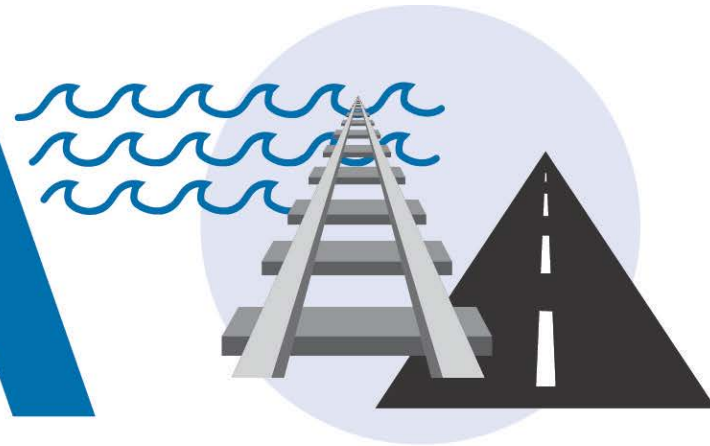

IANA



INTERMODAL ASSOCIATION OF NORTH AMERICA

Are You Prepared?

Understanding the Sanitary Transportation of Human and Animal Food Rules and the Potential Risks

MARCH 31TH 2017, 2:00 PM ET

With

Theodore Prince, Chief Operating Officer, Tiger Cool Express LLC

Stephanie Penninger, Senior Litigation Associate, Benesch, Friedlander, Coplan & Aronoff LLP

Christopher Lalak, Attorney, Benesch, Friedlander, Coplan & Aronoff LLP

Housekeeping

- Panelist presentations will be followed by audience question and answer session
- Audience audio will be muted
- Submit questions at any time for Q&A session at the end of the webinar presentations



Our Panel

Theodore Prince, Chief Operating Officer, Tiger Cool Express LLC



Stephanie Penninger, Senior Litigation Associate, Benesch, Friedlander, Coplan & Aronoff LLP

Christopher Lalak, Attorney, Benesch, Friedlander, Coplan & Aronoff LLP



Structure

- ✓ Overview—What is FSMA and the Sanitary Transportation Rule?
- ✓ Covered Entity Requirements
- ✓ Examples
- ✓ Practical Advice
- ✓ Q & A



Sanitary Food Transportation



Food, Drug and Cosmetic Act

- Prohibits distribution of “adulterated” food
- Defines food product as “adulterated” if, among other things:
 - . . . It has been . . . Held . . . under insanitary conditions whereby . . . It may have been rendered injurious to health.
- Regardless of whether filth is actually found in the food itself

Sanitary Transportation of Human and Animal Food – New Regulations

- Required by Food Safety Modernization Act of 2011
- The FDA Food Safety Modernization Act (FSMA) rule on the Sanitary Transportation of Human and Animal Food (STF rule) became final on April 6, 2016
- The STF rule creates requirements for shippers, loaders, motor carriers, rail carriers, and receivers involved in the transportation of food subject to the rule

Who is Covered?

- Carriers
- Freight Brokers
- Receivers
 - Warehouseman and consignee may be considered “receivers” when they receive food after transportation
 - Do not have to constitute the final point of receipt
- Loaders
 - Persons that load food onto a motor or rail vehicle during transportation
 - Warehousemen often perform this function
- Shippers
 - Domestic
 - International



Scope and Application

- **What food is covered by the STF rule?**
- Generally speaking, all human and animal foods, additives and dietary supplements are covered by the rule
- Foods regulated under the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 341 et seq., including animal food (pet food and feed for livestock), food additives, and dietary supplements

Notable Exemptions

- Small Shippers, receivers, or carriers
- Food that is completely enclosed by a container, unless the food requires refrigeration for safety
- Compressed food gases
- Human food byproducts for use as animal food
- Live food animals (except mollusks and shellfish)
- Transshipments of food through the United States, e.g. from Canada to Mexico, if the food will not be distributed in the United States
- Frozen Foods?

International Shipments



- Sanitary Transportation Rule requirements apply to international shippers exporting food to the U.S. by ocean or air in a freight container if:
 - Arranging for intact container's transloading onto a motor or rail carrier
 - For transport in U.S. commerce
 - Food will be consumed or distributed within the U.S.
- Exporter is a “shipper” arranging a segment of transportation of food by motor or rail vehicle
 - If foreign exporter cannot be identified, Carrier/Receiver could be responsible for ensuring food is transported safely
 - Food with safety concerns is not allowed into U.S. commerce/interstate transport

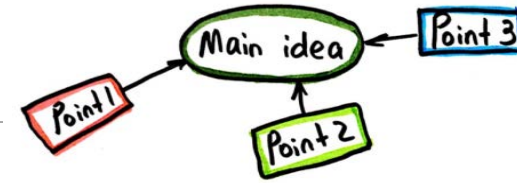
Primary Areas of Regulation

- Vehicles and Transportation Equipment
- Design and maintenance of transportation equipment
- Transportation Operations
- Measures taken to prevent food from becoming unsafe during transportation
- Training
- Training of Carrier personnel in sanitary transportation practices
- Record Keeping
- Maintenance of written procedures, agreements and training records

General Requirements

- Taking measures such as isolation, segregation, and use of packaging to prevent contamination during transportation
- Taking measures to ensure that food that requires temperature control for safety is transported under adequate temperature control
- If any party in the process becomes aware of a material failure of temperature control or other condition which could cause the food to become unsafe, it must take appropriate action to ensure the food is not distributed or sold until determined safe by a qualified individual

Highlights



- Vehicles and transportation equipment:
 - To be designed and maintained and stored to prevent food from becoming unsafe
 - Adequately cleanable for intended use
 - Capable of maintaining temperatures necessary for safe food export
- Transportation Operations:
 - Must develop measures to ensure food safety:
 - Adequate temperature controls
 - Prevent contamination of ready to eat food from touching raw food
 - Protection of food from contamination by non-food items in the same load
 - Protect food from cross-contact (i.e. accidental incorporation of food allergen)

Highlights

- No continual temperature monitoring devices/reporting
 - But transportation operations that prevent food from becoming unsafe during transport
- No Burden Shift:
 - If covered person learns of possible temperature control failure or other conditions that may render the food unsafe during transport → cannot sell/distribute until safely determination made by a “qualified individual”
- Waivers:
 - Export of Grade A milk/milk products exported
 - Food Establishments (e.g. restaurants, supermarkets, grocery delivery)

Allocation of Responsibilities by Agreement

- Parties subject to the rule can allocate certain responsibilities between them with a written agreement
- Parties should approach this carefully to avoid unanticipated liability

Shipper/Broker Responsibilities

- Communicate to the carrier in writing the necessary specs for transportation equipment to maintain sanitary conditions
- Specify to the carrier, in writing, an operating temperature, including pre-cooling, for shipments requiring temperature control for safety
- Written procedures to ensure that vehicles used are appropriate and sanitary, including bulk vehicles
- Retain records showing that the shipper provided the required specifications (temp and equipment) to carriers, as well as any written agreements allocating responsibility

Loader Responsibilities

- Determine, in accordance with the shipper's instructions, that the transportation equipment provided is in an appropriate sanitary condition for transporting food
 - Confirming that it is in adequate physical condition, free from visible evidence of pest infestation or previous cargo that could cause the food to become unsafe during transport
- For food shipments requiring temperature control, verify, taking into consideration the shipper's instructions, that each mechanically refrigerated storage compartment or container has been adequately prepared to transport temperature controlled food
 - When necessary, that it has been properly pre-cooled
- Any failure of the loader to fulfill this obligation will be considered an act or default of the shipper and a defense to any cargo claim resulting for the condition of the trailer

Receiver Responsibilities

- Upon receipt of food that requires temperature control for safety take steps to adequately assess that the food was not subjected to significant temperature abuse, including determining:
 - Food's temperature
 - Ambient temperature of the vehicle
 - Vehicle's temperature setting
 - Conducting a sensory inspection, *e.g.*, for off-odors

Carrier Responsibilities

- If assumed by contract:
 - Ensure that transportation equipment meets Shipper specifications
 - Demonstrate that it has maintained temperature conditions consistent with the operating temperature provided by Shipper
 - Pre-cool equipment as necessary
 - Upon request, provide information on prior cargos (bulk transport only)
 - Implement written procedures re: equipment sanitation, compliance with temperature control, and training of personnel

Training



- Carrier to provide training, upon hire and as needed thereafter to personnel engaged in transportation operations
 - Awareness of potential food safety problems that may occur during food transportation
 - Basic sanitary transportation practices to address potential problems
 - Responsibilities of the carrier under the STF Rule
- No “one size fits all” approach re frequency, subject matter or length
 - Tailored to business operations
- FDA to offer course through website to meet reg. requirements
 - Suggested alliances such as the Seafood HACCP Alliance would be useful for developing and promoting training for sanitary food transportation

Recordkeeping

- Written procedures and agreements assigning duties
- Training
- Documents containing the shipper's written specifications (including temperature requirements) for all food shipments
- Original, true copies or electronic records
- Available to duly authorized individuals promptly upon written/oral requests
- Offsite storage of records if can be retrieved within 24 hours of request



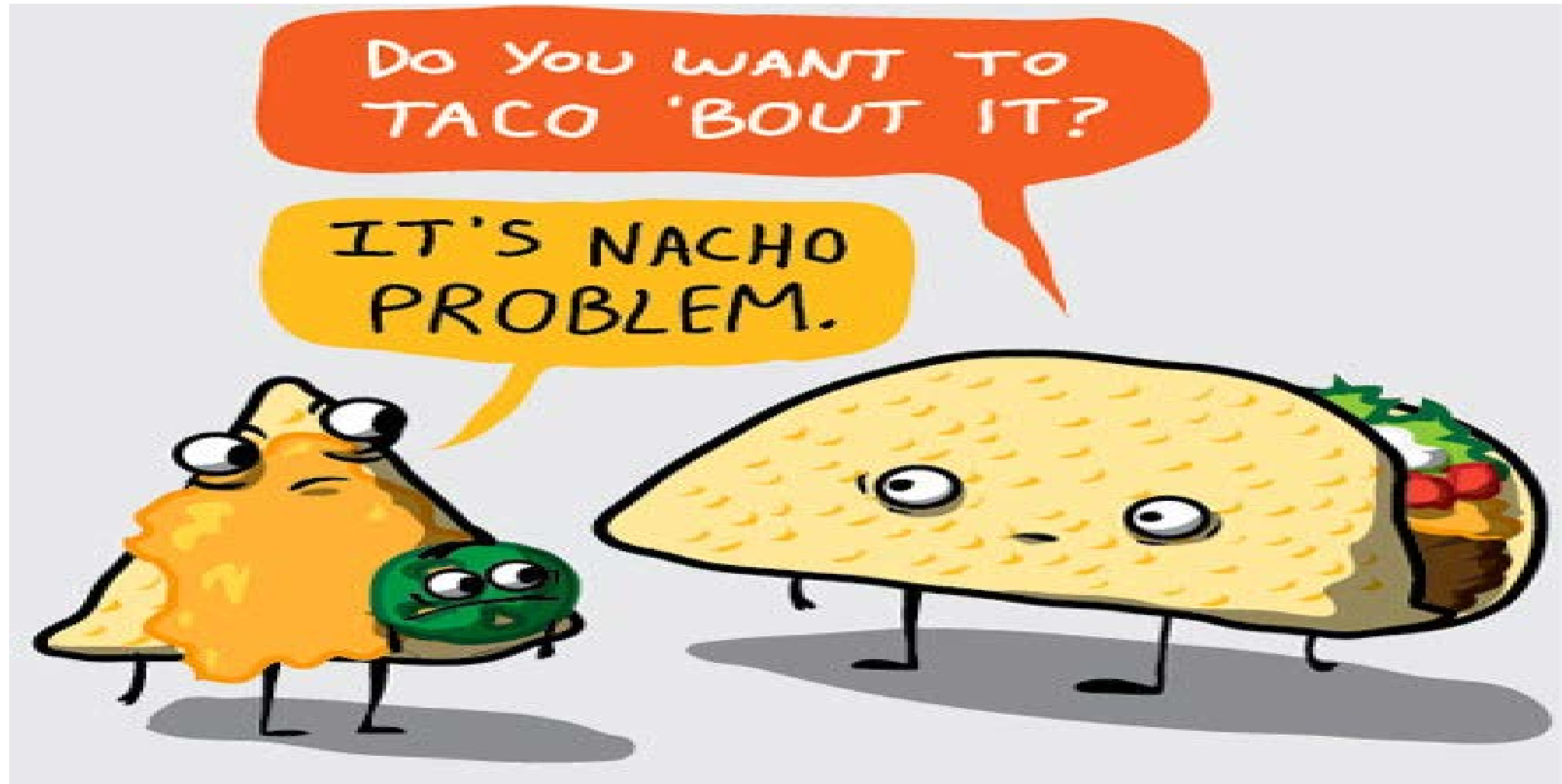
Enforcement

- DOT
 - Authorized and trained to conduct transportation safety inspections to ID food shipments in violation of the regulations
- FDA
 - Generally responsible for taking action against violators
 - Can have the U.S. DOJ seize food product or stop its transport
 - Can criminally prosecute and fine those who violate
 - Max. fine for individual: \$100K or \$250K if death
 - Max. fine for organizations: \$200K or \$500K if death

Compliance Dates

- When must affected entities be compliance with the rule?
- April 6, 2017 unless a “small business”
- Small businesses have an additional year to comply





Real World Examples:

Mecca & Sons Trucking v. White Arrow, 2016 WL 5859018 (D.N.J. Sept. 16, 2016)

- Can a motor carrier be held liable for cheese rejected due to temperature variance without any evidence of physical damage?
- 11 of 17 pallets of cheese were rejected by Trader Joe's based on TempTale readings exceeding the maximum temperature set by Trader Joe's in its Master Vendor Agreement with shipper Singleton Dairy
- White Arrow argued that bad condition at destination was not proven when the cheese was not inspected, no pulp temperatures of the cheese were taken to determine its condition, and White Arrow's expert found that the cheese was in good condition when he inspected it two months after Trader Joe's rejected some of the cheese and yet accepted other cheese in the same reefer car that were subjected to the same temperatures

Court Findings

- Trader Joe's rejection of the cheese was reasonable and sufficient in itself to satisfy the damage at destination element of the shipper's Carmack Amendment claim
 - "[F]act that temperatures registered inside the trailer exceeded 40 degrees is sufficient to establish liability because the shipping temperature, like a seal, is a reasonable precaution to assure food safety"
- Like a seal, a temperature threshold is a reasonable safeguard to assure food integrity, prolong shelf life, minimize deterioration, and protect Trader Joe's and its customers

Court Findings

- Impossible to verify crabmeat was stored at requisite temperature and was safe to consume with TCR
- Selling the crabmeat without proof of temperature maintenance could expose Farmers and Ipswich to civil or criminal liability

STF Questionnaire Example

If your business employs greater than 500 full-time employees or earns more than \$27.5 million in annual receipts, will your business be in compliance with the Sanitary Transportation of Human and Animal Food Final Rule (“STF Rule”) by April 6, 2017?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If your business employs fewer than 500 full-time employees or earns less than \$27.5 million in annual receipts will your business be in compliance with the STF Rule by April 6, 2018?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are the motor vehicles and transportation equipment (“Equipment”) used by your business designed, maintained and cleaned so that they are able to prevent food from becoming adulterated during transportation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is your Equipment stored in a manner that prevents it from harboring pests or contamination?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is your Equipment able to provide adequate temperature control during transportation to prevent food from becoming adulterated?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Request for FSMA Controls

- Dear Shipper:
 - In April of 2016 the Food and Drug Administration published final regulations (“Final Regulations”) implementing the Food Safety Modernization Act (“FSMA”). Under Section 1.908 of the Final Regulations, shippers must establish controls for the transportation of their freight and provide such controls to freight carriers. Please submit your FSMA controls to **CARRIER** no later than February 15, 2017
 - If you have any questions, please contact your **CARRIER** Account Executive

Watch Out?

- More than the STF Rule Requires:
 - Food that has been transported or offered for transport under conditions that are not in compliance with the shipper's instructions as provided to Carrier by the shipper, through Broker or otherwise, will be considered “adulterated” within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 342(a)(i)(4), 342(i)
 - Carrier understands that adulterated shipments may be refused by the consignee or receiver upon their tender for delivery, with or without inspection

Watch Out?

- Broker/Carrier Contract Addendum:
 - To the extent Carrier received contradictory or confusing instructions regarding any shipment; Carrier must resolve the contradictory or confusing instructions prior to accepting the shipment for transport
 - Failure to resolve any issue with the instructions prior to transport shall bar Carrier from using the contradictory or confusing instructions as a defense

Shipper/Carrier Contract - Example

- Shipper must specify all instructions to be followed to maintain the safety of the food, including, without limitation, all temperature control requirements and temperature control documentation requirements, including an operating temperature for the transportation and, when necessary, all precooling requirements, all sanitation requirements and sanitation documentation requirements for the Covered Food Shipment
- Carrier shall not be liable to Shipper for cargo loss or damage if Shipper fails to provide the required notice and accompanying instructions for the Covered Food Shipment if such food becomes adulterated or is deemed unsafe as a result of Shipper's failure to provide such instructions

Shipper/Carrier Contract - Example

- Shipper acknowledges and agrees that consignee has a duty to accept food shipments offered at delivery, unless an inspection by an expert is conducted, at no cost to Carrier, and the shipment is found “adulterated”

Shipper/Carrier Contract - Example

- In the event that Shipper provides notice of a Covered Food Shipment, and in the event that the safety of any portion of a Covered Shipment is reasonably called into question, the parties agree to split the cost of a mutually agreed qualified expert's inspection of the Covered Food Shipment
- Upon finding by the qualified expert that a portion or all of the Covered Food Shipment has become adulterated while in Carrier's possession, Carrier will pay the invoice amount of any adulterated portions of the Covered Food Shipment, subject to the limitation of liability and claims procedure detailed above
- Carrier will not be liable for Covered Food Shipments that are rejected by the shipper or consignee without an inspection by the mutually agreed qualified expert



A Difficult Burden?

- [Upon request] Carrier will provide, for each shipment, evidence that the Goods have not been adulterated and have been transported under sanitary conditions that will protect against temperature abuse or excessive fluctuations and any physical, chemical, or microbial contamination

Lookout for Seals

- Shipper and/or its customer may reject any shipment that has not been locked or sealed in accordance with the Seal Requirements and reserves the right to deem such shipment(s) worthless
- FDA thoughts on the matter:
 - “A broken cargo seal or any evidence of food cargo tampering would not necessarily create a per se presumption of adulteration. However, we advise persons engaged in transportation operations that, if such situations should arise, they should carefully evaluate the facts and circumstances of each incident, on a case-by-case basis, to determine whether the safety of the food cargo may have been compromised”

When You're In a Pickle



Practical Considerations and Application

Practical Application

- How should the shipper provide the information to you?

Practical Application

- How does training impact employment status for carriers?

Practical Application

- If my carrier is exempt, is the transaction exempt?

Practical Application

- If the consignor shipper tells broker shipper “See BL,” who is responsible for reviewing the bill of lading?

Practical Application

- Does non-rejection of equipment for loading imply acceptance that the equipment is clean and sanitary?

Practical Application

- How is a carrier to demonstrate temperature control?

Practical Application

- How do lumpers factor into this framework?

A green semi-truck is driving on a multi-lane road. In the background, there are stacks of colorful shipping containers (blue, red, white) and a blurred white car. The word "Questions?" is overlaid in large white text.

Questions?

Enter your questions in the control panel

Thank You!



Stephanie S. Penninger
Benesch, Friedlander, Coplan & Aronoff
Chicago, Illinois
312-212-4981
spenninger@beneschlaw.com

Christopher J. Lalak
Benesch, Friedlander, Coplan & Aronoff
Cleveland, Ohio
216-363-4557
clalak@beneschlaw.com



Ted Prince
Tiger Cool Express, LLC
913-305-3512
ted@tigercoolexpress.com

Visit intermodal.org for more information
about intermodal freight and IANA,
or e-mail: info@intermodal.org



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