Cold Chain Loss Control in the Supply Chain

Marine Insurance Day

October 2nd, 2015

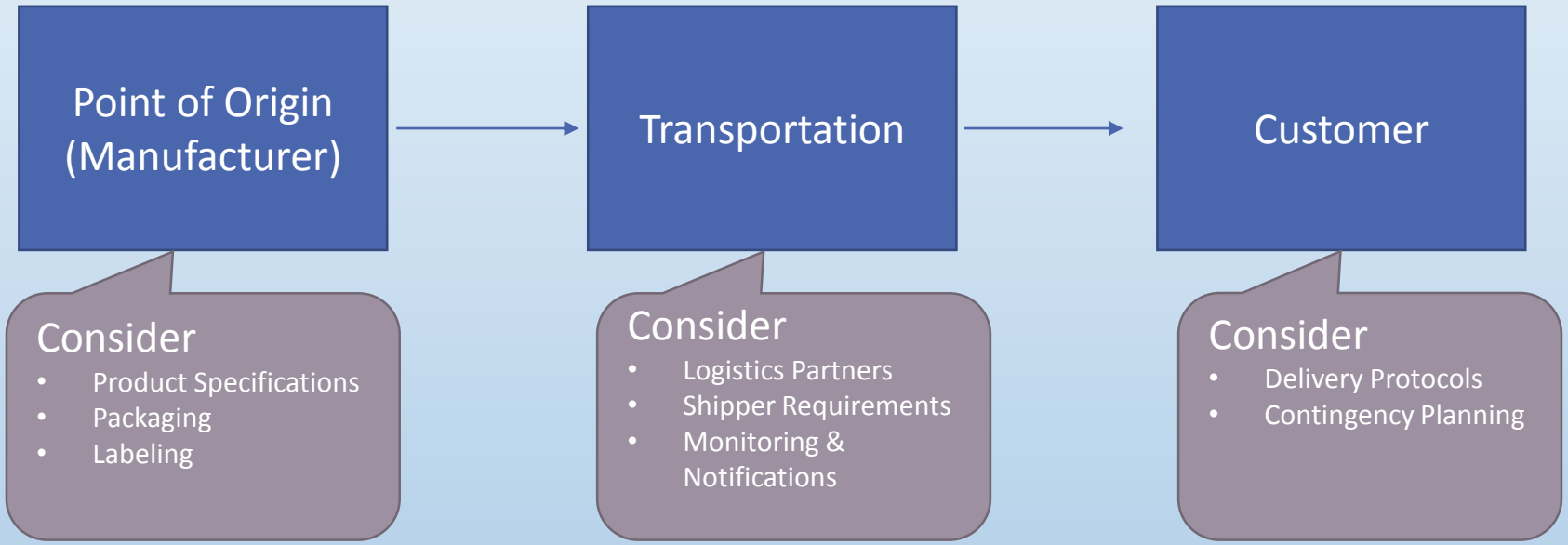
Presenters

PRESENTER, TITLE	CONTACT INFORMATION
Peter J. Scrobe Vice President, Loss Control Services	Starr Marine Phone: (646)-227-6414 E: peter.scrobe@starrcompanies.com
Scott K. Parry Cargo Risk Engineer	FM Global Cargo Phone: (631)-603-5273 E: scott.parry@fmglobal.com
Richard Lawson Sr. Marine Risk Consultant	Allianz Risk Consultants (ARC) Phone: (646)-483-6743 E: richard.lawson@agcs.Allianz.com
Mike Burke Regional Vice President, Ocean Marine	Travelers Phone: (631)-501-8131 E: meburke@travelers.com
Sherman Drew AVP, Marine Advisory Services	ACE Commercial Marine Phone: (215)-640-2074 E: Sherman.Drew@acegroup.com
Richard P. Falcinelli Vice President, Sr. Manager – Marine Risk Engineering	Liberty International Underwriters Phone: (212)-208-9576 E: Richard.Falcinelli@LibertyIU.com

Background

The exposures associated with the logistics operations of temperature controlled products such as pharmaceuticals and food products create unique challenges that insurers need to be aware of. To better examine these challenges, insurers should consider these challenges as the product moves through the supply chain.

Cold Chain – Example Supply Chain



Packaging and Labeling Considerations

1. Does the packaging prevent contamination?
2. Selection of Temperature Control Products: Insulation, refrigeration packs / gels, etc.
3. Labeling (i.e., Fahrenheit vs. Celsius)
4. Make sure those you trust with your product understand the same challenges as you.

Cold Chain products have minimal tolerance for variation when it comes to the correct packaging, storage and transportation. The essential concerns relate to a:

1. Knowledge of the Product:
   - Stability Data & Validation by Stability Testing

2. Identification of the Packaging Design Implications
   - Active versus Passive shipping configuration
   - External/internal materials
   - Monitoring devices
   - Assessments/Trainings
   - Logistics and Communications Processes

Product Stability issues and Concerns

- Temperature sensitive products must be shipped in a manner to ensure products will be maintained within an acceptable temperature range
- Products can be shipped outside their respective label storage conditions provided stability data or scientific/technical justification exists demonstrating that the Product Quality is not affected
- Stability studies should be available to demonstrate the « robustness » of a product in case of temperature deviation

Packaging Selection – Materials

A packaging system includes an insulated package and a refrigerant. To best control the temperature and protect against physical damage during shipment, there are a number of different factors to consider.

1. **The product being shipped:**
   - What are the physical characteristics of the material to be shipped?
   - What temperature range needs to be maintained and for how long?
   - What regulations impact packaging selection?
   - Marking and labeling ? Temperature requirement in both **Fahrenheit** & **Celsius**

2. **The transit corridor:**
   - What transit conditions (vibration, shocks, extreme temperatures, etc.) do you expect?
   - What season(s) do you expect to ship in?
   - What temperature ranges will the shipment be exposed to during transit?
   - How long will the package be in transit?

3. **Packaging use and cost:**
   - Do you plan to re-use the packaging? Can it be re-used? How many times?
   - Are you maximizing the cost benefit? Is the packaging adequate, or is it more sophisticated and costly than it needs to be?

Insulating Materials

	Expanded Polystyrene (EPS) Foam	Polyurethane (PUR) Foam	Vacuum Insulated Panels (VIPs)
Definition	A closed-cell, lightweight, rigid-foam plastic typically molded (rather than formed) into panels.	A rigid piece of polyurethane foam molded into shape or used as an insulating panel.	A special insulating material (e.g., carbon) formed into a solid core and then vacuum-sealed.
Benefits	• Lightweight • Inexpensive • Recyclable • Re-usable • Superior dry ice sublimation	• Sturdy protection from rough distribution environments • Re-usable many times	• Lower dimensional weight reduces shipping costs • Requires less refrigerant • Recyclable • Re-usable many times
Trade-Offs	• Doesn't withstand multiple re-use as well as PUR or VIP • Bulkier design requires lots of storage space	• More expensive than EPS • Cannot be recycled	• More expensive than EPS or PUR • Can lose their vacuum seal, decreasing efficiency
R-Value[3]	• Lowest	• Medium	• Highest
Best Suited For	• Refridgerated or frozen materials shipped within a short transit duration	• Larger payloads • Extended domestic shipping windows	• Highly temperature-sensitive shipments • High-value shipments • Extended shipping windows • International shipments

The three most common types of insulated packaging for non-bulk shipments of temperature sensitive materials are expanded polystyrene (EPS) foam, polyurethane (PUR) foam, and vacuum insulated panels (VIP). The relative merits of each type are detailed in the table above. In addition to the insulating materials detailed above, the cold chain marketplace offers a myriad of other options to explore, including insulated pallet shippers, insulating (soft-sided) pouches, hard-cased thermal chests and boxes, cryogenic units, and active thermal systems.

Refrigerants

	Dry Ice	Gel Packs	Phase Change Material (PCM)
Definition	The solid form (typically in pellets or blocks) of carbon dioxide.	A rigid plastic container or soft-sided pouch containing a liquid (e.g., water or refrigerant gel) available in a variety of shapes, sizes, and thicknesses.	A material that changes phases (from solid to liquid or liquid to gas) at a given temperature.
Benefits	• Inexpensive • Readily available • Does not require pre-conditioning	• Can be re-washed, re-conditioned, and then re-used • Simplifies pack-outs; no need to weigh it as the packaging system specifies the number to use • Rugged; suitable for rough environments	• Can be re-washed, re-conditioned, and then re-used • Protects against temperature excursions for extended time windows • Provides the tightest temperature control • Enables temperature control outside of frozen or refrigerated ranges (i.e., controlled room temperature) • Simplifies pack-outs
Trade-Offs	• Special handling and training is required for use (See the 49 CFR) • Regulated as a hazardous material in air transport • Must weigh the dry ice to ensure the required amount is used • Not for use if product is adulterated by extreme cold • As it sublimates (turns to vapor), void spaces will open and the product may shift in transit	• Non-rigid gel packs may not maintain shape as they freeze • May contain hazardous materials • If received at room temperature, may take a few days to re-condition them to the correct temperature	• May contain hazardous materials • May not be recyclable

Three of the more common refrigerants are listed below along with some of the relative merits of each type. Keep in mind that refrigerants and insulating packaging must be considered as a complete system.

Logistics Partners – Considerations

Five tips to ensuring product integrity in temperature-sensitive distribution

1. Think outside the package to understand the transportation environment. Consider : Shipping container characteristics, refrigeration options; duration of transit; size of the shipment; ambient or outside temperatures anticipated will dictate packaging selection. This can range from small insulated boxes that require dry ice or gel packs, reefer containers

2. Develop a risk management plan for temperature-sensitive products.

3. Limit supply chain handoffs.

4. Ensure visibility solutions provide actionable data.

5. Create a transportation-specific quality agreement.

Logistics Partners – Considerations

Shipper Expectations:

- Certified and Calibrated Monitoring
- Current Good Manufacturing Practice (cGMP) Audited by a Third-party
- Qualified Cold Chain Transportation Partners
- Back Up systems-Monitoring, Power and Refrigeration
- Complete Tracking of Temperature Storage Conditions
- Validated Storage Areas
- Compliant Documentation
- Procedures to Handle Temperature Excursions Shipper expectations

Logistics Partners – Considerations

Know Transport – Risk Assessment:

- The transport process is a succession of steps which are reoccurring along the distribution route, transferable from one route to another, unlinked to the carrier and any other specific details Critical Components include:
  1. PREPARATION PHASE
  2. ROAD transport phase
  3. AIR/SEA/OCEAN/RAIL Transport Phase
  4. STORAGE in-transit
  5. RECEPTION PHASE

Sample Risk Assessment Matrix

Risk ID	Exposure	Consequence	Existing controls	Potential Impact	Likelihood (1-5)	Consequence (1-5)	Risk Potential (LxC)
Shipment Preparation (Reefer Truck Selection)							
A	Truck technical features enable temperature inside to fluctuate outside required temperature for period of time or in places (inadequate cooling unit, wrong calibration, infrequent maintenance, weak insulation,….)	Temperature deviation leading to destruction of part/total truck load					
		From shipper plant direct to end customer/consignee	1. Only temperature controlled trucks are used 2. Strong monitoring to correctly assess the quality of the load and to limit loss in case of localized temperature abuse 3. Use of approved carriers in accordance w/SOP 4. For specific business some trucks &/or vans are subjected to additional vetting	Business Risk			
B		From shipper plant to departure airport	Nominated transportation intermediaries are dedicated and validated according to shippers established SOP; packaging used for air transportation protects from minor excursions; monitoring devices inside the shipping boxes	Business Risk			
C		From airport to airport or from airport to customer	No general rule; packaging is protecting the load for minor excursions; monitoring devices inside the shipping boxes	Business Risk			

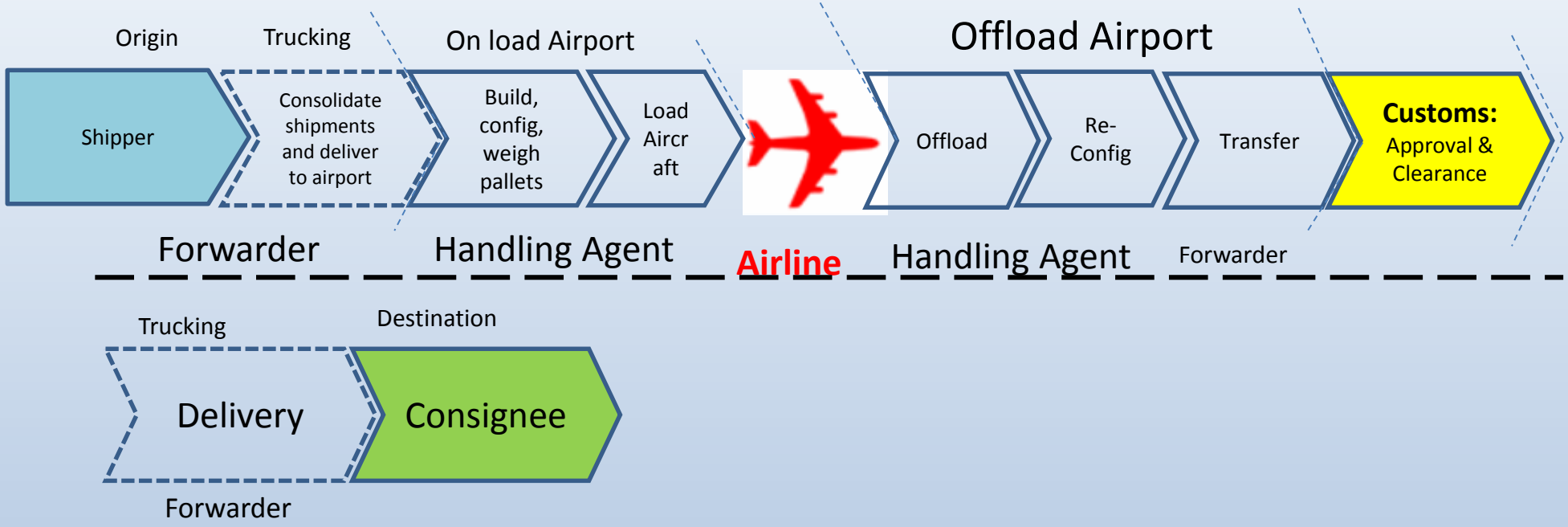
For each step and activity in the process, a risk assessment matrix defines potential threats, risks, current measures and additional mitigation plan to bring the route under control.

Logistics Partners - Considerations

Transport Considerations

- Modal Choice including “last mile” issues – timing, warehousing/labor availability, traffic congestion, parking, validated cold storage breach of integrity
- Concentrate the activities with preferred carriers
- Customs Procedures
- Technical Assessment of facilities
- Route selection
- Prefer direct flights or transits.
- Special process handling for high risk routes (i.e. Thermal covers, unloading supervision, …)

Sample Air Transportation Logistics



It is important to understand the full logistics of transporting your product to each destination in order to select the proper route and carrier to the final destination. This should include a detailed description of the Distribution Routes (Physical Process Flows)

You should conduct a comprehensive risk assessment of the transportation logistics process to identify and implement adequate solutions and improvements (SOP's, packaging, …) to assure a successful venture

Logistics Partners - Considerations

Logistics & communication process

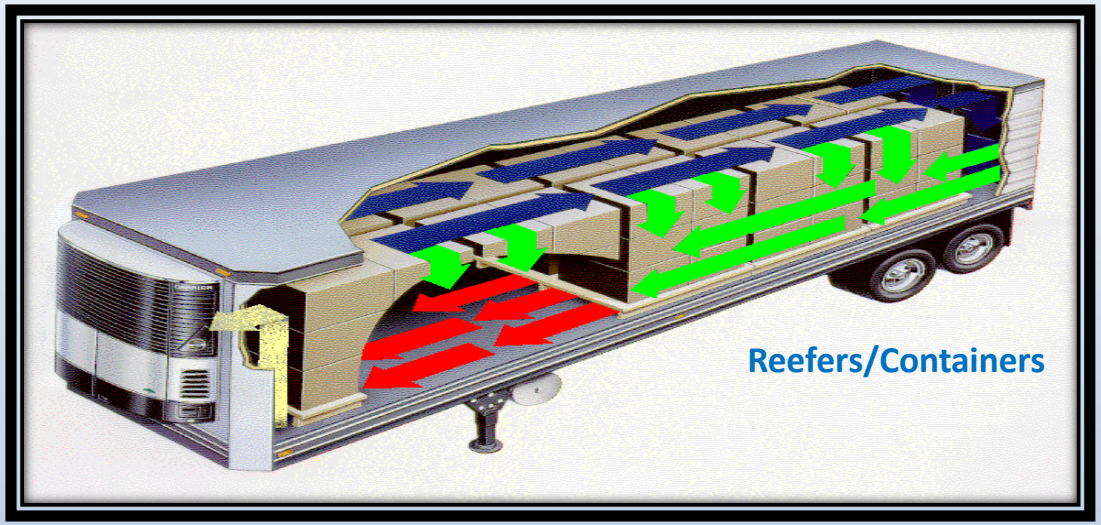
- Adequate track and trace system – deviations reported immediately including details (time & T°)
- Have a good pre-advise system to allow for a quick pick-up of the goods at destination and anticipate any in transit interventions e.g. customs clearance
- Receiving network or local organization should support quick pick-up - shorter time at airport as possible

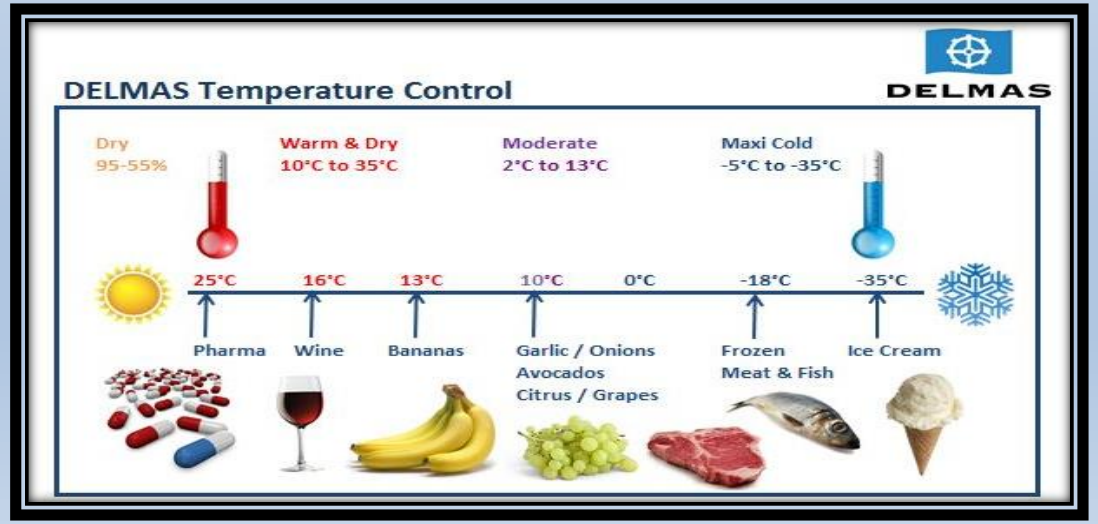
Cold Chain – Transportation

Considerations in Preparing Product for Shipment:

- Goods being shipped and where are the goods being shipped
- Degree of perishability and length of time in transit
- Geographic locations and climates
- Regulatory bodies and inspections or transshipment that may delay the shipment
- Chain of Custody and method(s) used to maintain and monitor the desired temperature
- Contingency Planning with customer and 3PL partners

Cold Chain Transport





Considerations

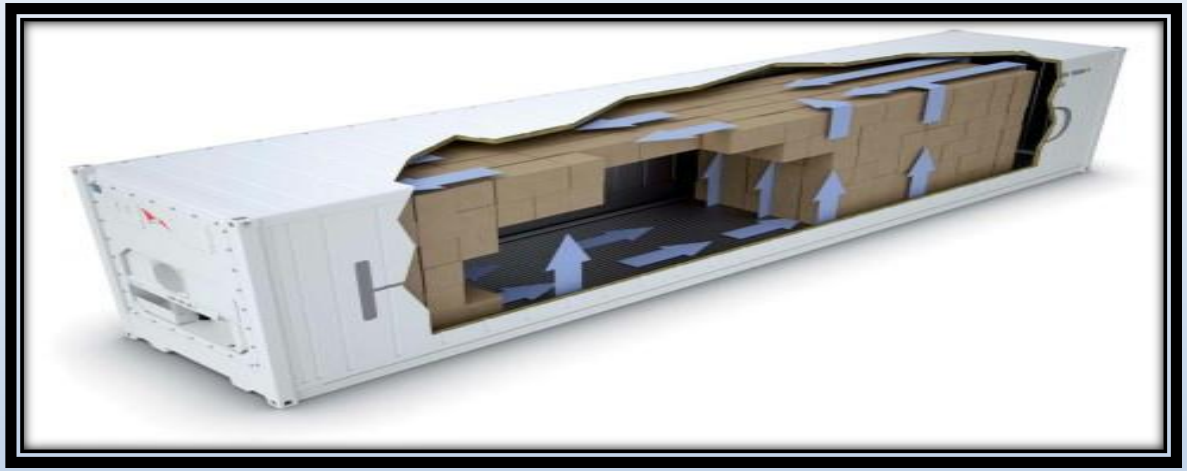
- Shipper obligations to properly prepare and stow cargo for reefer transit.
- Reliable power source
- On board Gensets provide cooling capability for segments when power source may not be available.
- The reefer container is designed to maintain a proper temperature.

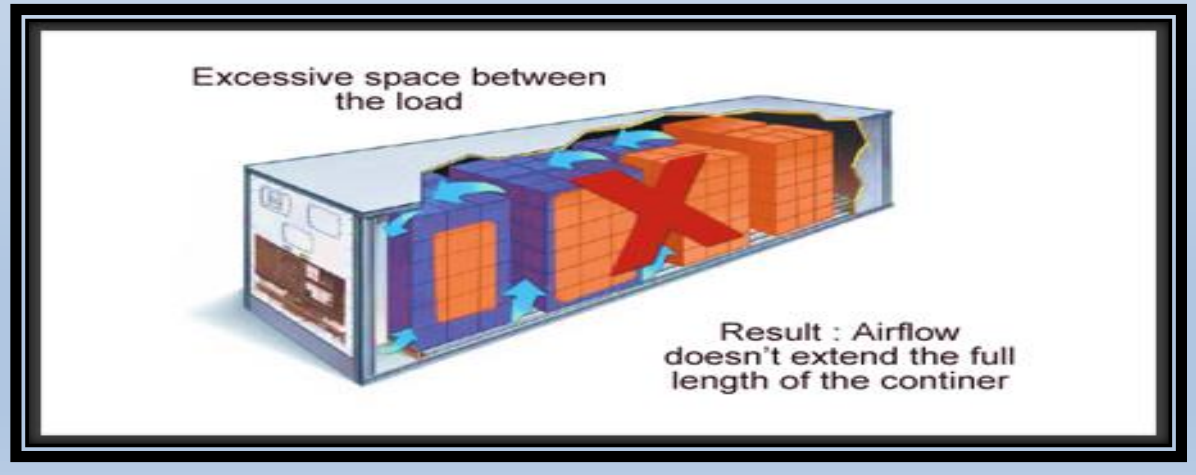
<u>To(o) Cool or not to Cool….</u>

- Unless the loading takes place in a controlled environment, which is seldom the case, pre-cooling a container may be a recipe for cargo damage (condensation and external frost)

Loading Process

- Pre-cooled Cargo
- Expedited loading process
- Airflow is Key
- Hot spots
- Short circuits





Summary of Good Practices

- A well maintained working unit Reefer and Trailer
- Determine Loading environment is conducive to a Pre-Cooled or Ambient box
- Good loading conditions and practice

Air Transit

- Carrier Selection Criteria
- Scheduling
- Handling

Monitoring and Escalation

Collaboration between all parties(shippers, warehouse, forwarder , steamship lines, terminals and yes, the end customer.

- Reefer temperature monitoring and set points
  - Consistency(eg. C or F)
  - Accuracy (-2-8 or 2-8)
  - Awareness
  - Accountability

- Shipper installed monitoring (Temperature and Security)
  - Embedded devices
  - Constant monitoring

- Temperature excursion and escalation
  - Who (Dedicated contacts . Carrier, shipper, consignee)
  - What (Identify issue and execute action plan)
  - Where (Predetermine response for breakdown or delay)
  - When (If a plan is being developed upon notification, it is likely too late)

Consequences

- Chilled pork Optimum 29 Degrees F

- Rule of thumb : **2 Degree Increase = 10% decrease in shelf life**

- 29F - 100% Life Attainable
- 32F - 70%
- 34 F-60%
- 36 F - 50%
- 41 F - 30%

Cold Chain – Transportation

Final Considerations:

- Goods being shipped and their value
- Degree of perishability, are goods replaceable and length of time in transit
- Distance being shipped, time of year and the regions of the world
- Mode(s) of transportation and carrier's level of expertise
- Method(s) used to maintain and monitor the desired temperature
- Contractual provisions in place to protect you as the shipper
- "The Last Mile"

Cold Chain: Loss Control for the Supply Chain Risk Improvement

There are numerous consideration when looking to eliminate or reduce exposure to loss, whether in transit or when stored in a facility.

The first and foremost, in our opinion, is:

- Communication;
- Documentation;
- Clear and concise instructions/protocols;
- Follow up.

Cold Chain: Loss Control for the Supply Chain Risk Improvement

There are numerous devices available to record, listen and track the whereabouts, as well as the temperature of shipments during transit. Similarly, there are other devices available for cold chain products in storage.

The benefits of having these various systems can mean the difference in having a small or no loss and/or a larger or total loss.

Such devices are:

- TempTale or similar device;
- Specialized locks, which include temperature monitoring;
- Refrigeration gauges that signal an increase/decrease on a specific temperature setting or range;
- Back-up generator.

Cold Chain: Loss Control for the Supply Chain Case Studies

At some point in time, anyone insuring product requiring refrigeration has suffered a Cold Chain loss in transit or in a facility.

The following case studies relate back to “Risk Improvement” or “Evaluating a Risk” slides on what is and should be considered when dealing with Cold Chain product in transit or storage.

Cold Chain: Loss Control for the Supply Chain Case Studies

This first case was a Cold Chain shipment with a short “shelf life” (couldn’t be o/o desired temperature range for more than 12 hours) on a vaccine being transported by a refrigerated truck from the east coast to the southwest.

Arrangements were made for the trucker to deliver the vaccine within a 96 hour period.

Five days later (???), the client calls requesting status on delivery and no one, at he shippers operation knows where the shipment is. Why?

Because, - that’s the reason we hire a trucking firm!

Needless to say there was a claim, as the truck broke down and required repair, but there was no notification and no follow up.

Cold Chain: Loss Control for the Supply Chain Case Studies

The next shipment was frozen meat that was loaded into a refrigerated container which was to be set at 0*F. The length of voyage was to be approx. 35 days from Australia to east coast US.

The voyage was on time, however, the temperature was set for 0*C (32*F) and was never checked to determine if correct, or not.

The shipment was rejected and sold for salvage (export).

Cold Chain: Loss Control for the Supply Chain Case Studies

This particular loss occurred after the Icelandic volcano eruption.

The pharmaceutical shipment, emanating from Europe, was packed in dry ice with a 36 hour window for delivery to final destination in the US.

After the volcano erupted, there was an approx. week long delay in clearing flights.

Needless to say, the shipment - also delayed, remained at the airport as the dry ice expired and so, unfortunately, did the product. The product heated well beyond the acceptable levels and was considered a total loss.

Back to basics, why didn't the assured, 3PL, etc. check status and add dry ice to extend time element and/or decide to transfer the product to a safe area (reefer/climate controlled) until flights were cleared to go?

Cold Chain: Loss Control for the Supply Chain Case Studies

This case involves a situation where the vessel carriers used a re-designed container, with no side channels for air flow, to ship frozen product.

Note: typical reefer container/trailer has channels along the floor and sides to allow for air circulation.

The product was stowed adjacent to the walls, front/rear and the required height limit.

On receipt, there was significant thawing damage to cartons on the outer perimeter due to the lack of cold air flow.

Remediation: designed a portable wall system to allow for air flow and eliminate/limit potential for damage.

Questions?

Thank You!