaccine safety risks

Exposure to heat can damage vaccines by changing the tertiary protein structure, dissociating polysaccharides from protein carriers in polysaccharide conjugate vaccines and reducing the effectiveness of live-attenuated vaccines. The impact of heat damage is usually cumulative, and one coping method is the use of Vaccine Vial Monitoring (VVM), in which a sticker or label is affixed to a vaccine vial which aims to estimate the remaining shelf life of vaccines when exposed to continuous heat (Chen and Kristensen, 2009). The mechanism of VVM is a colour change based on the Mean Kinetic Temperature, which indicates the total thermal stress vaccine experiences in a period (Ross et al., 2020). Besides vial monitoring, other monitoring is needed in the vaccine cold chain shipping container, e.g., the use of data loggers and sensors, etc.

Apart from the potential harm from heat damage, vaccine shipping containers can also be subject to freezing. Freezing of vaccines can also affect them adversely, e.g., causing clustering of the adjuvanted particles, antigen degradation and molecular changes, which poses additional stress to the cold chain (Kurzątkowski et al., 2013). The WHO Shake Test is designed to detect if freezing occurs in a vaccine vial. During a Shake Test, first, one vial from a batch is selected as the control vial. Then it is frozen overnight and subsequently thawed. Second, another vial is selected for testing, and then the sedimentation rates of the two vials are visually compared. When the sedimentation rate of the test vial is the same as or greater than the controlled one, it indicates that freeze/thaw has occurred in this test vaccine vial. In this case, the whole batch of vaccines should be abandoned (WHO, 2015). However, the shake test is usually done on only one vial of a pack.

Poor handling of the vaccine cold chain packaging can lead to product safety issues. Improper handling can damage the passive cooling systems, e.g. causing leakage of PCM packs or bottles, broken sensors, vial leakage, etc., and this can lead to hazardous consequences for the vaccine and cold chain personnel. For vaccines that require ultra-low cold chain storage and transportation, liquid nitrogen and dry ice are sometimes used, and improper handling of these substances can cause safety hazards. Improper handling of the vaccine packaging can also interfere with the air circulation and compression forces, which can lead to physical damage of the packages and disruption of the temperature.

Fraud and expiration of the vaccines are other issues that can lead to vaccine safety risks. Expired vaccines have decreased potency and are more likely to cause safety issues to human health. Vaccines are usually monitored by government supervision departments, which require random sampling to ensure vaccine safety. Many data will be generated along with the vaccine shipping solutions, such as batch packing records, batch production records, inspection records, and inoculation records. However, it is still possible to tamper with the records. Information technology management systems like IoT and blockchain can be used to manage the data, but they may be subject to cybersecurity-related problems. Factors that can potentially lead to technology-related risks are shown in Figure 6.3.

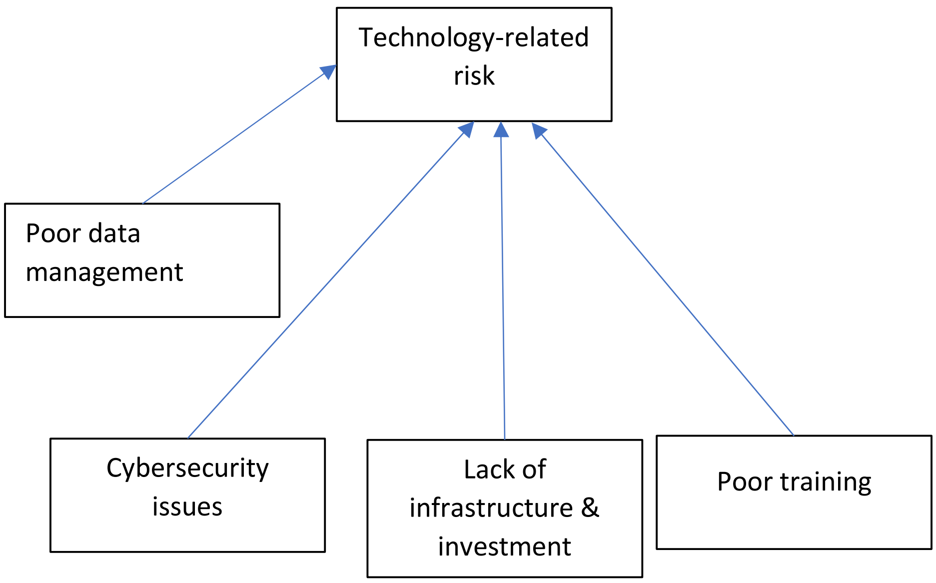


Figure 6.4: Factors that may lead to technology-related risks in vaccine cold chains

Cybersecurity is an issue for many supply chains. Cybersecurity actors exist at both individual and national level. In January 2021, the US healthcare system's refrigeration systems faced cybersecurity threats through data tampering of their temperature sensors used in COVID-19 vaccine cold chain transportation and storage. More than 3,000 doses of Pfizer and 16,000 doses of Moderna vaccine were affected (Long et al., 2021). Intentional electromagnetic interference can disrupt and tamper with the output of temperature sensors. To ensure public confidence in vaccine efficacy, it is important to reduce cybersecurity-related risks. Precautions of physical and administrative controls can reduce the risks of cybersecurity threats. Other technology-related risks include poor data management, poor training, and a lack of infrastructure and investment in vaccine cold chain packaging.

6.3.1.2 Occupational safety risk

Occupational safety related risks are also important. Working in a low-temperature environment is certainly not risk-free, and rigid monitoring is needed. Lack of personal protective equipment, poor training and handling of the packages can all lead to occupational risks. In Figure 6.4, factors that can potentially lead to occupational safety related risks are shown.

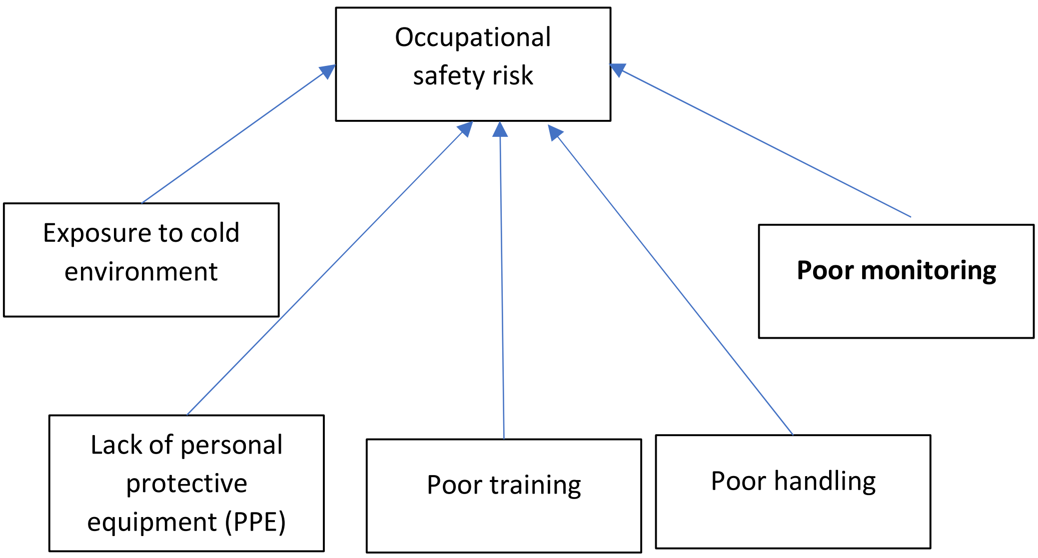


Figure 6.5: Factors that can potentially lead to occupational safety-related risk

Vaccine cold chain packaging workers sometimes need to work in a cold chain or ultra-low temperature environment. Repeated exposure to cold environments can cause health hazards. Exposure to a cold environment can cause injuries, cognitive and motor impairments such as impaired tactile sensitivity, muscle function, proprioception, finger mobility, grip strength, increasing arousal levels and distracting attention (Ray et al., 2019). Poor handling of packages can lead to physical harm to workers, and broken packages can cause leakage of phase-change materials or refrigerants, which are hazardous and can harm human health.

Real-time monitoring and efficient training should be given to personnel working with cold chain packaging. The monitoring systems should be able to handle vague information and aid in decision-making, and personalized training should be given to the personnel involved. With the emergence of information management and AI technologies, there have been many applications incorporating these techniques. Zhan et al. (2022) proposed a real-time occupational safety monitoring system based on IoT and digital twin technologies. Thielmann et al. (2020) proposed an online learning program called Keep Cool to assure optimal vaccine storage conditions with the aid of tailored training for individuals. Individuals may have different tolerance to the cold environment, and factors like body fat, level of physical fitness, diet, blood pressure, heart rate, skin temperature, mean body temperature, core temperature, etc., impact individuals' adaptation to cold (Zlatar et al., 2019). Tsang et al. (2018) proposed an IoT-based risk monitoring model for managing personal health data in cold chains.

6.3.1.3 Cold chain shipping solutions' relationship with product and occupational safety risks of vaccines

Specially designed cold chain shipping containers are often used for vaccines. These shipping containers normally contain packaging systems to maintain temperatures within specific ranges and monitoring systems to keep track of temperature fluctuations. However, poor shipping container designs can cause temperature disruption, leading to decay in vaccine quality and safety, while human error can also lead to safety issues or even cause injuries. Poor handling of vaccine cold chain shipping containers can lead to product and occupational safety related risks, so it is crucial to conduct safety and risk management for handling them. Risk factors that can potentially lead to product and occupational safety risks are listed in Figure 6.5.

Cold chain shipping containers can provide regulation of the internal environment as well as monitoring throughout the cold chain. Also, many companies have launched training, recycling and reuse programs along with their cold chain shipping solutions. Personalized solutions are usually provided to meet the specific requirements of the cold chain. Therefore, the risk management of product and occupational safety risks for vaccines needs to be analysed from the perspective of comprehensive shipping solutions. This will enable logistics providers to locate weaknesses in their chains and continuously improve their operations. The proposed risk management model for vaccine shipping solutions is illustrated in Figure 6.5.

6.3.2 RISK ASSESSMENT

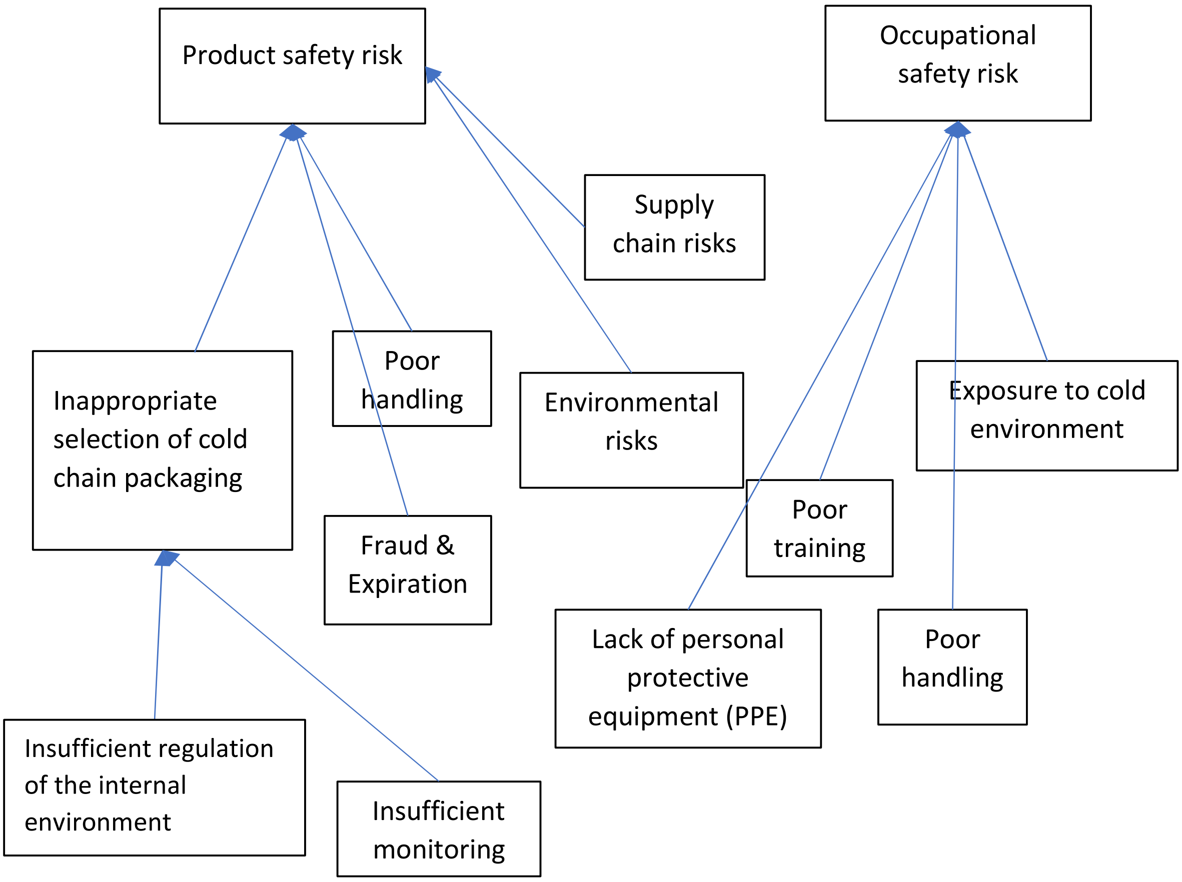


Figure 6.6: Risk factors of vaccine cols chain shipping solutions that can lead to product and occupational safety risks

To ease the calculation process, the risk assessment focuses on vaccine shipping container risk and handling risk, illustrated in Figure 6.6. Shipping containers contain monitoring devices and materials and devices for regulating the internal environment in the container. The risk factors for vaccine cold chain shipping solutions, as listed in Table 6.1, include product safety risk, occupational safety risk, container risk, handling risk, monitoring risk and packaging risk. The possible causes of these risks are included, as well as the possible consequences.

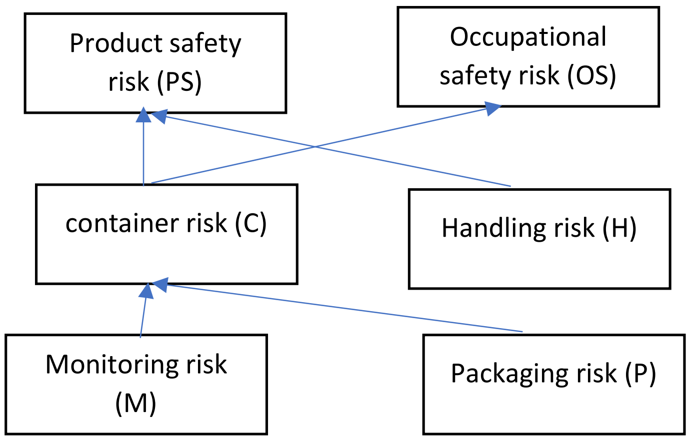


Figure 6.7: BN model of safety risks of vaccine cold chain shipping containers

The causal relationships of different risk factors are illustrated in Figure 6.6 above. Domain experts were asked to describe the prior and conditional probabilities of the nodes. Because of the complicated sources of information, expert judgment in linguistic expressions is employed to describe the risk probability to alleviate the problem of imperfect data. Linguistic terms are used to determine the fuzzy probabilities of each factor, which indicates the range of probabilities.

The selection of linguistic terms and membership functions depends on specific scenarios and expert judgements. A membership function is selected based on how we quantify certainty or degree of truth of a variable according to selected linguistic values. In this case study, a seven-point Likert scale is used, as recommended by the International Maritime Organisation (IMO). The list of likelihoods and their definitions are shown in Table 6.2. The ranges of values of each term are also listed. Take "Likely" as an example, it falls the range (0.57. 0.71]. Triangular fuzzy membership sets are used for the fuzzification step. All membership functions in this case study use narrow ranges of intervals for calculation so the spread of the posterior probabilities is not too wide.

Table 6.1: Identified safety risk factors in cold chain packaging

Risk factor	*What can cause it?*	*What are the possible*

		consequences?
Product safety risk	*Contamination, loss of vaccine potency, over-thawing, mechanical damage*	*Vaccine not being effective, health harm*
Occupational safety risk	*Working in extreme cold temperature, improper training on handling shipping containers*	*Injuries, cold-related illness, slipping on cold surfaces*
Container risk	*Poor packages used, poor monitoring during cold chain*	*Temperature disruption, quality decay, safety hazards*
Handling risk	*Insufficient training, vague instructions, lack of sanitation*	*Safety hazards, damage to products, injuries, waste*
Monitoring risk	*Insufficient monitoring devices, poor monitoring devices, poor traceability*	*Over-thawing, lack of traceability, temperature disruption*
Packaging risk	*Inappropriate materials used, inappropriate capacity, unsafe packages, packages lack sustainability*	*Environmental hazards, insufficient temperature control*

Table 6.2: Seven-point Likert scale of Likelihood

Likelihood	*Value range*	*Definition*
Extremely rare	*[0,0.14]*	*Never or extremely rarely occurs.*
Rare	*(0.14,0.29]*	*Very unlikely to occur, only expected under extreme circumstances*
Unlikely	*(0.29, 0.43]*	*Not likely to occur in most circumstances*
Possible	*(0.43, 0.57]*	*Possible to occur at some points*
Likely	*(0.57. 0.71]*	*Likely to occur in some circumstances*
Frequent	*(0.71, 0.86]*	*Very likely to occur in most circumstances*
Very frequent	*(0.86,1]*	*Can be expected to occur in most circumstances or all the time*

Tables 6.3, 6.4 and 6.5 demonstrate the fuzzy prior probabilities of nodes M, P and H. For node M, there are 2 possible values, M1 and M2. The possibility of occurrence is described with the linguistic term ‘Possible'. Then the linguistic term is further described as a fuzzy triangular set (0.49, 0.5, 0.51) based on the value range in Table 5.2. The most likely value of M1 is 0.5. The lower and upper likely values of M1 are 0.49 and 0.51. Similarly, nodes P and H have fuzzy number sets of P1 (0.19, 0.1, 0.21) and H1 (0.59. 0.6, 0.61). These values are average values from three experts based on Table 6.2.

Table 6.3: The occurrence probabilities of ‘Monitoring risk’ (M)

	P(M)
M1	*(0.49. 0.5, 0.51)*

M2	*(0.49, 0.5, 0.51)*

Table 6.4: The occurrence probabilities of 'Packaging risk' (P)

	P(P)
P1	*(0.19. 0.2, 0.21)*
P2	*(0.79, 0.8, 0.81)*

Table 6.5: The occurrence probabilities of 'Handling risk' (H)

	P(H)
H1	*(0.59. 0.6, 0.61)*
H2	*(0.39, 0.4, 0.41)*

Tables 6.6, 6.7 and 6.8 demonstrate the fuzzy conditional probabilities of nodes C, PS and OS. The conditional probabilities of 'container risk' with respect to 'monitoring risk' and 'packaging risk' are listed in Table 6.6. The fuzzy probabilities of all combinations of the causes are listed. 'Container risk' is extremely rare if 'Monitoring risk' and 'Packaging risk' are not present, with a fuzzy possibility of (0.04, 0.05, 0.06). If both monitoring and packaging risks are present, then 'Container risk' is frequent, with a fuzzy possibility of (0.74, 0.75, 0.76). When there is only 'Monitoring risk' and no 'Packaging risk' present, then 'Container risk' is unlikely, with a fuzzy possibility of (0.34, 0.35, 0.36). When there is only 'Packaging risk' and no 'Monitoring risk' present, then 'Container risk' is possible, with a fuzzy possibility of (0.54, 0.55, 0.56). Similarly, the conditional probabilities of 'Product safety risk' and 'Occupational safety risk' are listed in Tables 6.7 and 6.8.

Table 6.6: the conditional probability of 'Container risk' (C)

		P (C1|P, M)	*P (C2|P, M)*
M1	*P1*	*(0.74, 0.75, 0.76)*	*(0.24, 0.25, 0.26)*
	P2	*(0.34, 0.35, 0.36)*	*(0.64, 0.65, 0.66)*
M2	*P1*	*(0.54, 0.55, 0.56)*	*(0.44, 0.45, 0.46)*
	P2	*(0.04, 0.05, 0.06)*	*(0.94, 0.95, 0.96)*

Table 6.7: The conditional probabilities of 'Product safety risk' (PS)

		P (PS1|C,H)	*P (PS2| C, H)*
C1	*H1*	*(0.84. 0.85, 0.86)*	*(0.14, 0.15, 0.16)*
	H2	*(0.34, 0.35, 0.36)*	*(0.64, 0.65, 0.66)*
C2	*H1*	*(0.59, 0.6, 0.61)*	*(0.39, 0.4, 0.41)*
	H2	*(0.01, 0.02, 0.03)*	*(0.97, 0.98, 0.99)*

Table 6.8: The conditional probabilities of 'Occupational safety risk' (OS)

		P (OS1|C,H)	*P (OS2| C, H)*
C1	*H1*	*(0.64. 0.65, 0.66)*	*(0.34, 0.35, 0.36)*
	H2	*(0.44, 0.45, 0.46)*	*(0.54, 0.55, 0.56)*
C2	*H1*	*(0.19, 0.2, 0.21)*	*(0.79, 0.8, 0.81)*
	H2	*(0.04, 0.05, 0.06)*	*(0.94, 0.95, 0.96)*

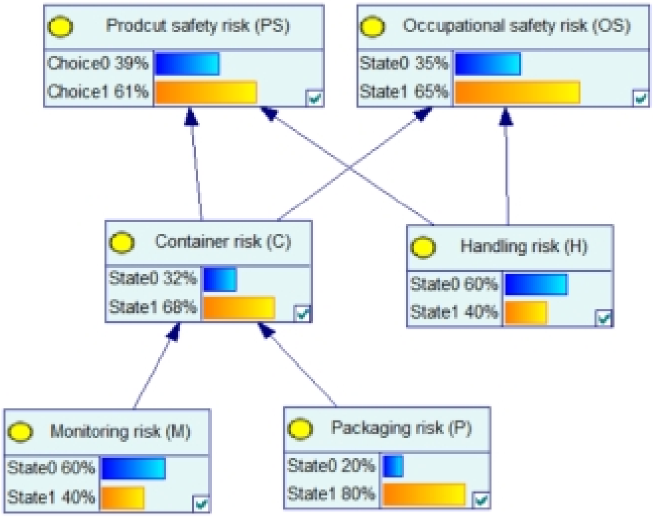


Figure 6.8: BN model consisting of all the nodes, using GeNIe

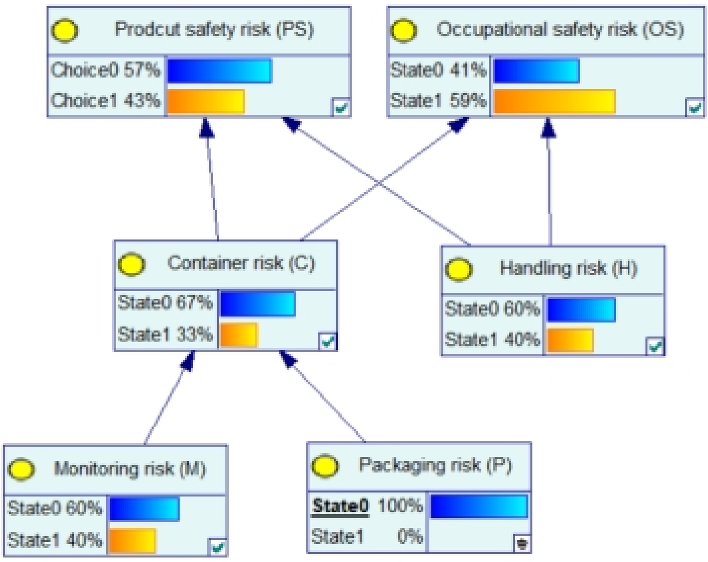


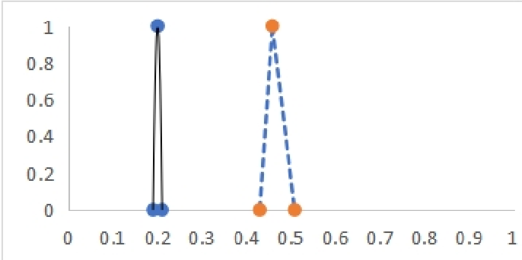
Figure 6.9: BN model consisting of all nodes

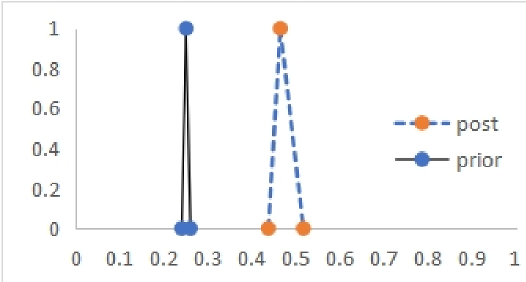
Figure 6.7 and 6.8 detail the BN-based risk management model for vaccine cold chain shipping containers, and sensitivity analysis is carried out. As we can see in Figure 6.8, when state0 or prior probability of "Packaging risk" is 100%, "Product risk" 's state0 changes to 57%. So "Packaging risk" increases with "Product risk". This is consistent with the sensitivity test results in Table 6.9.

The purpose of sensitivity analysis is to analyse the impact of changing an independent variable on a particular dependent variable and therefore see how uncertainties of different inputs can affect the overall uncertainty of the model (Nguyen et al., 2019). To conduct sensitivity analysis, changes of the prior probabilities of one variable are needed, and the changes in the posterior probabilities are logged to assess the impact. For this case study, the variable ‘Packaging risk’ is selected for sensitivity analysis, and 7 different values are input: (0.19,0.2,0.21), (0.24,0.25,0.26), (0.29,0.3,0.31), (0.34,0.35,0.36), (0.39,0.4,0.41), (0.44,0.45,0.46) and (0.49,0.5,0.51). The corresponding posterior probabilities are calculated and shown in Table 6.9, which shows that as P(P=P1) gradually increases, P(PS=PS1|P=P1) also steadily increases, which is also shown in Figure 6.8, validating the reliability of the results.

Table 6.9: Sensitivity analysis results between P(X=X1|W=W1) and P(X=X1)

No	*P(P=P1)*	*P(PS=PS1|P=P1)*
1	*(0.19,0.2,0.21)*	*(0.429518245, 0.457676,0.507992767)*
2	*(0.24,0.25,0.26)*	*(0.436882455, 0.46388, 0.516307357)*
3	*(0.29,0.3,0.31)*	*(0.444246665, 0.470084, 0.524621947)*
4	*(0.34,0.35,0.36)*	*(0.451610875, 0.476288, 0.532936537)*
5	*(0.39,0.4,0.41)*	*(0.458975085, 0.482492, 0.541251127)*
6	*(0.44,0.45,0.46)*	*(0.466339295, 0.488696, 0.549565717)*
7	*(0.49,0.5,0.51)*	*(0.473703505, 0.4949, 0.557880307)*


1
0.8
0.6
0.4
0.2
0
0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9 1


1
0.8
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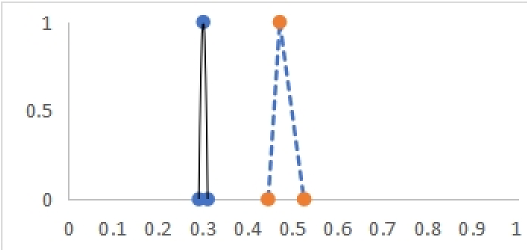
post
prior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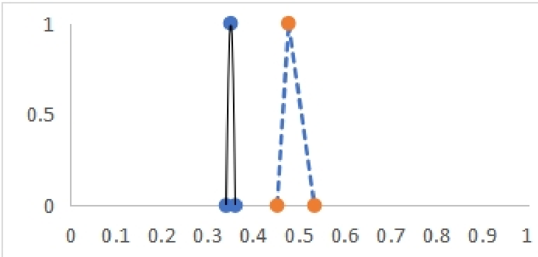
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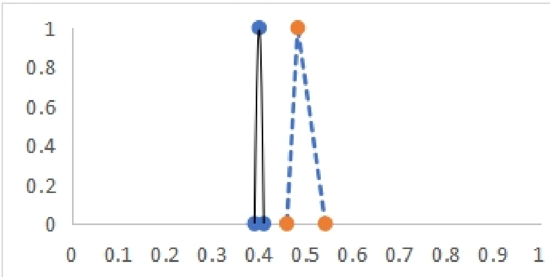
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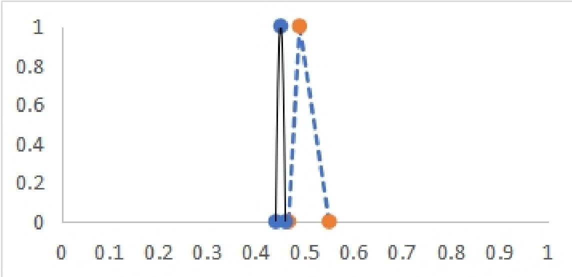

Figure 6.10: Sensitivity analysis results by manual calculations

6.3.3 RISK MITIGATION

6.3.3.1 Risk mitigation strategy identification

This section focuses on the final stage of the risk management process: the identification and assessment of risk mitigation strategies. The risk mitigation strategies are identified through a review of literature and documentation review and by direct observation, then further validated through questionnaires. Table 6.10 lists the risk mitigation strategies identified for vaccine cold chain packaging.

Table 6.10: List of risk mitigation strategies

Risk mitigation strategy	*Details*
Multi-skilled workforce	***Reduce chances of operation failure, respond quickly to disruption; Certifications can help upskill personnel.***
Information management	***Select suppliers with strong focus on quality, buyer–supplier (upstream–downstream) collaboration.***
Multi-sourcing	***So when one suppler fails, the cold chain will not be entirely disrupted.***
Refrigeration management	***Optimize temperature control and monitoring through data and information sharing and management.***

Multi-sourcing

Due to the increasing demand for vaccines, managing the value chain of perishable items is of great importance. Logistics providers play an important role in this sector. Many companies choose third-party logistics providers for the transportation and storage of their vaccines. However, choosing a suitable third-party logistics provider is not easy, especially in today's global environment. Singh et al. (2017) proposed a model for selecting third-party logistics providers, a choice where geopolitical risks can have a great impact. To combat the consequent uncertainties, a strategy of multi-sourcing can be used to diversify the supplier profile, thereby reducing potential risks. Multi-sourcing is a supply chain strategy in which buyers source similar inputs from various suppliers (Baiman and Rajan, 2002).

Supply-related risks are unavoidable. Many factors can cause supply uncertainty, such as yield uncertainty, natural disaster, or supplier bankruptcy (Wu et al., 2019). Vaccine cold chains face high uncertainties of demand and supply. During a pandemic, the demand for related vaccines and other pharmaceutical products increases suddenly but with limited logistical capacity due to rigid storage and temperature requirements. For instance, the Pfizer COVID-19 vaccines require a storage temperature of -70 C; therefore, specially made ultra-low-temperature freezers were needed. However, most countries do not have the capacity for such infrastructure. Due to the perishability and seasonality of cold chain products, this can lead to product quality decay or even safety issues if cold chains are not able to be maintained. Therefore, many companies choose to multisource as a strategy to reduce related risks. For example, influenza vaccine providers source vaccines from Sanofi Pasteur, Seqirus, GlaxoSmithKline, etc.; by having multiple suppliers, companies can reduce the risk of inventory or shortage risks. Such an act is called risk diversification (Babich et al., 2007).

The strategy of global sourcing is used by some companies and involves a trade-off between reliable high-cost local suppliers and unreliable low-cost offshore suppliers (PrasannaVenkatesan and Kumanan, 2012). Factors like price, exchange rate risk and supplier reliability need to be considered during sourcing, and the multi-sourcing strategy can diversify the risks in vaccine development and delivery. Take the COVID-19 vaccine, for example: there were R&D champions in different countries, which accelerated the development rate of the vaccines and enabled countries to multi-source the manufacturing, transportation and storage of vaccines all around the world.

Multi skilled workplace

Multi-skilled workplaces can decrease supply chain risks. Cold chain packaging is a multi-disciplinary area that involves supply chain management, cold chain logistics and packaging management. Therefore, a multi-skilled workplace is necessary for all steps of the cold chain. The design and planning of cold chain packaging should be started during the vaccine development stage to see if any existing cold chain packaging fits the requirements or new solutions need to be found. This requires a varied range of skills, such as supply chain management, refrigerated transportation and storage, vaccine packaging, vaccine development, etc.

Taking the COVID-19 pandemic as an example, governments, research centres and logistics providers from all around the world needed to all work together to plan the cold chain of the COVID-19 vaccines. Multi skilled workplaces are extremely important in this situation since no single person or organisation can do it all. Training and skills in multiple areas are needed. Also, the situation may change quickly at any the time, so it is important to have a resilient and agile cold chain when facing high uncertainty. This can reduce the chances of operation failure and allows a rapid response to disruptions.

Certification can help upskill personnel in different fields, such as risk analysis, cold chain management, etc. There are many certifications involved with cold chain packaging. The Cold Chain Manager certificate is offered by the Global Cold Chain Alliance, which involves logistics, cold chain temperature control, compliance, etc. For specific cold chain industries, there are different certifications available. The medical industry has the Good Distribution

Practice certificate, which involves compliance with related cold chain guidelines and regulations. International Safe Transit Association certificates are related to cold chain packaging. There is also the food cold chain professional certificate offered by the international association for Cold Storage Construction, and the Hazard Analysis and Critical Control Points certification for food safety and risk management. Certifications can make people more quality conscious and promote continuous improvement.

Information management

Information management and sharing is very important in cold chain packaging management. Cold chains involve many stakeholders, and it is important to investigate how to create a more transparent and responsible cold chain. Especially with the continuous advancement of technologies, like data loggers and Internet of Things (IoT), blockchain, etc., how to manage information and data has become significantly important. Shen et al. (2022) developed a block-chain-based incentive mechanism to guide cold chain logistic providers to participate in supply chain information sharing. Kim et al. (2020) developed a blockchain cold chain system based on Hyperledger Fabric to increase visibility in the blood supply chain. Feng et al., (2020) developed a model using blockchain, K-means clustering and SVM based multi-sensor monitoring system to classify and predict quality loss in frozen shellfish. Xing et al. (2020) utilized evolutionary game theory to study the behaviours of cold chain stakeholders and found that subsidies and punishment are needed to promote information sharing and compliance with regulations.

Cold chain products can be transported by refrigerated trucks and railcars, refrigerated cargo ships, reefers and air cargo. The continuous advancement of information technologies has transformed the cold chain into a digital realm. Smart containers make it possible to circulate information between carriers, terminal operators and cargo owners. Information like identification of the container, its location and physical characteristics are recorded, stored and shared. For example, the location coordinates can tell the estimated arrival time of the products. Data like the history of temperature, humidity, air pressure and fluctuations are monitored. Notifications can be sent out when the package enters a specific area. Shock detection is assessed to make sure that it does not exceed the threshold of the endurable stress level. Information about the container doors and locks is also monitored for safety purposes (Notteboom, 2022).

Refrigeration management

Efficient refrigeration is needed for the entire cold chain from the time vaccines are manufactured until the final injection of the vaccines. All links of the cold chain should be covered, and special attention needs to be paid to the in-between links, e.g., loading and unloading. Depending on the mode of transportation, detailed refrigeration management plans during loading and unloading need to be included in the route planning. For example, sea transportation involves selection of types of rerefers, vessels, ports, how to load and unload the products in ports, how to store the products during loading and unloading, as well as tariff requirements.

Efficient refrigeration management should meet the requirements of specific vaccines. If more than two types of vaccines are transported together, the temperature control requirements of the two vaccines should be carefully assessed. The stacking of the packages inside the reefer affects the cooling performance and ventilation of the products: thawing and refreezing of the vaccines can lead to potency loss, which is sometimes hard to monitor since a temperature monitor can only tell when temperature disruption occurs. Shake tests can be done to test the freezing/thawing conditions of the vaccines (Hanson et al., 2017).

Backup plans for refrigeration management always need to be prepared in case of any emergency situations like extreme weather, power outage, political instability, etc. Extreme weather may lead to distorted compression forces on the packaging, low or high air flow in the package, disruption of the temperature alert and monitor systems, or freezing of the vaccines. Power outage may cause refrigerators to stop working, leaving products unrefrigerated. Political instability can lead to delay of the transportation, and reefers need to have enough capacity to last longer with limited access to resources. These events can lead to risks related to product quality and occupational safety, but an efficient refrigeration management system can alleviate some of the issues.

A combination of active and passive cooling systems should be used for cold chain packaging; during power outages, passive cooling systems can still maintain the temperature within the required range without the need for any power supply. Passive cooling systems include the use of PCMs and other insulation materials, which can be costly sometimes, but there are options of reusable PCM gel packs which also have the advantages of being lightweight and easy to access, like quilts, ice, clays, etc. In addition, the use of solar energy can be considered for supplying power to cold chains.

6.3.3.2 Evaluation of risk mitigation strategies

The identified strategies are prioritized and analyzed using the Fuzzy TOPSIS method. Technique for order Preference by Similarly to Ideal Solution (TOPSIS) is one of the most popular decision-making techniques for multi-criteria decision-making (MCDM) problem (Hwang and Yoon, 1981). And TOPSIS aims to rank possible alternatives that have the longest distance from the negative ideal solution and the shortest distance from the positive-ideal solution. One issue TOPSIS has to deal with is the vagueness and imprecision from the input of the decision-makers. The incorporation of the fuzzy set theory with the TOPSIS can solve such issues.

As indicated in Figure 4.11, the first step of fuzzy TOPSIS is to identify the risk mitigation strategies through literature review and questionnaires. Then the appropriate linguistic terms need to be chosen for alternatives regarding the criteria, followed by a computation of the aggregate fuzzy ratings for the alternatives. The it is necessary to construct the weighted normalized fuzzy decision matrix, then the fuzzy decision matrix and the normalized fuzzy decision matrix. Next, the distance of each alternative from FPIS and FNIS is determined. Finally, the closeness coefficient of each alternative is calculated and the alternative is ranked. The calculation details for each step us shown below:

Step 1: Create a decision matrix: create all the criteria, alternatives and linguistic terms for the fuzzy TOPSIS analysis.

Step 2: Aggregate the weight of criteria to get the aggregated fuzzy weight $\tilde{w_j}$ of criterion C_j and calculate the aggregated fuzzy rating $\tilde{x_{ij}}$ of alternative A_i under criterion C_j based on expert opinions. The fuzzy ratings of all experts are described as TFN $\tilde{R}_k=(a_k,b_k,c_k)$, $k=1,2,\ldots K$ then the aggregated fuzzy rating is given by $\tilde{R}=(a,b,c)$ $k=1,2,..K$ where

$$a = \min_k\{a_k\},\ b = \frac{1}{k}\sum_{k=1}^{k} b_{ki}\ ,c = \max_k\{c_k\} \quad (4.2)$$

Assume that the fuzzy rating of the kth expert is $\tilde{x}_{ijk}=(a_{ijk},b_{ijk},c_{ijk})$,$i=1,2,\ldots m$,$j=1,2,\ldots n$ then the aggregated fuzzy ratings $\tilde{x}_{ij}$ of alternatives with respect to each criterion are given by $\tilde{x}_{ij}(a_{ij},b_{ij},c_{ij})$, where

$$a = \min_k\{a_{ijk}\},\ b = \frac{1}{k}\sum_{k=1}^{k} b_{ijk}\ ,c = \max_k\{c_{ijk}\} \quad (4.3)$$

Step 3: Develop the fuzzy decision matrix and the normalized fuzzy decision matrix, which the fuzzy decision matrix for alternative D~ is calculated as follows:

$$\begin{array}{cc} & C_j \\ A_i & \begin{bmatrix} \tilde{x_{11}} & \cdots & \tilde{x_{1n}} \\ \vdots & \ddots & \vdots \\ \tilde{x_{m1}} & \cdots & \tilde{x_{mn}} \end{bmatrix} = \tilde{D} \end{array} \quad (4.4)$$

(4.5)

$\tilde{w}=[\tilde{w}_1,\tilde{w}_2,\ldots,\tilde{w}_j,\ldots,\tilde{w}_n]$

where $\tilde{x}_{ij}$, $i=1,2,\ldots,m;j=1,2,\ldots,n$ and $\tilde{w}_j$, $j=1,2,\ldots,n$ are linguistic TFNs, $\tilde{x}_{ij}=(a_{ij},b_{ij},c_{ij})$ and $\tilde{w}_j=(a_{j1},b_{j2},c_{j3})$. Note that $\tilde{x}_{ij}$ is the performance rating of the i^{th} alternative, A_i, with respect to the j^{th} criterion, $\tilde{w}_j$represents the weight of the j^{th} criterion, C_j. The normalized fuzzy decision matrix denoted by $\tilde{R}$ is shown below:

(4.6)

$\tilde{R}=[\tilde{r}_{ij}]m\times n$

where B and C are the set of benefit criteria and cost criteria, respectively, and

$\tilde{r}_{ij}=(a_{ij}c_{j*},b_{ij}c_{j*},c_{ij}c_{j*}),\ j\in B;$

$\tilde{r}_{ij}=(a_{j-}c_{ij},a_{j-}b_{ij},a_{j-}a_{ij}),j\in c;$

$c_{j*}=maxic_{ij}\ if\ j\in B;$

(4.7)

$a_{j-}=minia_{ij}\ if\ j\in C.$

Step 4: Determine the weighted normalized decision matrix by calculating the weight of each criteria in the fuzzy decision matrix based on the weights of each criteria, as indicated in the formula below:

(4.8)

$$\tilde{V}_{ij} = \tilde{r}_{ij} * W_{ij}$$

Where W_{ij} represents the weight of criteria c_j

(4.9)

$$\tilde{v} = \begin{bmatrix} \tilde{v_{11}} & \cdots & \tilde{v_{1n}} \\ \vdots & \ddots & \vdots \\ \tilde{v_{m1}} & \cdots & \tilde{v_{mn}} \end{bmatrix} = \begin{bmatrix} \tilde{v_{11}}\tilde{r_{11}} & \cdots & \tilde{v_{1n}}\tilde{r_{1n}} \\ \vdots & \ddots & \vdots \\ \tilde{v_{m1}}\tilde{r_{m1}} & \cdots & \tilde{v_{mn}}\tilde{r_{mn}} \end{bmatrix}$$

Step 5: Determine the fuzzy positive ideal solution (FPIS) A^* and fuzzy negative ideal solution (FNIS) A-. The FPIS and FNIS of the alternatives can be calculated using the following equations:

(4.10)

$$A^* = \{\widetilde{v_1^*},\ \widetilde{v_2^*},\widetilde{v_3^*},\} = \{(max_j v_{ij}|i \in B), (min_j v_{ij}|i \in C)\}$$ (4.11)

$$A^- = \{\widetilde{v_1^-},\ \widetilde{v_2^-},\widetilde{v_3^-},\} = \{(min_j v_{ij}|i \in B), (max_j v_{ij}|i \in C)\}$$

Where $\widetilde{v_i^*}$ is the maximum value of I for all the alternatives and $\widetilde{v_i^-}$ is the minimum value for all the alternatives. B and C represent the positive and negative ideal solutions.

Step 6: Calculate the distance between the fuzzy positive ideal solution A* and each alternative as well as the distance between the fuzzy negative ideal solution A^- and each alternative.

(4.12)

(4.13)

$$S_i^* = \sum_{j=1}^{n} d(\tilde{v}_{ij}, \widetilde{v_j^*})\quad i = 1,2 \ldots m$$

$$S_i^- = \sum_{j=1}^{n} d(\tilde{v}_{ij}, \widetilde{v_j^*})\quad i = 1,2 \ldots m$$

Where d is the distance between two fuzzy numbers.

And given the two triangular fuzzy numbers (a_1, b_1 , c_1) and (a_2, b_2 , c_2) , calculate the distance between the two using the equation below:

(4.14)

$$\boldsymbol{d_v}(\widetilde{M}_1, \widetilde{M}_2) = \sqrt{\frac{\mathbf{1}}{\mathbf{3}}[(a_1 - a_2)^2 + (b_1 - b_2)^2 + (c_1 - c_2)^2]}$$

Where $d(\tilde{v}_{ij}, \widetilde{v_j^*})$ and $d(\tilde{v}_{ij}, \widetilde{v_j^-})$ are crisp numbers

Step 7: Calculate the closeness coefficient using the following equation

$$CC_i = \frac{S_i^-}{S_i^+ + S_i^-} \tag{4.15}$$

The detailed calculation process for the risk mitigation of the case study is listed below:

Step 1: Choose the appropriate linguistic ratings values for alternatives with respect to criteria.

Three experts were asked to construct a linguistic scale for the judgements. Basic linguistic terms like very low, low, average, high and very high are used. The linguistic terms are used to measure performance of the identified risk mitigation strategies. Table 6.12 shows the responses from the experts. For example, expert 1 has rated A1 as “H”, A2 as “A”, A3 as “H” and A4 as “VH”.

Table 6.11 linguistic terms used for the risk mitigation strategy evaluation

Linguistic term	Fuzzy numbers
Very low (VL)	1,1,3
Low (L)	1,3,5
Average (A)	3,5,7
High (H)	5,7,9
Very high (VH)	7,9,9

Table 6.12 the ratings of alternatives for the quality risk under sub criteria product quality risk

	Alternative	Expert 1	Expert 2	Expert 3
Product safety risk (PS)	Multi skilled workplace (A1)	H	A	H
	Multi sourcing (A2)	A	A	A
	Information management (A3)	H	VH	H
	Refrigeration management (A4)	VH	VH	VH

Table 6.13 Fuzzy evaluation matrix for implementing risk mitigation strategies

	Alternative	Expert 1	Expert 2	Expert 3
Occupational safety risk (OS)	Multi skilled workplace (A1)	5,7,9	3,5,7	5,7,9
	Multi sourcing (A2)	3,5,7	3,5,7	3,5,7
	Information management (A3)	5,7,9	7,9,9	5,7,9
	Refrigeration management (A4)	7,9,9	7,9,9	7,9,9

Step **2**: Aggregate the weight of criteria to get the aggregated fuzzy weight w_j of criterion C_j and pool the experts' opinions to get the aggregated fuzzy rating x_{ij} of alternative A_i under criterion C_j.

Table 6.14 Aggregate fuzzy decision matrix for the implementation of risk mitigation strategies

	PS	OS
A1	3, 6.33, 9	5, 8.33, 9
A2	3, 5, 7	1, 3.67, 7
A3	5, 7.67, 9	5, 7.67, 9
A4	7, 9,9	3, 5.67, 9

Step **3**: Construct the fuzzy decision matrix and the normalized fuzzy decision matrix. **In this**

research, the criteria are the two targeted risk factors as per the goal mitigation of these risks are required.

Table 6.15 Normalized fuzzy decision matrix for the implementation of risk mitigation strategies.

	PS	*OS*
A1	*0.33,0.7,1*	*0.56,0.93,1*
A2	*0.33, 0.56, 0.78*	*0.11, 0.41, 0.78*
A3	*0.56, 0.85, 1*	*0.56,0.85, 1*
A4	*0.78, 1, 1*	*0.33, 0.63, 1*

Step 4; Construct the weighted normalized fuzzy decision matrix. **This step is to obtain a fuzzy weighted evaluation matrix.**

Table 6.16 weighted normalized fuzzy decision matrix for the implementation of risk mitigation strategies

	PS	*OS*
A1	*1.67, 4.93, 9*	*3.89, 8.33, 9*
A2	*1.67, 3.89, 7*	*0.78, 3.67, 7*
A3	*2.78, 5.96, 9*	*3.89, 7.67, 9*
A4	*3.89, 7, 9*	*2.33, 5.67, 9*

Step **5**: Determine the fuzzy positive ideal solution (FPIS) and fuzzy negative ideal solution (FNIS). In this study, all the sub-criteria risks are the cost criteria. Hence, fuzzy positive-ideal solution

(FPIS,A_*) and fuzzy negative-ideal solution (FNIS, A_-) as v_*= (0,0,0) and $\tilde{v}_-$=(1,1,1) for all these sub-criteria. Then compute the distance d_v of each alternative form FPIS (A_*) and FNIS (A_-).

Table 6.16 Fuzzy positive ideal solution, fuzzy negative ideal solutions and distance from alternatives to them

	d+	*d-*	*CC*	*Ranking*
A1	*1.756019746*	*4.734861051*	*0.729463566*	*2*
A2	*5.925987948*	*0*	*0*	*4*
A3	*1.257529588*	*4.929234689*	*0.796738726*	*1*
A4	*1.779077765*	*4.35480257*	*0.70995884*	*3*

6.3.3.3 Sensitivity analysis

A sensitivity analysis is conducted to evaluate the impact of the criteria weights on the selection of the implementation of risk mitigation strategies. If the ranking of the alternatives changes when changing the weight of the criteria weights, then the model is sensitive; if not, then it is robust. Therefore, the weight of each criteria is changed, and the relative closeness to the ideal solution is calculated. The results of the sensitivity analysis are shown in Figure 6.9 and Table 6.18 below.

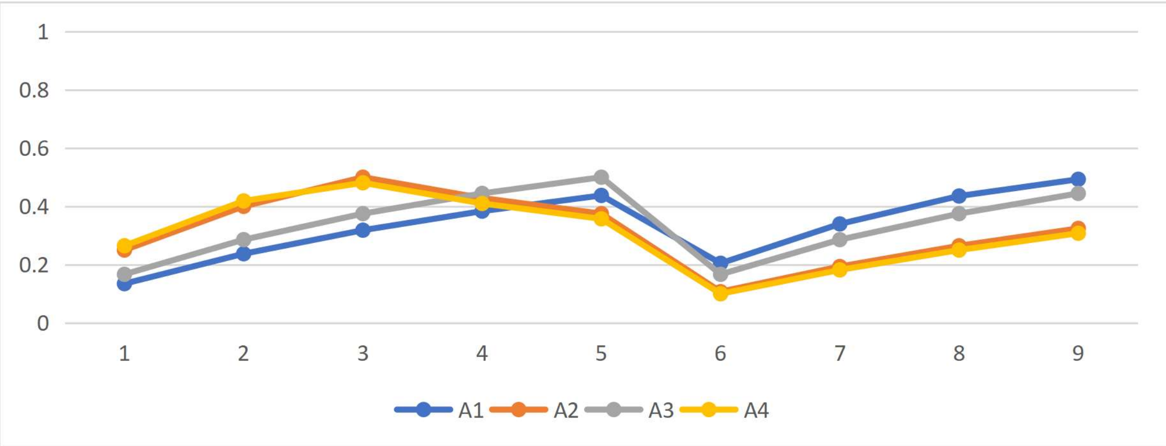

Figure 6.11: Sensitivity analysis: computation of relative closeness to the ideal solution after inputting evaluated combinations.

Table 6.11: Results of sensitivity analysis

No.	*Weights*	*A1*	*A2*	*A3*	*A4*
1	*PS=0.1, OS= 0.5*	*0.1346*	*0.25*	*0.1667*	*0.2648*
2	*PS=0.2, OS= 0.5*	*0.2373*	*0.4*	*0.2857*	*0.4186*
3	*PS=0.3, OS= 0.5*	*0.3182*	*0.5*	*0.375*	*0.4808*
4	*PS =0.4, OS= 0.5*	*0.3836*	*0.4286*	*0.4444*	*0.4098*
5	*PS=0.5, OS= 0.5*	*0.4375*	*0.375*	*0.5*	*0.3571*
6	*PS=0.5, OS=0.1*	*0.2045*	*0.1071*	*0.1667*	*0.1*
7	*PS=0.5, OS=0.2*	*0.3396*	*0.1935*	*0.2857*	*0.1818*
8	*PS=0.5, OS=0.3*	*0.4355*	*0.2647*	*0.475*	*0.25*
9	*PS=0.5, OS=0.4*	*0.493*	*0.3243*	*0.4444*	*0.3077*

Risk mitigation is an important step in cold chain risk management since it is the step that can reduce relative risks if implemented appropriately. Fuzzy TOPSIS is used to rank the important levels of risk mitigation identified with respect to product safety risk and occupational safety risk. The fuzzy TOPSIS method is good for analysing vague and subjective information and data. These strategies also consider the impact on potential risks in these categories.

As we can see from the graph in Figure 6.6, when the weight of the product safety risk increases, strategies “Information management” and “multi-skilled workplace” keep increasing with it, while strategies “Refrigeration management” and “Multi-sourcing” increase at the beginning and then decrease after PS = 0.4 with OS constant at OS = 0.5. When the criterion “Occupational safety risk” weighs more than “Product safety risk”, the ranks of strategies “Information management” and “Multi-skilled workplace” go up. When

“Product safety risk” and “Occupational safety risk” are of equivalent significance, the risk mitigation strategies are ranked in the following order: “Information management”, “Multi-skilled workplace”, “Multi-sourcing”, “Refrigeration management”.

6.3.3.4 Discussion of the results

The most important alternative is A2, “Multi-sourcing”. At the start of a pandemic outbreak, there will be a lack of infrastructure and resources available to develop and distribute vaccines. Having multiple research centres work on the development and planning of vaccines can be helpful. A regular vaccine development process normally takes about 10 years for the development of the vaccines and planning of the distribution. However, during a pandemic, fast paced development and administration are needed due to the urgent need for vaccines.

Taking the development of COVID-19 vaccines as an example, there were 183 vaccines in clinical development and 199 in pre-clinical development by the end of March 2023 (WHO, 2023). By the end of 2022, there were 12 COVID- 19 vaccines on the emergency use list of the WHO (WHO, 2024). This could not have been achieved without the multi-sourcing strategy. Multi-sourcing can also utilize resources available all around the world. However, the cost and reliability of suppliers and providers should be carefully assessed.

The second most important alternative is A4, “Refrigeration management”. Refrigeration is important for COVID-19 vaccines, since some of them are based on live mRNAs, which are live bacteria. A temperature management system can optimize temperature control and monitoring through data and information sharing and management. Depending on the brand of the COVID-19 vaccine, different refrigeration requirements need to be followed. Most vaccines require to be kept at a temperature range of 2-8°C. However, since some companies need to import vaccines into their country, vaccines need to be transported into a national distribution centre first and then distributed to local hospitals or clinics.

Take the Pfizer/BioNTech vaccine as an example: there are two distribution centres; one in MI USA and one in Germany. They need to be stored under -70°C for storage before administration. There are three modes of refrigeration available: ultra-low temperature freezers which last for 18 months; Pfizer thermal shippers plus dry ice which last for 5-30 days; refrigeration & freezer units at clinics or pharmacies, which can last for up to 10 weeks (Cold Chain Report 23, 2023).

Also, not only can high temperature disruption harm the potency of vaccines, but they also face freezing risks. Live vaccines are both heat- and freezing-sensitive, whereas inactivated vaccines are relatively heat-stable but freeze-sensitive (Kartoglu and Milstien, 2014). However, emerging vaccine manufacturing innovations have made it hard to categorize vaccines into simple heat/freeze-sensitive groups. Because freeze sensitivity depends on the additives and adjuvants in vaccines and many vaccines contain adjuvants, research attention has shifted from heat to freeze damage on vaccines (Matthias et al., 2007). It has been found that freezing issues exist in many vaccines, and the freezing and thawing of the vaccines can lead to loss of potency or even safety concerns for human health.

Factors like unit of analysis (refrigerators, cold boxes, etc.), cold chain segments (storage, transport, outreach), sample sizes and occurrence of temperatures below the freeze threshold are reported and analysed (Hanson et al., 2017). The number of articles concerning vaccine freezing increased from 33 studies in 2007 to 45 studies in 2017, which shows rising awareness of the freezing issue in the cold chain, mainly due to improved monitoring technologies and more rigorous monitoring techniques. Therefore, a comprehensive refrigeration management system and relevant training should be implemented to ensure the quality and safety of vaccines.

It is essential for refrigeration systems to be carefully managed during the entire cold chain. Cold chain solutions can only maintain the temperature of the products but cannot reduce those temperatures. Professional pre-processing or cooling is needed to reduce the temperature of products at the beginning of the cold chain. It is also worth paying more attention to the in-between links of cold chains when temperature control is lacking.

A “Multi skilled workplace” is important for the occupational safety of cold chain personnel. Cold related injuries can be caused when working in a low-temperature environment or even sometimes under ultra-low freezing temperatures. Also, because COVID-19 vaccines were relatively new and needed to be distributed and administered within a short period, a multi-skilled workplace was able to improve the overall resilience of the cold chain. By having a multi-skilled workplace, the organisation will be more prepared to respond to any emergency situation.

“Information management” is ranked last in this case study. This is because during a pandemic, response and actions need to be made fast, given a limited amount of time for planning. Vaccines need to be distributed and administered as fast as possible. However, this does not mean that information management is not important. Information management is important for all types of cold chains, and information and data can be used to continuously improve the process and alerts can be sent out when temperature disruption is detected. The Internet of things (IoT) has received an increasing amount of attention in the past few years. Other technological advancements can have a huge impact on the monitoring and information management of cold chains, as well. Therefore, it is important to keep updated with new technologies and carefully evaluate the challenges and opportunities they bring.

6.4 CONCLUSION OF THE CHAPTER

A case study on the risk management of vaccine cold chain packaging in Thailand was conducted to illustrate the application of the proposed risk management model proposed in Chapter 4. Risk factors like container risk, handling risk, packaging risk, monitoring risk, product risk and occupational safety risks were identified and then assessed by the proposed Fuzzy BN approach. Sensitivity analysis was conducted to test the impact of changing the prior probabilities on posterior probabilities, and it is found that the Fuzzy BN model is robust since "Product safety" risk increases as "Packaging risk" increases.

Fuzzy TOPSIS was used to rank the identified risk mitigation strategies, producing the following ranking: "Multi-sourcing", "Refrigeration management", "Multi skilled workplace", "Information management". A sensitivity analysis of the results is included, which shows that the fuzzy TOPSIS model is very sensitive since the changes of inputs can change the ranking results.

CHAPTER 7 CONCLUSION

7.1 INTRODUCTION

This chapter concludes the research and introduces future research directions. First of all, a summary of the main research findings is given. Then the contribution to established knowledge and its practical implications are summarised, after which the limitations of the research are stated, followed by suggestions for the directions of possible future work.

7.2 RESEARCH FINDINGS

From the literature conducted in Chapter 2, some research gaps have been found. One research gap found is that there is still a lack of focus on the cold chain packaging system as a whole since most studies focus on one component of cold chain packaging. Another gap is that packaging related gaps are often overlooked in cold chain risk management studies. To address these gaps, some research questions are developed in this research. And to answer these questions, this research proposes a research framework consisting of a conceptual framework to measure the cold chain packaging performance and an integrated risk management model for cold chain packaging. Followed by a case study, it illustrates the uses of the proposed risk management model. A summary of the research outputs specific in relation to each research question is listed as follows:

RQ 1: What are the major factors impacting the performance of cold chain packaging?

- A research framework which includes a conceptual framework to measure the cold chain packaging performance and an integrated risk management model is proposed in this research. The whole lifecycle of the cold chain packaging and existing cold chain packaging solutions or systems have been analyzed. An overview of industry cold chain shipping solutions is developed, comprising a summary and discussion of existing cold chain shipping solutions and technologies, and a hierarchical Pallet-Parcel-Coolant-PCM structure of cold chain shipping solutions is proposed. The scope of cold chain packaging and key terms are defined in this research as well. Then a conceptual framework to measure the cold chain packaging system performance is proposed consisting of the key performance metrics for the cold chain packaging system. Key performance metrics such as "Efficient regulation of the internal environment", "Information management", "Sustainability", "Operation optimization", "Ensured quality and safety", "Profit" and "Customer satisfaction" have been found.

RQ 2: What risk factors can lead to adverse consequences of cold chain packaging performance?

- First the risk factors are identified from literature reviews and then verified by experts. Focusing on packaging related risks, particularly, "Product safety risk", "Occupational safety risk", "Handling risk", "Container risk", "Packaging risk" and "Monitoring risk" are found to have the potential to cause disruptions to the cold chain packaging system. Fuzzy BN is used for the assessment of the risk factors identified. The casual relationships are determined based on literature review and then verified by experts. Then prior and posterior probabilities are assigned by experts using linguistic terms first, which then is converted into fuzzy number sets through fuzzification. A seven Likert scale of likelihood is used for the fuzzy BN assessment. Then after a defuzzification process, the fuzzy number sets are turned into crisp numbers, which are inputted into a software called GeNie for the BN inferencing. It is found that "Packaging risk" and "Monitor risk" can lead to "Container risk"; "Container risk" and "Handling risk" can lead to

"Product safety risk" and "Occupational safety risk". At the end, sensitivity tests are done to test the sensitivity of the fuzzy BN model. The state0 or prior probability of "Packaging risk" is changed from (0.19,0.2,0.21) to (0.49,0.50,0.51), and "Product safety risk" tend to increase along with it. When the prior probability of "Product safety risk" is changed from 20% to 100%, the posterior probability of "Product safety risk" changes from 39% to 57%. Therefore, we can conclude the fuzzy BN model to be robust.

RQ 3: What risk mitigation strategies can be used to assist industry and government to alleviate the risk factors above and help produce more sustainable and safer cold chain packaging?

- Risk mitigation strategies are first derived from literature review and verified by experts. Identified strategies include: "Information management", "Multi-sourcing", "Refrigeration management" and "Multi skilled workplace". After that, the risk mitigation strategies are assessed using the Fuzzy TOPSIS method. The criteria used for the Fuzzy TOPSIS method include "Product safety risk" and "Occupational risk", which are the risk factors identified from the risk assessment step. The likelihoods of each mitigation strategies or alternatives are assigned first by expert opinions, which are then turned into fuzzy number sets. A five point Likert scale likelihood table is used for this. Then the best alternative is the one that is closest to the positive ideal solution and furthest away from the negative ideal solution. After the fuzzy TOPSIS analysis, the risk mitigation strategies are ranked as: "Multi-sourcing", "Refrigeration management", "Multi skilled workplace", "Information management". "Multi-sourcing" is found to be the best risk mitigation strategy. Sensitivity tests are done on "Product safety risk" and

"Occupational safety risk" 's impact on the four risk mitigation strategies. It is found that the fuzzy TOPSIS model is sensitive in relation to the "Product safety risk" input since ranking changes when the likelihood of "Product safety risk" changes.

7.3 RESEARCH CONTRIBUTIONS

This thesis makes several useful theoretical and practical contributions. Unlike most of the existing studies on cold chains, which focus on one specific cold chain product or one segment of the cold chain, this research is the first study in cold chain packaging that studies cold chain packaging as a whole and incorporates the perspectives of packaging, risk management and cold chain. Also, the scope of cold chain packaging is defined, and key terms used in the field of cold chain packaging are defined as well. This can add new knowledge to the field of cold chain packaging and provide a systematic overview of the field. This is the first study to provide key performance metrics of the cold chain packaging systems.

A research framework for research of cold chain packaging has been proposed, which consists of a conceptual framework with key performance metrics of the cold chain packaging system and an integrated risk management model. This provides a research framework for studies in the field of cold chain packaging, and thus drawing more research attention into the field. More case studies can be conducted utilizing the proposed framework. Also, no studies have conducted risk management using both qualitative and quantitative methods covering risk identification, assessment and mitigation in the setting of cold chain packaging. The proposed integrated risk management model is based on fuzzy BN and fuzzy TOPSIS incorporating expert opinions in the decision-making process. Uncertainties of the data is also considered by this model, which fuzzy logic theory are used.

This study also holds practical implications for cold chain logistics and shipping container managers. A case study about vaccine cold chain packaging in Thailand is conducted utilizing the proposed risk management model, which can illustrate the use of the proposed model and can also reflect the latest situation about vaccine cold chain packaging in actual situations. Stakeholders of the vaccine cold chain packaging industry can evaluate their current risk management status and make relative improvements. For example, particular attention needs to be paid to occupational safety and to temperature disruption during loading and unloading, which are often overlooked in cold chain logistics. This can improve the overall product and occupational safety of the cold chain packaging industry.

7.4 RESEARCH LIMITATIONS

Despite the contributions of the thesis, it is subject to limitations, as outlined below:

- First, cold chain packaging is a broad topic which needs more time and depth to study. Due to the time frame of the research, the risk factors and risk mitigation strategies are mainly derived from existing literature and expert opinions.

- The proposed integrated risk management model is highly dependent on participants' knowledge, experience, expertise and attitudes. This may lead to some subjective biases. Some people may be more risk averse than others. Therefore, the risk attitudes can be considered to see their impact on the results, and more experts from various background can be included to further improve this model.

- Also, due to the complex nature of the cold chain packaging industry, there are different and personalized cold chains designed for different cold chain products with different requirements, e.g. locations, infrastructure availability, etc. This study conducts one case study on vaccine cold chains, but this is not enough.

- For other cold chain products, such as food cold chains, the critical risk factors and risk mitigation strategies would be very different. Factors like humidity, air pressure and bacteria presence need to be considered for food cold chains. Even within the vaccine cold chain itself, different vaccines have different detailed storage and transportation requirements.

7.5 RECOMMENDATIONS AND FUTURE RESEARCH

In the future, more work can be done in the following directions:

- More case studies can be carried out to further test and improve the cold chain packaging risk management model. For example, studies on the impact of technical advances on the risk management of cold chain packaging can be conducted to explore how new technologies and other innovations can change the way cold chains and packages work.

- The impact of cold chains and packages on sustainability needs to be explored. To achieve the goal of sustainability, resources used, waste and carbon emissions should be minimized while maintaining product integrity and safety. Life cycle assessments can be carried out on packages and materials to analyse their entire life cycles from extraction or production to disposal.

- A broader coverage of data needs to be included in the future to further improve the risk management model. Historical temperature data can be analysed and used as inputs to the model, with the aid of modern technologies like the Internet of Things, etc.

- Further, the implementation of risk mitigation strategies can incorporate constraints of cost and time to more closely resemble a real-life scenario. Strategic implementations require substantial investments; thus it is important to analyse situations to provide some guideline support for decision-makers.

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APPENDIX ONE

Questionnaire used for the risk assessment step in Chapter 6

1. What is your type of organization?

a. Pharmaceutical companies

b. Third party logistic companies

c. Hospitals

d. Research institutes

e. Other

2. What is your job title?

3. How many years' experience do you have in this industry?

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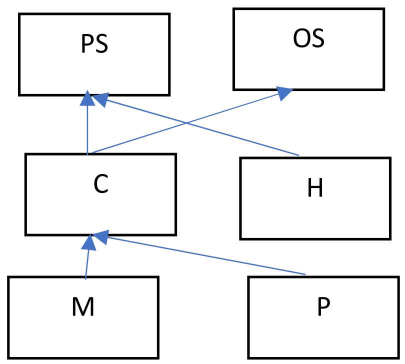
4. Based on the research, several risk factors have been identified in cold chain packaging, which include "Product safety risk"(PS), "Occupational safety risk"(OS), "Container risk"(C), "Handling risk" (H), "Packaging risk" (P) and "Monitoring risk" (M). Please draw the casual relationships of the risk factors. An example is given below.



This is an example

5. Please tick the probabilities/likelihood of each risk factor in the tables below:

The details of the likelihood terms are listed below.

Prior probabilities:

	Probability/Likelihood						
	Extremely rare	Rare	Unlikely	Possible	Likely	Frequent	Very frequent
Occupational safety risk							
Product safety risk							

Container risk							
Handling risk							
Packaging risk							
Monitoring risk							

Conditional probabilities:

Product safety risk	Probability/Likelihood						
	Extremely rare	Rare	Unlikely	Possible	Likely	Frequent	Very frequent
Occupational safety risk							
Container risk							
Handling risk							
Packaging risk							
Monitoring risk							

Occupational safety risk	Probability/Likelihood						
	Extremely rare	Rare	Unlikely	Possible	Likely	Frequent	Very frequent
Product safety risk							
Container risk							
Handling risk							
Packaging risk							
Monitoring risk							

Container risk	Probability/Likelihood						
	Extremely rare	Rare	Unlikely	Possible	Likely	Frequent	Very frequent
Occupational safety risk							

Product safety risk							
Handling risk							
Packaging risk							
Monitoring risk							

Handling risk	Probability/Likelihood						
	Extremely rare	Rare	Unlikely	Possible	Likely	Frequent	Very frequent
Occupational safety risk							
Product safety risk							
Container risk							
Packaging risk							
Monitoring risk							

Packaging risk	Probability/Likelihood						
	Extremely rare	Rare	Unlikely	Possible	Likely	Frequent	Very frequent
Occupational safety risk							
Product safety risk							
Container risk							
Handling risk							
Monitoring risk							

Monitoring risk	Probability/Likelihood						
	Extremely rare	Rare	Unlikely	Possible	Likely	Frequent	Very frequent
Occupational safety risk							
Product safety risk							
Container risk							

Handling risk							
Packaging risk							

6. Any feedback, comments or suggestions?

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APPENDIX TWO

Questionnaire used for the risk mitigation step in Chapter 6

1. What is your type of organization?

a. Pharmaceutical companies

b. Third party logistic companies

c. Hospitals

d. Research institutes

e. Other

2. What is your job title?

3. How many years' experience do you have in this industry?

4. Based on the research, several risk mitigation strategies in cold chain packaging have been identified, which include "Multi skilled workplace", "Multi sourcing", "Information management", "Refrigeration management". Please verify the results or suggest any other risk mitigation strategies below:

5. Please tick the level of importance of each risk mitigation strategy in the tables below:

Criteria	Risk mitigation strategy	Level of importance rating				
Product safety risk (PS)		Very Low	Low	Average	High	Very High
	Multi skilled workplace (A1)					
	Multi sourcing (A2)					
	Information management (A3)					
	Refrigeration management (A4)					
Occupational safety risk (OS)	Multi skilled workplace (A1)					
	Multi sourcing (A2)					
	Information management (A3)					
	Refrigeration management (A4)					

6. Any feedback, comments or suggestions?