

January 2, 2015

RE: FSMA Proposed Rule on Sanitary Transportation of Human and Animal Food

The regulatory environment had made sweeping changes in the past few years. In September 2009, the FDA introduced the RFR (Reportable Food Registry). The RFR requires a responsible party to file a report through the RFR electronic portal when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Such foods are "Reportable Foods." The FSMA (Food Safety Modernization Act) was passed on January 4, 2012. As part of that act a number of laws were changed. As part of FSMA, many areas are awaiting proposed guidance or guidance has been made available for comment and is being finalized.

Two very significant shifts were (i) the requirement for preventive controls for all manufacturers of human and animal food and (ii) a shift from "reasonable probability" to "reason to believe" was made. As has now been extensively demonstrated through precedent this wider interpretation gives the FDA far more latitude. The FDA is also adopting risk levels to assist in determining which areas to monitor and deploy resources. Since the inception of RFR, the greatest number of entries with subsequent recalls have been related to potential allergen contamination. Hence, allergens and enforcement actions around the potential for cross contamination are an area the agency is actively pursuing.

As with many aspects of FDA, this is not finite and is left open for interpretation. As our food manufacturers are required to have HACCP plans, the condition not only of the product, but how the product was handled and what risks may be present must be addressed too. Our customers also have these, and at times, additional requirements.

The current FDA guidance states-

In our effort to assist the food transport industry in preventing food safety problems during transport while we are implementing the 2005 SFTA, we want them to be aware of the following problem areas where food may be at risk for physical, chemical, or biological contamination during food transport:

- *Improper refrigeration or temperature control of food products (temperature abuse).*
- *Improper management of transportation units (or storage facilities used during transport) to preclude cross-contamination, including improper sanitation, backhauling hazardous materials, not maintaining tanker wash records, improper disposal of wastewater, and aluminum phosphide fumigation methods in railcar transit;*
- *Improper packing of transportation units (or storage facilities used during transport), including incorrect use of packing materials and poor pallet quality;*
- *Improper loading practices, conditions, or equipment, including improper sanitation of loading equipment, not using dedicated units where appropriate, inappropriate loading patterns, and transporting mixed loads that increase the risk for cross-contamination;*
- *Improper unloading practices, conditions, or equipment, including improper sanitation of equipment and leaving raw materials on loading docks after hours;*
- *Poor pest control in transportation units (or storage facilities used during transport);*
- *Lack of driver/employee training and/or supervisor/manager/owner knowledge of food safety and/or security;*

- *Poor transportation unit design and construction;*
- *Inadequate preventive maintenance for transportation units (or storage facilities used during transport), resulting in roof leaks, gaps in doors, and dripping condensation or ice accumulations;*
- *Poor employee hygiene;*
- *Inadequate policies for the safe and/or secure transport (or storage during transport) of foods, e.g., lack of or improper use of security seals;*
- *Improper handling and tracking of rejected loads and salvaged, reworked, and returned products or products destined for disposal; and*
- *Improper holding practices for food products awaiting shipment or inspection, including unattended product, delayed holding of product, shipping of product while in quarantine, and poor rotation and throughput.*

To address some of the problems enumerated above, we recommend that persons engaged in food transport concentrate their efforts at this time on the following, broadly applicable preventive controls:

- *Appropriate temperature control during transport;*
- *Sanitation, including:*
 - *Monitoring and ensuring the sanitation and condition of transportation vehicles as appropriate;*
 - *Pest control; and*
 - *Sanitation associated with loading/unloading procedures;*
 - *Appropriate packaging/packing of food products and transportation units (e.g., good quality pallets, correct use of packing materials);*
 - *Good communications between shipper, transporter and receiver; and*
 - *Employee awareness and training.*

(Source: Guidance for Industry: Sanitary Transportation of Food, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm>)

However, as required by their HACCP plans, when a deviation (e.g. product transported in mixed loads containing allergens or hazardous materials) is encountered, the plant will weigh those risks and if they cannot be insured with a high degree of probability the product was not compromised they must (and will reject it).

We ask that the potential for cross-contamination, sanitations, and mixed loads be carefully managed by the transporter to prevent such rejections. Also, be aware that this guidance MAY ultimately become law at any time. We request your cooperation and understanding as we are bound to protecting the integrity of the product regardless.

Sincerely,



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