

# FSMA Compliance 2016 Carrier Concerns

# DOJ and FDA Say Criminal Prosecution of Food Companies is a Priority

“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.** In fact, in prepared remarks released recently, 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.**”

“If you sell adulterated food - or have some role in handling, distributing, or **maybe even transporting anywhere along the food chain** of that adulterated food, you would be liable to some extent - regardless of the cause or **origination of the contamination.**” Dr. David W. K. Acheson stated in an article.

**Is this reason enough for a carrier to go talk to their shipper?**

# How Do FSMA Rules **Directly** Relate To Carriers?

- **Sanitary Transportation of Human and Animal Food - FSMA Section 111**
  - Published: April 5, 2016
  - Effective: June 5, 2016
  - Compliance Date: April 6, 2017**

# Sanitary Transportation of Food – Carrier Concerns

- **Do carriers know what risks they are assuming when they sign a written agreement with their shipper?**
  - Responsibility
  - Temperature control
  - Temperature Records Exchange
  - Training
  - Record retention
  - Sanitary condition
  - Written procedures
  - Pre-cool requirements
  - Equipment spec per shipper

# STF Carrier Concern

## Responsibility

1.908(a)(1) An entity subject to this subpart (shipper, loader, carrier, or receiver) **may reassign, in a written agreement, its responsibilities under this subpart to another party subject to this subpart.** The written agreement is subject to the records requirements of § 1.912(d). (Pages: 33-34)

**Do you really know what you are signing for as a carrier?**

**Does your cargo insurance company know what you are signing?**

# STF Carrier Concern

## Written procedures - Shippers

1.908(b)(3)to(5)

A **shipper must** develop and implement written procedures, adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate **sanitary condition** for the transportation of the food.

**A shipper of food transported in bulk must** develop and implement written procedures, adequate to ensure that a **previous cargo** does not make the food unsafe.

**A shipper of food that requires temperature control for safety under the conditions of shipment must** develop and implement written procedures to ensure that the food is **transported under adequate temperature control**.

**Measures to implement these procedures may be accomplished by** the shipper or by the carrier or another party covered by this subpart **under a written agreement**. (Page: 192)

# STF Carrier Concern

## Written Procedures – Carriers

1.908(e)(6)(i) **A carrier must develop and implement written procedures subject to the records requirements of § 1.912(b) that:**

- (i) Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides** for use in the transportation of food to maintain the vehicles and the transportation equipment in appropriate **sanitary condition** as required by § 1.906(b).
- (ii) describe how it will comply with the temperature control requirements** in 1.908(e)(2) (Page: 149)

# STF Carrier Concern

## Sanitary condition

1.908(b)(3) A **shipper must** develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that vehicles and equipment used in its transportation operations **are in appropriate sanitary condition for the transportation of the food**, i.e., will prevent the food from becoming unsafe during the transportation operation. **Measures to implement these procedures may be accomplished by the shipper or by the carrier** or another party covered by this subpart **under a written agreement** subject to the records requirements of § 1.912(a). (Page: 194)



# STF Carrier Concern

## Temperature control

1.908(b)(3)to(5) **The shipper of food that requires temperature control for safety** under the conditions of shipment **must develop and implement written procedures**, subject to the records requirements of § 1.912(a), to ensure that the food is transported under adequate temperature control. **Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement**, subject to the records requirements of § 1.912(a) and must include measures equivalent to those specified for carriers under § 1.908(e)(1) to (3). (Page: 201)

# STF Carrier Concern

## Temperature Records Exchange

(Response 100) “We reconsidered this proposed provision and have determined **that persons subject to this rule should be able to use any effective means to monitor temperature control**, such as those suggested by the comments, and that it is not necessary to retain this proposed requirement.”

(Response 101) We have removed the requirement that vehicles and transportation equipment be equipped with a temperature indicating device from this final rule. **Therefore, there is no need to establish temperature measuring equipment calibration requirements in this final rule.** (Page: 143)

# STF Carrier Concern

## Temperature Records Exchange

**“We are looking for the carrier to, in the form of a record, provide FDA [with] records that demonstrate that they do conduct this information exchange with shippers,** that they do provide, as a part of their operation, information about the maintenance of temperature control to shippers.” (Page: 230)

# STF Carrier Concern

## Training

1.910 **Carriers must provide training** to personnel engaged in transportation operations **that provides an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems “and the responsibilities of the carrier” under this rule.** The training must be provided upon hiring and as needed thereafter. We also proposed to require that carriers must establish and **maintain records documenting the aforementioned training.** Such records must include the date of the training, the type of training, and the person(s) trained. (Page: 219)

**“The training that is mandated as a minimum by § 1.910(a) is intended to raise awareness rather than set out carrier-specific duties.”**

**Table 9--§ 1.910 What Training Requirements Apply to Carriers Engaged in Transportation Operations?**

# STF Carrier Concern

## Training – details

Response 160: Beyond the general requirements stated in § 1.910, **we are not prescribing details on aspects of the training** such as its frequency, length, and subject matter. Given the diversity of food transportation operations, **we do not intend to require that the entire industry use a single training approach.** Training may vary in particular aspects, e.g., length, provided that it meets the requirements of this rule. Thus, firms conducting differing types of transportation operations may **employ training that is tailored to their operations provided that it meets the requirements of this rule.** (Page: 221)

# STF Carrier Concern

## Pre-cool

1.908(b)(2) to require that **the shipper specify to the carrier**, and, when necessary, to **the loader**, an operating temperature required for the given transportation operation, including, if necessary, the **pre-cooling phase**. (Page: 179)

**If pre-cooling the food product is necessary to meet the requirements of this rule**, we would expect that **the shipper and the loader would ensure that this step is effectively applied** as part of their responsibilities under this rule. (Page: 189)

**“the loader must** verify that each mechanically refrigerated cold storage container is adequately prepared for the transportation of such food, including that it has been **properly pre-cooled**, if necessary, and meets other sanitary conditions for food transportation.” (Page: 274)

# STF Carrier Concern

## Equipment spec

1.906(a) Specifies **that vehicles and transportation equipment must be designed** and of such material and workmanship to be suitable and **adequately cleanable** for their intended use to prevent the food...from becoming unsafe. (Page: 128)

1.906(c) requires that vehicles and **transportation equipment used in transportation operations for food requiring temperature control for safety must be designed**, maintained, and equipped, as necessary, to provide **adequate temperature control** to prevent the food from becoming unsafe during transportation operations. (Page: 129)

# STF Carrier Concern

## Record retention

1.912(a) Split requirement into 2 parts: (Page: 225)

(1) **Requires shippers** to retain records that demonstrate that they provide specifications and operating temperatures **to carriers** for 12 months beyond termination of the agreement with the carriers.

(2) **Requires shippers** to retain **records of written agreements** and procedures required by 1.908(b)(3), (4), and (5) for a period of 12 months beyond when the agreements and procedures are in use.

1.912(b) **Carriers must retain certain written agreements and records of written procedures for 12 months** beyond when the agreements and procedures are in use. (Page: 225)

**Table 10**--§ 1.912 What Record Retention and Other Records Requirements Apply to Shippers, Receivers, Loaders, and Carriers Engaged in Transportation Operations?



# Additional STF Topics of Concern

## **PART 1--GENERAL ENFORCEMENT REGULATIONS - General Provisions Sec.**

Add subpart O, consisting of §§ 1.900 through 1.934, to part 1 to read as follows: (Page: 264)

- **Subpart O--Sanitary Transportation of Human and Animal Food**

1.900 Who is subject to this subpart? (Page: 266) and (Page 55, Table 5)

The requirements of this subpart apply in addition to any other requirements of this chapter that are applicable to the transportation of food.

1.904 What definitions apply to this subpart? (Page 267)

The definitions and interpretations of terms are applicable when used in this part. The following definitions also apply:

Examples:

**Shipper** means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

**Carrier** means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

# How Do FSMA Rules **Indirectly** Relate To Carriers?

- Hazard Analysis and Preventive Controls - Published September 17, 2015  
FSMA Section 103
- Intentional Adulteration / Food Defense - Published May 26, 2016  
FSMA Section 106
- In the case of dual jurisdiction establishments, FDA would inspect in accordance with its **existing MOU** with USDA. The STF rulemaking will complement USDA's & FSIS's efforts to promote the application of sanitary food transportation practices for USDA & FSIS-regulated meat, poultry, and egg products. (See STF Response 12)

FSIS: Food Safety and Inspection Service / STF: Sanitary Transportation of Food – Human and Animal / MOU: Memorandum of Understanding

**Don't be held hostage as a carrier for not knowing this could happen to you!**

# Hazard Analysis and Preventive Controls Carrier Concern

How have you defined these requirements for refrigerated transportation practices? (Written Procedures)

- **Page 13:** This portion of the rule requires registered food facilities to maintain a **food safety plan**, **perform a hazard analysis**, and **institute preventive controls** for the mitigation of those hazards, unless an exemption applies. Facilities must also **monitor their controls**, conduct verification activities to ensure the controls are effective, **take appropriate corrective actions**, and **maintain records documenting** these actions.
- **Due date: September 19, 2016**
- The bold print is the page number of the rule and the narrative that follows is copied from the rule.

# Hazard Analysis and Preventive Controls Carrier Concern

Do you have an existing detailed **HACCP Plan** for refrigerated food transportation practices? (Written Procedures)

- **Page 879:** The hazard evaluation **must consider the effect of the following** on the safety of the finished food for the intended consumer: (i) The formulation of the food; (ii) The condition, function, and design of the facility and equipment; (iii) Raw materials and other ingredients; (iv) **Transportation practices**; (v) Manufacturing/processing procedures; (vi) Packaging activities and labeling activities; (vii) Storage and **distribution**.
- The bold print is the page number of the rule and the narrative that follows is copied from the rule .

# Hazard Analysis and Preventive Controls Carrier Concern

What experience does your “Preventative Controls Qualified Individual” have with refrigerated transport operations?

- **Page 305:** It is the responsibility of the facility’s preventive controls qualified individual to **identify the hazards** requiring a **preventive control** associated with the facility and the food it stores, as well as **the appropriate preventive controls** and preventive control management components.
- The bold print is the page number of the rule and the narrative that follows is copied from the rule .

# Hazard Analysis and Preventive Controls Carrier Concern

How do you intend to do that?

What are your temperature tolerances (+/-)? Safety or Quality?

- **Page 437:** For the purpose of the hazard analysis, whether a particular facility would identify food transportation as a critical control point through its hazard analysis would depend on the circumstances, such as whether the food is a TCS food. **We expect a facility that identifies temperature control, including during transportation, as a preventive control (whether or not as a CCP), to communicate the need for appropriate temperature control to the person transporting the food.**
- The bold print is the page number of the rule and the narrative that follows is copied from the rule .

# Intentional Adulteration / Food Defense Carrier Concern

**While in transit is Food Defense a concern to you?**

## **STF Response 11: on page 27**

FDA will be addressing food defense concerns in its upcoming final rulemaking on **Intentional Adulteration**; however, to the extent **that certain food defense issues are not covered in the FSMA rulemakings**, and it becomes apparent as we implement the rules that **there are food defense concerns** that would benefit from additional regulation, we will consider initiating such rulemakings in the future.

Review the entire STF Response 11 for context to this topic. / STF: Sanitary Transportation of Food – Human and Animal

# Go Talk To Your Shippers

If I were a carrier I would make the first page my fleet name and information.

I would print all of these pages as discussion topics and then ask each of my shippers, specifically per topic; how are we going to deal with that because I do not want anything to do with page #2.