How Food Safety is Changing the US Cold Chain Transport?
Agenda

Food Safety Modernization Act
Sanitary Transportation of Food Act
Insights into Transportation
What does it mean for the Industry
Food Safety Modernization Act

Annually Foodborne incidents:
• 48 million people (1 in 6 Americans) get sick
• 128,000 are hospitalized
• 3,000 die

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on January 4, 2011.

The law moves FDA from a regulatory agency to a new law enforcement authority designed to achieve higher rates of compliance with prevention- and risk-based food safety standards.

The major mandates of the Act are:

1. Registration
2. Hazard Analysis & Preventive Controls
3. Verification
4. Inspection & Frequency
5. Record Keeping Requirements
6. Penalties
The Department of Justice (DOJ) has formally announced that it has partnered with FDA and has adopted a policy of initiating criminal investigations against any company (or its employees) that sells a product that cause human illness.

The Principal Deputy Assistant Attorney, Benjamin C. Mizer indicated that FDA and DOJ view any human illness caused by a food product as a potential violation of the law.
Enforcement Funding

Transport Company recently paid $19.4M settlement.

The company also must pay all costs of supervision, inspections, investigations, analyses, examinations and reviews necessary for FDA’s oversight. The current rates for such services, according to the order, range from $89.35 to $107.09 per hour.
Enforcement

PCA’s president ordered that products for which the salmonella testing results were not yet available be shipped to the customer, writing “s**t, just ship it. I cannot afford to lose (sic) another customer.”

- **Stewart Parnell**, 61 yr – 28 yr
  - Selling misbranded food, adulterated food, fraud, conspiracy
- **Michael Parnell**, 57 yr – 20 yr
- **Mary Wilkerson**, - 5 yr
  - Obstruction of justice
- **Kilgore** – 6 yr
- **Lightsey** – 3 yr
Sanitary Transportation of Food

Rules were originally formulated.

Rules were brought about in 2005 legislative process.

Rules finally adopted and brought into FSMA’s Sanitary Transportation of Food.

Final Sanitary Transportation of Food Act is released which significantly expands the powers of the Food and Drug Administration.

Rules become enforceable for most businesses on April 7, 2017.
STF: Final Rule

FSMA has identified the shipper as the key stakeholder in keeping food safe during transportation:

- Trailer Design
- Sanitary Cleaning
- Pre-Cool Requirement
- Temperature Transport Requirement
- Shipper / Loader / Carrier Data Retention
- Food Safety Training Requirement
Sanitary Transport Definitions

- **Shipper**: The one who initiates the load
- **Loader**: The one who prepares for transport and loads trailer
- **Carrier**: The one who physically moves the food by motor transport
- **Receiver**: The one who received the load after transport
Shipper

- Manufacturer or a freight broker who arranges for the transportation of food

- A Shipper **MUST** develop and implement written procedures
Spec and Equipment Design

Requires that the shipper provides in writing to the carrier and loader, the necessary sanitary specification for the carrier’s vehicle and transportation equipment to prevent the food from becoming unsafe.

Shipper mandates in writing Carrier trailer spec and design requirements.
Sanitary Requirements

Requires that the shipper provide in writing to the carrier and, when necessary, the loader all necessary sanitary specifications for the carrier’s vehicle and transportation equipment to prevent the food from becoming unsafe.

Shipper mandates Carrier

- Cleaning procedure
- Cleaning frequency
Temperature Management

Shipper of food that requires temperature control for safety – **must develop** and **implement** written procedure

- Pre-Cool
- Temperature monitoring
- Temperature information exchange (shipper/receiver)
- Record retention
Records Retention

Records subject to FDA inspection upon oral or written request

Records can be stored off-site if they can be retrieved within 24 hours.

Shippers, receivers, loaders, and carriers must retain written agreements assigning tasks in compliance for a period of 12 months beyond the termination of the agreements.
Training Requirement

Carrier and Loader are subject to the training requirement

- Designed for their part in the transport process
- Record must be maintained for 12 months beyond the job function
Carrier Concern: Responsibility

In this final rule, the demonstration must only be made if the shipper or receiver requests it, which is consistent with industry best practices and would likely only be done in situations in which it is suspected that there has been a material failure of temperature control.
Building a Smart TRU

Pre Cool
Pre-cool validation

Temperature Management
Daily temperature log during delivery route

Data Retention
On-demand as required by shipper agreement

Data Exchange
Available at the request of shipper or receiver
Preventative Controls for Human Foods

FDA Preventive Controls for Human Food has published a draft guidance document that impact transport distribution.
IRTA, FDA discuss refrigerated transportation best practices

January 17, 2017

Representatives from the U.S. FDA attended a board of directors meeting for the International Refrigerated Transportation Association (IRTA), a partner of the Global Cold Chain Alliance (GCCA), on Thursday, Jan. 12. The FDA representatives in attendance were instrumental in the development and writing of the FDA’s Sanitary Transportation of Human and Animal Food Rule (STF) and provided details on the STF rule to the group.

In 2016, IRTA published the IRTA Refrigerated Transportation Best Practices Guide, a guide to assist shippers, carriers, loaders, and receivers in understanding the STF rule and the best practices they need to observe to maintain compliance with the rule. The guide has since been downloaded by over 600 industry stakeholders, IRTA reports.

Most recently, representatives of industry associations including the American Frozen Food Institute, the Grocery Manufacturers Association, and the American Trucking Associations participated in a roundtable hosted by IRTA in Washington, D.C. during GCCA’s Assembly of Committees in August 2016.

IRTA is working collaboratively with FDA to further refine the IRTA Refrigerated Transportation Best Practices Guide as a primary guidance document to inform the perishables industry of important best practices.
Building Best Practices

STF identifies Shippers as primary responsible stakeholder for determining appropriate standards

- An Industry Standard to meet compliance
- Provide comprehensive resource to review current operational business practices then complete a gap analysis
- A Carrier resource to have a conversation with Shippers

www.gcca.org/resources/transportation-guide
Building Best Practices

Analyze Current Situation
- Fleet age review
- Trailer Spec review
- Maintenance protocol
- Sanitize Trailer
- Training

Knowledge Engagement
- FSMA compliance requirements – STF rule, trade associations, articles, council, FDA engagement

Talking To Shipper/Carrier
Shippers by rule will be setting the conditions of which they will operate

Execute Written Plan
After you review, develop written plan, it is now time to execute – risk avoidance
FDA has changed from a reactionary regulatory body to respond to a problem in the food supply chain (re-call) to a law enforcement entity to prevent a problem in the food supply chain before it gets to the consumer (powers to fine or imprisonment).

Shippers will now have the responsibility of writing the rules around transport operations on how to keep food safe within the cold chain.

Transport companies will have to assess how these new regulatory demands will impact their assets to include:

spec & design · maintenance · services · lifecycle management · residual value
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