

# Freshness is Cumulative

## Risk Management, Shrink Reduction, and Brand Protection in the Era of FSMA

FDA's Final Rule on Sanitary Transport of Human and Animal Food requires stakeholders to implement and document a program ensuring the safe transport of food within the United States. The Rule in many aspects is vague and open to different interpretation. However, one thing is clear. If there is a food safety incident the following will be required:

- Proof that vehicles used in transport did not allow food to become unsafe
- Written procedures of the company's food transport safety program
- Verification that employees were adequately trained on proper safe pre-cooling and transport procedures
- Proof product was transported under safe temperature conditions

### Temperature Monitoring - A Best Practices Approach

Instead of reacting to a food safety transport incident, PakSense<sup>TM</sup> recommends a proactive approach - one that mitigates risks, reduces shrink, protects your brand, and modernizes your supply chain.

First, recognize that freshness is cumulative. The perishable supply chain is complicated, with many hand-off points. If temperature abuse occurs in any segment, food quality and safety can be compromised, shrink occurs, and your brand may suffer. Second, recognize technology has advanced significantly whereby automated temperature monitoring records can be generated in both real and near-real time with no human intervention. It is time to leverage these technology advances and modernize your program.<sup>1</sup>

Here are some basic temperature monitoring guidelines that can help you create your written program for FSMA compliance.

### Step One – Establish Precooling Processes

First, before product is transported, it should be pre-cooled by the supplier to the correct transit temperatures. It is important to get the thermal mass of the perishable product to the correct temperature before shipping, as this can have a direct impact on product quality, safety, and shelf life. If product is not pre-cooled, it can continue to aspirate in the enclosed truck trailer or other container. In some cases, the product will actually generate heat (called respiration), which results in product degradation. Product should be pulped to ensure proper temperatures have been reached before loading begins. Successful temperature control starts at the beginning with the supplier.

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<sup>1</sup> Contact PakSense for more information on our automated temperature monitoring solutions

Pre-cooling of the transit container by the carrier should occur when the container is connected to the cold storage unit. This is because product temperature and container temperature need to be in equilibrium. A container not connected to a cold storage unit should NOT be pre-cooled. This is because when doors are opened and loading occurs, hotter air will enter the container causing condensation. This can create numerous problems including the formation of ice and structural damage to shipping containers.

### **Step Two – Establish Proper Loading Practices for Optimal Air Circulation**

Product should be loaded in a manner that promotes air flow through the transport container. Product should not be loaded above the “load” line. In addition, the product packaging itself should promote air flow.

### **Step Three – Establish and Communicate Proper Transport Temperatures**

After pre-cooling and proper loading, product is then shipped to distribution centers within acceptable temperature ranges for the particular commodity. This practice should be considered for any perishable products backhauled to the DC as well. The following are the commonly accepted transport temperature ranges for various commodities that you can communicate to your supply chain stakeholders<sup>2</sup>:

**56°F (13.3°C) to 62°F (16.6°C)** – bananas

**42°F (5.5°C) to 54°F (12.2°C)** – tomatoes, yellow onions, potatoes

**32°F (0°C) to 39°F (3.8°C)** – general produce. This is the largest category and includes leafy greens, apples, broccoli, carrots, cauliflower, mushrooms, green onions, berries, corn

**28°F (-2.2°C) to 39°F (3.8°C)** – meat (beef, pork, poultry, seafood)

**32°F (0°C) to 39°F (3.8°C)** – dairy

**-10°F (-23.3°C) to 15°F (-9.4°C)** – general frozen foods

### **Step Four – Temperature Monitoring Device & Placement Procedures**

Place a digital temperature monitoring device on your load to monitor product temperatures as the reefer download will only provide ambient container reads and may not have been calibrated recently. These devices will give you the most accurate information. Establish consistent placement location(s) in the trailer.

### **Step Five – Receipt at Distribution Center**

When product is received at the distribution center, quality assurance staff checks the data from the temperature monitoring device for any temperature breaches. It is important this data is checked because it provides historical information on what happened to product during transit. A pulp temperature upon arrival in and of itself is not sufficient as it only provides temperature at that particular point in time. There have been blind tests where product arrived at a distribution center, was pulped, and shown to be at the correct temperature. However, when data from the temperature monitoring device was reviewed, it showed the refrigeration unit had been turned off for a significant amount of time during transit, creating the risk of product degradation and bacteria growth. Though the damage might not be immediately visible, this temperature abuse would be apparent in the future quality and shelf life of the product. Temperature monitoring devices provide historical data and help prevent the receipt of substandard products. They are the “eyes and ears” of quality teams when product is outside of their direct control.

### **Step Six – Distribution Center to Store**

Once product is consolidated at distribution centers it is regrouped and sent to the individual store or restaurant location. Product is shipped either on company-owned vehicles or subcontracted out to

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<sup>2</sup>Contact PakSense™ for additional perishable product ranges.

carriers. This area of the cold chain is subject to the same risks, but many times independent monitoring devices are not used to validate temperatures have been maintained. However, freshness is cumulative, and PakSense™ recommends that to complete your continuous monitoring program, this segment be monitored.

### **Step Seven – Stationary and Yard Monitoring**

Don't forget perishable products held in stationary facilities are part of the cold chain. Make sure you address this segment with a facility monitoring program. Also important to consider is product preloaded for shipment and waiting for transport in the yard. These temporary holding facilities should be monitored as part of your comprehensive program as well.

### **Best Practices Summary**

A world-class temperature monitoring program includes the following elements:

- Recommended safe temperature transport range guidelines for the most popular commodities established and communicated down the cold chain.
- Requirement perishable products be pre-cooled to acceptable transit temperatures before transport begins.
- Documented handling procedures when loading into a container attached to a cold storage unit versus a container not attached to a cold storage unit.
- Temperature monitoring devices utilized on perishable products in all segments of the cold chain including supplier to distribution center, distribution center to retail/restaurant location, and stationary monitoring. These recording devices will help suppliers, carriers, and retailers pinpoint where weak points in the cold chain exist so solutions can be implemented to mitigate risk, reduce shrink, and protect your brand.
- A system where temperature logs of your cold chain are available anywhere and on demand.

Remember, freshness is cumulative. Don't wait for a FSMA audit. Implementing these measures today will mitigate your risks, reduce shrink, and protect your brand.

## **Risk Management, Shrink Reduction, and Brand Protection in the Era of FSMA**

### **Who is Subject?**

Shippers, receivers, loaders, and carriers engaged in transportation operations. Responsibilities can be reassigned in a written agreement. For example, the shipper can assign these responsibilities to the carrier in a written agreement.<sup>3</sup> Competent supervisory personnel ensuring the safe transport of food must be assigned.<sup>4</sup> Staff must be properly trained on procedures and this training must be documented.<sup>5</sup>

### **Requirements for vehicles and transportation equipment and transport operations**

- Vehicles must be designed appropriately to ensure safe transport of food.<sup>6</sup>
- Vehicles must be maintained in a sanitary condition and equipped to provide adequate temperature control to prevent food from becoming unsafe.<sup>7</sup> We believe this encourages trailer mapping.

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<sup>3</sup> §1.908(a)

<sup>4</sup> §1.908(a)(2)

<sup>5</sup> §1.910

<sup>6</sup> §1.906(a) – a vehicle mapping program may be in order as well as secondary temperature monitoring devices to ensure proper refer calibration.

<sup>7</sup> §1.906(c) - a vehicle mapping program may be in order as well as secondary temperature monitoring devices to ensure proper refer calibration.

- Effective measures such as segregation, isolation, or use of packaging to protect food from contamination of raw foods and non-food items must be in place.<sup>8</sup>
- If any party becomes aware of an indication of possible failure of temperature control that renders the food unsafe, the food shall not be sold. Appropriate communication action must be taken.<sup>9</sup> This particular section suggests the need for a secondary temperature device to help in this determination.
- Before loading foods, the loader must verify each cold storage compartment or container is adequately prepared (pre-cooled) for the transport of the food.<sup>10</sup> Verification in record keeping is required and we suggest placement of a temperature recorder at this point would be helpful.
- Requirements of Receivers – upon receipt, the receiver must take steps to ensure the food was not subjected to significant temperature abuse.<sup>11</sup> A secondary temperature device aids in this determination.
- Requirements to carriers – Carriers must demonstrate, if requested by the shipper and receiver, that it has maintained temperature conditions during the transportation operation consistent with the temperature specified by the shipper. This can be done with ambient reefer temperature reads or time/temperature data from a recorder taken during shipment<sup>12</sup> which can provide a more accurate assessment.

### Written Procedures and Records

An overarching theme is the requirement that the shipper create and document a program that ensures the safe transport of human and animal food and that these documents be shared with the carrier.<sup>13</sup> Both the shipper and carrier must maintain these documents during active contracts and 12 months after a contract is terminated. Shippers, receivers, loaders, and carriers must make the records and written procedures available on demand to a duly authorized individual.<sup>14</sup> Included in these written procedures are:

- Specifications and operating temperatures for shipments<sup>15</sup> including the precooling phase.<sup>16</sup>
- Training records that carrier personnel have been adequately trained on proper loading practices and temperature settings<sup>17</sup> for up to 12 months after the termination of agreements.

Records and documents can be originals or other accurate reproductions or electronic.<sup>18</sup>

**Bottom Line:** The shipper (or carrier if so designated) must have written procedures that detail how they will safely transport food and this includes a temperature monitoring component. They must have records their personnel have been adequately trained on these procedures. They must share these procedures with carriers. These records must be maintained for a period of 12 months after contract termination.

### Contact

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<sup>8</sup> §1.908(a)(3)(i)

<sup>9</sup> §1.908(a)(6)

<sup>10</sup> §1.908(c)(2) and 1908(e)(3) if assigned to the carrier

<sup>11</sup> §1908(d) – a temperature recorder is the definitive method to accomplish this.

<sup>12</sup> §1.908(e)(2)

<sup>13</sup> §1.912(a)

<sup>14</sup> §1.912(e)

<sup>15</sup> §1.912(a)(1)

<sup>16</sup> §1.908(b)(2) and §1908(b)(5)

<sup>17</sup> §1.912(c)

<sup>18</sup> §1.912(g)