HACCP in the Cold Chain Industry: Food, Pharma & Healthcare

Presented at

The 2nd West Africa Cold Chain Summit & Exhibition 2019

By
Jane Omojokun
MD/Lead Consultant
Nugata Consults Limited, Lagos

Radisson Blu Hotel,
30/40 Isaac John Street
Ikeja, Lagos-Nigeria.
5th -6th November 2019
Presentation Outline

- Introduction
  - Cold Chain Industry
  - Cold Chain Logistics
  - HACCP
Introduction

- HACCP (Hazard Analysis and Critical Control Point) is a systematic preventive approach to food safety from biological, chemical and physical hazards that can cause the finished product to be unsafe and measures designed to reduce these risks to a safe level.

- HACCP is recognized internationally as a logical tool for adapting traditional inspection methods to a modern, science-based, food safety system.
Introduction

- It is now used by other sectors such as cosmetic and pharmaceutical industries and can be applied to the cold chain industry.

- HACCP is a useful tool to analyze the processes of the cold-chain, assess the potential risks for each operation link, and then identify the critical control points and give the appropriate risk weights so as to ensure the safety, quality and reliability of the cold-chain.
Introduction

- A **cold chain** is a temperature-controlled supply chain.

- It is an uninterrupted series of **refrigerated production, storage and distribution activities**, along with associated **equipment and logistics**, which maintain a desired low-temperature range.

- The cold-chain consists of complicated operations and some uncertain factors during the process of implementing.

- Cold chain services are designed to provide ideal transportation and storage conditions to retain the safety and quality of temperature-sensitive products from production to the final consumer.
Introduction

- Few years ago, the pharmaceutical cold-chain meant products requiring storage at 2–8 °C. Increasingly, products today must be shipped at controlled ambient temperature (15–25 °C), or at extremely cold temperatures such as -20 °C, and in even lower cryogenic temperatures such as -180 °C.

- Similarly, temperature control is a critical food safety element, as it helps to prevent foodborne diseases and outbreaks that can result in public health issues. Fresh produce must be kept at 0–16 °C or colder, while frozen and deep-frozen foods must generally be kept at 0 to -25 °C or colder. In this sense, temperature control is necessary in both of these industries.

- The food and beverage sector and pharmaceuticals are considered separate industries but are actually similar in a number of aspects and can learn a lot from each another.
Presentation Outline

- Introduction

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  - Cold Chain Logistics

  - HACCP
Cold Chain Industry

- Food supply has to be preserved in order to alleviate hunger and malnutrition in rapidly enlarging populations in the poorest countries where there is already food shortages.

- Maintaining the Cold chain is essential for efficient food supply and reduction of postharvest food losses and waste.

- A commercially sustainable cold chain would enable farmers to diversify production to include high-value perishable crops, link them to regional and international markets, and increase earnings in addition to offering a variety of safe food products to consumers.
In the pharmaceutical sector, failures of vaccine storage can lead to:
✓ loss of potency of the vaccines
✓ expensive product losses and
✓ administration of compromised vaccines to patients.

Unmonitored temperatures of 3 refrigerators for storing vaccines at a large public health office in Alberta for 20 days caused many vaccines to be re-administered and the loss of a large store of vaccines including DaPTP-Hib (diptheria, acellular pertussis, tetanus, polio, Haemophilus influenzae type B), MMR (measles, mumps, rubella), varicella, and meningococcal vaccines.
Presentation Outline

▪ Introduction

▪ Cold Chain Industry

  ▪ Cold Chain Logistics

▪ HACCP
Cold Chain Logistics

- The cold chain generally caters for the chemical industry, food sector and pharmaceutical industry.

- Cold chain logistics system involves people, technologies, policies, procedures, cold chain equipment along with vehicles working together to ensure that sensitive products reach their destination safe and without getting damaged.

- The global cold chain market size was valued at USD 167.99 billion in 2018 and is expected to expand at a CAGR of 15.1% from 2018 to 2025.

- Growing penetration of connected devices and automation of refrigerated warehouses across the globe is anticipated to spur the growth.

- Increasing number of organized retail stores in emerging economies is leading to increased demand for cold chain solutions.

- Based on type, the cold chain market has been categorized into storage, transportation, and monitoring components.

- Maintaining an unbroken cold chain is very vital for getting effective results as well as improving the shelf life of food, drugs, chemicals and vaccines.
Cold Chain Logistics

- Cold chain logistics includes the planning and management of the interactions and transitions between production, storage and distribution, in order to keep products at their optimum temperature for maintenance of quality, safety and prevention of waste and economic losses.

- Goods need to be transported and stored in temperature controlled environments whilst in transit, in warehouses and while waiting to be loaded onto transport.

- Temperature management is an important factor affecting the safety and quality of products in the cold chain supply system.

- Speed is often the key to success when handling and marketing perishable goods using a cold supply chain.

- Cold Chain Logistics can be challenging, but if done well can provide major benefits and competitive advantages.
Cold Chain Equipment

Temp rising alert system

Solar freeze
Cold Chain Equipment for Vaccines

- Walk in freezers
- Walk in coolers (WIC)
- Deep freezers
- ILR-Basket
- Dial Thermometer
- Cold boxes
- Vaccine carriers
- Day carriers
Pharmaceutical Cold Chain Management

- Cold chain management of biopharmaceutical products begins with the manufacture, storage and movement through the distribution chain till it gets to the end user at the time of administration.

- Pharmaceutical and life sciences cold chains require storage of life-saving medicines, vaccines, and other products in temperature-controlled packaging and must be maintained within strict temperature boundaries.

- Biopharmaceuticals are held and distributed in a controlled environment because they are delicate biological substances that can become less effective or destroyed if they are frozen, exposed to heat or exposed to direct sunlight or fluorescent light. Many pharmaceuticals also react to humidity, vibration, and shock.

- Increased concerns over adequate control in cold chain management is due to increasing volumes of products that require cold chain maintenance, complexity of the product and complexity of the supply chain (worldwide supply).
Food Cold Chain Management

Cold chain in Food Sector

Industry Temperature Standards

<table>
<thead>
<tr>
<th></th>
<th>Banana</th>
<th>Chill</th>
<th>Frozen</th>
<th>Deep Frozen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>13 C</td>
<td>2 C</td>
<td>-18 C</td>
<td>-29 C</td>
</tr>
</tbody>
</table>
# Food Cold Chain Management

<table>
<thead>
<tr>
<th>Product</th>
<th>Refrigerated Shelf Life (Days)</th>
<th>Optimum Temperature (Celsius)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apple</td>
<td>90-240</td>
<td>0</td>
</tr>
<tr>
<td>Bananas</td>
<td>7-28</td>
<td>13.5</td>
</tr>
<tr>
<td>Bell Peppers</td>
<td>21-35</td>
<td>7</td>
</tr>
<tr>
<td>Cabbage</td>
<td>14-20</td>
<td>1</td>
</tr>
<tr>
<td>Eggs</td>
<td>180</td>
<td>1.1</td>
</tr>
<tr>
<td>Onions</td>
<td>30-180</td>
<td>1</td>
</tr>
<tr>
<td>Lettuce</td>
<td>12-14</td>
<td>0.6</td>
</tr>
<tr>
<td>Fresh Meat (beef, lamb, pork, poultry)</td>
<td>14-65</td>
<td>-2</td>
</tr>
<tr>
<td>Oranges</td>
<td>21-90</td>
<td>7</td>
</tr>
<tr>
<td>Pears</td>
<td>120-180</td>
<td>-0.6</td>
</tr>
<tr>
<td>Potatoes</td>
<td>30-50</td>
<td>10</td>
</tr>
<tr>
<td>Seafood (shrimp, lobster, crab)</td>
<td>120-360</td>
<td>-17.8</td>
</tr>
<tr>
<td>Strawberries</td>
<td>5-10</td>
<td>0.6</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>7-14</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>1 - 4 °C</td>
<td>5 - 9 °C</td>
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<tr>
<td>------------------</td>
<td>-------------------------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Apple</td>
<td></td>
<td>Avocado (temperate origin)</td>
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<tr>
<td>Asparagus</td>
<td></td>
<td>Zucchini</td>
</tr>
<tr>
<td>Broccoli</td>
<td></td>
<td>Bean (French)</td>
</tr>
<tr>
<td>Peach, plum</td>
<td></td>
<td>Passion fruit</td>
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<tr>
<td>Cherry</td>
<td></td>
<td>Eggplant</td>
</tr>
<tr>
<td>Grape</td>
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<td>Capsicum</td>
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<tr>
<td>Lettuce</td>
<td></td>
<td>Cucumber</td>
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<tr>
<td>Mushroom</td>
<td></td>
<td>Mandarin, orange</td>
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- HACCP
How Does HACCP Work?

- Potential **hazards** are identified at each step of the process
- **Significance** of hazards is determined
- **Control measures** are identified to address significant hazards
- **Critical control points** (CCP) are determined
- **Critical limits** are identified for each control point
- **Monitoring** procedures are implemented to evaluate conformance with critical limits.
- Predetermined **corrective actions** are developed to prevent potentially defective product reaching the consumer
- CCPs are **verified** to confirm compliance to the HACCP plan
- **Pre-requisite Programmes** must be in place for HACCP to work such as GHP, GMP, Good Storage and Distribution Practices, Good Transportation Practices
Identify Potential Hazards In the Cold Chain

Conduct hazard analysis of the cold chain/logistics activities such as:

- Pre-cooling
- Refrigerated Transportation
- Packaging
- Storage
- Distribution Centres/Retail Points of sale
- Temperature Control
- Humidity Control
- Vibration, shock, exposure to direct sunlight/florescent light (Pharma & Health Care Products)
- Vaccine stores
- Health Centres/Health Posts
- Cold Chain Equipment
- Calibration of Equipment
Implementation of HACCP: 5 Preliminary Steps

In the development of a HACCP plan, the five preliminary tasks before application of HACCP Principles are:

1. Assemble the HACCP team
2. Describe the product and its distribution
3. Describe the intended use and users of the product
4. Develop a flow diagram
5. Verify the flow diagram
Implementation of HACCP: 7 Principles of HACCP

▪ Principle 1: Conduct a hazard analysis.
▪ Principle 2: Determine the critical control points (CCPs).
▪ Principle 3: Establish critical limit(s).
▪ Principle 4: Establish a system to monitor the CCPs.
▪ Principle 5: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
▪ Principle 6: Establish procedures to verify that the HACCP system is working effectively.
▪ Principle 7: Establish documentation concerning all procedures
Principle 1: Conduct a Hazard Analysis

- Hazard evaluation
  - The team assesses the severity of the health consequences if a potential hazard is not properly controlled.
  - The team also determines the likelihood of a potential hazard occurring if not properly controlled.
  - The HACCP team decides and lists the hazards likely to occur.
Process Hazard Analysis & Critical Control Points

- Conduct risk assessment for each identified hazard
- Document results & risk evaluation (likelihood/severity)
- Use literature, knowledge & experience
- Take into consideration situations where you may have reduced staffing levels when you are evaluating the risks with process steps
- Define critical limits considering system, legal & other requirements as well as consumer complaints history
## Process Hazard Analysis & Critical Control Points

<table>
<thead>
<tr>
<th>Likelihood descriptions</th>
<th>Impact descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Unlikely</td>
<td>1 Minor</td>
</tr>
<tr>
<td>approx. Every 5 years</td>
<td>No significant impact</td>
</tr>
<tr>
<td>2 Occasional</td>
<td>2 Medium</td>
</tr>
<tr>
<td>approx. annually</td>
<td>Limited impact, isolated case</td>
</tr>
<tr>
<td>3 Likely</td>
<td>3 High</td>
</tr>
<tr>
<td>approx. monthly</td>
<td>Medical intervention needed</td>
</tr>
<tr>
<td>4 Frequently</td>
<td>4 Very high</td>
</tr>
<tr>
<td>approx. weekly</td>
<td>Health issue with possible fatal consequences</td>
</tr>
</tbody>
</table>
Process Hazard Analysis & Critical Control Points

Risk Analysis

Likelihood
- Frequent = 4
- Likely = 3
- Occasional = 2
- Unlikely = 1

Impact
- Minor = 1
- Medium = 2
- High = 3
- Very high = 4

Risk = Likelihood x Impact

Low risk - monitoring
Medium risk
High risk

Rating of 4 and above will be indicated in red and will require a control point to eliminate hazard occurrence.
Process Hazard Analysis & Critical Control Points

**Principle 2: Identify Critical Control Points (CCPs)**

For each hazard to be controlled by the HACCP plan, identify CCP(s) for the control measures identified.

A critical control point (CCP) is a point, step or procedure at which control can be applied and a safety hazard can be prevented, eliminated or reduced to acceptable levels.

- The HACCP team will use a CCP decision tree to help identify the critical control points in the process.
- A critical control point may control more than one safety hazard or in some cases more than one CCP is needed to control a single hazard.
- The number of CCPs needed depends on the processing steps and the control needed to assure safety.
CCP Decision Tree

Modify the step process or product

Yes

HAZARD

Is control necessary?

No

Are preventive measures in place?

No

Do the measures reduce the Hazard?

No

Could Hazards reach unacceptable levels?

No

Will a subsequent step reduce or eliminate the Hazard?

Yes

NOT a CCP

Yes

CCP
Principle 3: Establish Critical Limits

- Determine critical limits at each CCP and action criteria
- A critical limit (CL) is the maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard.
- The critical limit is usually a measure such as time, temperature, water activity (Aw), pH, weight, or some other measure that is based on scientific literature and/or regulatory standards.
- Critical limits shall ensure that the identified acceptable level of the safety hazard in the end product is not exceeded.
- The rationale for the chosen critical limits shall be documented
Principle 4: Monitor the CCP

- The HACCP team will describe monitoring procedures for the measurement of the critical limit at each critical control point to demonstrate that the CCP is in control.
- The monitoring system includes all scheduled measurements or observations relative to the critical limit(s).
- It consists of relevant procedures, instructions and records that cover the following:
  - measurements or observations that provide results within an adequate time frame;
  - monitoring devices used;
  - applicable calibration methods;
  - monitoring frequency;
  - responsibility and authority related to monitoring and evaluation of monitoring results;
  - record requirements and methods.
Monitoring procedures should describe:
- how the measurement will be taken,
- when the measurement is taken,
- who is responsible for the measurement and
- how frequently the measurement is taken
Principle 5: Establish Corrective Actions

- Corrective actions are the procedures that are followed when a deviation in a critical limit occurs.
- The HACCP team will identify the steps that will be taken to prevent potentially hazardous products from entering the cold chain and the steps that are needed to correct the process.
- This usually includes identification of the problems and the steps taken to assure that the problem will not occur again. Specify in the HACCP plan, corrections and corrective actions when critical limits are exceeded.
- The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented.
- Establish and maintain documented procedures for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated.
Principle 6 : Verification

It involves those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

The HACCP team may identify activities such as:
- auditing of CCPs
- record review,
- prior shipment review,
- instrument calibration and
- product testing as part of the verification activities.
Principle 7: Record Keeping

It is important for the HACCP plan to include recording information that can be used to prove product safely. The records also need to include information about the HACCP plan.

Records should include information on:

- the HACCP Team,
- product description,
- flow diagrams,
- hazard analysis,
- CCPs identified,
- Critical Limits,
- Monitoring System,
- Corrective Actions,
- Recordkeeping Procedures, and
- Verification Procedures.
HACCP: Cold Chain Logistics Flow Diagram
HACCP: Food Cold Chain Flow Diagram
HACCP: Pharma Cold Chain Flow Diagram
Conclusion

- The cold chain helps reduce postharvest losses and enables the pharmaceutical and healthcare industries maintain continual and safe stock of drugs from suppliers and distributors across varied locations.
- The global cold chain market size is huge, valued at USD 167.99 billion in 2018 and expected to expand at a CAGR of 15.1% from 2018 to 2025.
- Growing penetration of connected devices and automation of refrigerated warehouses across the globe is anticipated to spur the growth.
- Increasing number of organized retail stores in emerging economies is leading to increased demand for cold chain solutions.
- Maintaining an unbroken cold chain places the burden of delivering safe food, pharma and healthcare products as well as improving the shelf life of food, drugs, chemicals and vaccines on cold chain logistics industry and distributors
- The use of appropriate refrigeration throughout the entire cold chain and implementing a HACCP strategy as a tool to manage the cold chain would achieve the desired result of safety and quality in the food, pharma & healthcare industry.
Thank You!
References


