Section 111: Sanitary Transportation of Human and Animal Food (mandating execution of 21 U.S.C. 350e)

Overview

This section of the Food Safety Modernization Act (FSMA) mandates that the Food and Drug Administration (FDA) draft regulations regarding the sanitary transportation of food. This was a preexisting responsibility that had not been executed. The FDA was first mandated to draft these regulations by the Sanitary Food Transportation Act of 2005. To fulfill this mandate, the FDA has drafted proposed regulations. Michael R. Taylor, Deputy Commissioner for Foods, succinctly describes the regulations:

"Certain shippers, carriers, and receivers engaged in transporting food by motor or rail vehicles would be required to follow common sense sanitary practices, such as properly refrigerating food, adequately cleaning vehicles between loads, and properly protecting food during transportation."

Section 111 applies to both food for humans and food for animals. This primer will only address the impact on human food.

Important Definitions

There are three critical terms that must be defined before a discussion of the proposed regulations can begin. These terms identify the three groups that will be subject to the sanitary transportation regulations.

**Carrier:** "A person who owns, leases, or is otherwise ultimately responsible for the use of a motor vehicle or rail vehicle to transport food. The carrier is responsible for all functions assigned to a carrier . . . even if they are performed by other persons, such as a driver that is employed or contracted by a trucking firm. A carrier may also be a receiver or a shipper if the person also performs the functions of those respective persons . . . ."

**Receiver:** "[A]ny person who receives food after transportation, whether or not that person represents the final point of receipt for the food. A receiver may also be a carrier or a shipper if the person also performs those functions . . . . A receiver does not include an individual consumer or a person who receives or holds food on behalf of an individual consumer and who is not also a party to the transaction and who is not in the business of distributing food."
Shipper: “[A] person who initiates a shipment of food by motor vehicle or rail vehicle. The shipper is responsible for all functions assigned to a shipper . . . even if they are performed by other persons, such as a person who only holds food and physically transfers it onto a vehicle arranged for by the shipper. A shipper may also be a carrier or a receiver if the shipper also performs those functions . . . .”[^6]

Effective Date of Provision

Final regulations have not been adopted. However, as discussed in the primer for Section 103, the FDA entered into a consent decree after the Center for Food Safety brought a lawsuit to force the promulgation of overdue FSMA regulations.[^7] The consent decree established March 31, 2016 as the deadline for the final sanitary transport regulations.[^8] The proposed regulations set an effective date of 60 days after publication of the final rule.[^9] The FDA has proposed a range of compliance dates depending on the size of the business. The default compliance date is one year after the rule’s publication date. Small businesses are given additional time to comply and the FDA allows these businesses two years after the rule’s publication date to come into compliance.[^10] For the purpose of the proposed regulations, a small business is either a business (1) that employs less than 500 persons or (2) a motor vehicle carrier, i.e. non-rail carriers, which does not also function as a shipper and/or receiver and that has less than $25,500,000 in annual receipts.[^11]

Relevance to State and Local Authorities

An understanding of this section is critical for state and local authorities because it creates new requirements for regulated food transportation operations in their jurisdictions. In addition, the sanitary transportation requirements promulgated under this section may affect the duties of states that conduct contract inspections for the FDA. How these requirements will impact state inspections is not clear at this time.

Explanation of Statutory Provision and Potential Impacts

Who is required to comply with the proposed regulations?

Generally, the proposed regulations apply to shippers, receivers, and carriers engaged in food transportation operations, regardless of whether the food enters interstate commerce.[^12] However, the regulations provide several exceptions to this general rule, including:

1. **Air and Water Transport** – The proposed regulations only apply to food that is transported by motor vehicle or rail; air transport and water transport are not covered.[^13]
2. **Non-covered businesses** – The regulations specifically exclude shippers, receivers, and carriers engaged in transportation operations with less than $500,000 in annual sales.[^14] The regulations do not specify whether the annual sales must be based on food sales. For example, a carrier may have $800,000 in annual sales with only 50% of it coming from the transport of food. However, in the FDA’s preamble to the proposed regulations, the agency requests comments on whether they should limit the foods that comprise the $500,000 in total annual sales.[^15] This statement indicates that the annual sales numbers are based only on food transport.
3. **Shelf stable food completely enclosed in a container** – Shelf stable foods are defined, for the purpose of the proposed regulations, as “food that can be stored under ambient temperature and humidity conditions and, if the package integrity is maintained, will not spoil or become unsafe throughout its storage life.”[^16] The FDA highlights the following products as examples of shelf stable foods: “canned juice, canned vegetables, canned meat, bottled water and dry food items such as rice, pasta, flour, sugar, and spices.”[^17] The FDA has tentatively concluded that shelf stable foods that are completely enclosed in a container pose little risk of adulteration during transport because they do not require refrigeration and are not directly exposed to the transportation environment.[^18] As a result, they have excluded shelf stable foods that are completely enclosed in a container from the requirements of the proposed regulations by specifying that they are not covered in the term “transportation operations” which is the key term that triggers the requirements of this section.[^19]
4. **Live Animals** – The transportation of live animals is not covered by these regulations. The FDA excluded live animal transport by specifically removing it from the definition of “transportation operations” which triggers the

[^6]: [Shipper](#)
[^7]: [Effective Date of Provision](#)
[^8]: [Relevance to State and Local Authorities](#)
[^9]: [Explanation of Statutory Provision and Potential Impacts](#)
[^10]: [Who is required to comply with the proposed regulations?](#)
[^11]: [Air and Water Transport](#)
[^12]: [Non-covered businesses](#)
[^13]: [Shelf stable food completely enclosed in a container](#)
[^14]: [Live Animals](#)
requirements of the proposed regulations. The FDA indicated that United States Department of Agriculture’s (USDA) Food Safety and Inspection Services (FSIS) has a regulatory scheme in place to minimize the risk of adulteration by contaminants on the external surfaces of live food animals. These FSIS requirements are seen as sufficient protection.

(5) **Food gases** – Transportation of food gases, e.g., carbon dioxide used to carbonate beverages, is not covered in the proposed regulations. The FDA noted that food gases do not support microbial growth and are transported in pressurized containers that protect against chemical and physical contamination.

(6) **Raw Agricultural Commodities** – Farms that transport raw agricultural commodities are not required to follow the proposed transportation regulations. A raw agricultural commodity is “any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.” The regulations define a farm as a facility in one general physical location devoted to growing and harvesting of crops, the raising of animals, or both. The term farm also includes operations that pack or hold food, regardless of whether the food is grown, raised, or consumed on that farm or another under the same ownership.

(7) **Transshipped food and certain imported foods** – These regulations only apply to food that is distributed and consumed in the United States. As a result, they do not apply to foods that are transshipped through the United States, e.g., Mexican produce shipped through the United States to Canada. In addition, the proposed regulations do not cover food that is imported to the United States before it is exported to another country.

What are the specific food safety requirements of Section 111?

The FDA divided the proposed sanitary transportation requirements into four general categories.

(1) **Vehicles and transportation equipment**: The FDA has proposed a series of common sense requirements for vehicles and transportation equipment. Transportation equipment is defined in the regulations as equipment used in food transportation operations other than vehicles, e.g., bins, pallets, pumps, hoses, and loading systems. First, vehicles and equipment used in food transportation must be designed and built in a manner that makes them “adequately cleanable” to prevent food from becoming contaminated during transportation operations. Second, vehicles and equipment must be kept in sanitary condition to prevent the food they transport from becoming contaminated during operations. Third, if vehicles and transportation equipment are used to transport food that requires temperature control conditions to prevent the rapid growth of undesirable microorganisms, then they must be able to keep food under the appropriate temperature conditions. Fourth, freezer and refrigeration compartments on vehicles and transportation equipment must have a temperature measuring device to accurately monitor the compartment’s internal temperature. Fifth, vehicles and transportation equipment must be stored in a manner that prevents contamination and pest infestations that could make the food they transport unfit for consumption.

(2) **Transportation operations**: The proposed regulations divide these requirements into four categories: general requirements (duties assigned to all regulated parties), requirements applicable to shippers, requirements applicable to shippers and receivers, and requirements applicable to carriers.

   a. **General**: The responsibility for ensuring compliance with the conditions and controls required by this section must be assigned to “competent supervisory personnel.” The proposed regulations require that transportation operations are conducted in a manner that will prevent food from becoming contaminated, including the following measures:

      i. All regulated parties must prevent food from becoming contaminated by raw foods and non-food items in the same load;

      ii. They must also protect food transported in bulk vehicles or food not completely enclosed in a container from contamination and cross-contact during transport; and
iii. For food that can support the rapid growth of undesirable microorganism, regulated parties must ensure the food is transported in a manner that prevents the growth of the microorganism, e.g., provide appropriate temperature controlled conditions.

b. **Shippers:** There are five basic responsibilities assigned exclusively to shippers.

i. Shippers must provide their carriers with a written description of the vehicle and transport equipment requirements that will help prevent the shipped food from becoming “filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation.”

ii. The shipper must visually inspect a carrier’s vehicle and transportation equipment for cleanliness and verify that it is clean enough to transport food.

iii. Shippers must specify in writing to the carrier, with a few exceptions, the temperature conditions necessary for transporting any food that can support the rapid growth of undesirable organisms. The shipper must also specify the conditions for the pre-cooling phase.

iv. The shipper must verify that cold storage compartments have been pre-cooled to the appropriate temperature before loading any food that can support the rapid growth of undesirable microorganisms.

v. If the shipper has contracted with carrier to do so, they must (upon request) provide the receiver with proof that the appropriate temperature conditions were maintained during the transport of the food. This responsibility is normally placed on the carrier, but they can contract for the shipper to fulfill this obligation.

c. **Shippers and Receivers:** The proposed regulations have two basic transportation operation requirements that are shared by shippers and receivers. First, they must provide convenient hand washing facilities for employees who handle food that is not completely enclosed in a container. Second, they must ensure the appropriate temperature control conditions for loading and unloading of food that can support the rapid growth of undesirable microorganisms.

d. **Carriers:** The proposed regulations assign several obligations to carriers, including:

i. Carriers must provide vehicles and transportation equipment that meet all the sanitary requirements specified by the shipper;

ii. They must also provide verification to the shipper and, upon request, to the receiver that the appropriate temperature conditions were maintained during food transport;

iii. Carriers must pre-cool each cold storage compartment to the specifications provided by the shipper to prevent microorganism growth during transport;

iv. Carriers that use bulk vehicles for food transportation must provide the shipper with information regarding the three previous cargoes carried in the vehicle. The shipper and carrier can contract out of this requirement, if procedures are established to ensure the safety of the food; and

v. Bulk vehicle carriers must provide the shipper with information regarding the most recent cleaning of the vehicle. This provision can be waived, if the parties contract to have the carrier utilize certain cleaning procedures to ensure the safety of the food transported.

(3) **Training:** Carriers must provide their food transportation personnel with training on the safe and sanitary transport of food. This training must be provided at the time of hire and as needed thereafter. In addition, carriers must keep training records that including the date of the training and the personnel trained.

(4) **Records:** The proposed regulations create four categories of record keeping obligations. First, shippers must maintain records showing that they have provided their carriers with information regarding: (1) the vehicle and transport equipment sanitary requirements for transporting their food and (2) the temperature conditions necessary for transporting any food that can support the rapid growth of undesirable organisms. Second,
carriers must retain any shipping agreement in which the shipper agrees to (1) ensure that the proper temperature conditions were maintained during transport and (2) provide verification of temperature conditions to the receiver. **Third**, carriers must record their procedures for (1) cleaning and inspecting food transport vehicles, (2) complying with the food transport temperature control, and (3) bulk vehicle requirements. **Fourth**, carriers must retain food safety training records for at least 12 months after a person leaves a position for which the training was required.

(5) In regards to record storage, regulated parties may store most records at an off-site location six months after its creation. However, they must be able to retrieve the record within 24 hours for official inspection.

**Under what conditions will the FDA grant a waiver of the requirements of this section?**

The FDA can waive any of the requirements of this Section 111 as long as the agency determines that: (1) the waiver will not result in the transportation of food under conditions unsafe for human health and (2) the waiver is not contrary to the public interest. The FDA can grant a waiver in response to a regulated party’s petition or on its own initiative.

**How does a regulated party request a waiver?**

To file a waiver petition, regulated parties must follow the citizen petition procedures of 21 C.F.R. § 10.30 and a few additional requirements created by the proposed regulations. The regulated party must submit a petition to the Division of Dockets Management at the Department of Health and Human Services, either electronically or in hard copy. The petition must contain a specific description of the waiver requested, “including the persons, vehicles, food, or nonfood product(s) to which the waiver would apply” and the specific provision of the transport regulations to which the waiver would apply. The petition must also provide information that demonstrates that the waiver will not result in food transportation that is (1) unsafe for human health and (2) will not be “contrary to the public interest.” The FDA states that “[t]his could include information about the nature of the food, the manner in which it is transported, the controls in place to mitigate any food safety issues, and government and/or non-government oversight of the transportation of the food.”

The FDA may also request that the petitioner provide information regarding the economic impact of the requested waiver. Finally, the regulated party must certify that, to the best of their knowledge and belief, the petition contains all the information relevant to the waiver request, including information unfavorable to the petitioner.

**Who reviews the petition requesting a waiver?**

The petition can be reviewed by any of the following FDA officials: the Director or Deputy Director of the Center for Food Safety and Applied Nutrition (CFSAN) or the Director of the Office of Compliance, CFSAN.

**How does the FDA review petitions requesting a waiver?**

Again, the FDA will follow the administrative procedures provided in 21 C.F.R. § 10.30. These procedures provide the FDA with several options for reviewing the request including: conferences, meetings, public and regulatory hearings, and notices in the Federal Register requesting information and views on the waiver. If the FDA grants a waiver, the waiver and the reasons for granting it will be published in the Federal Register. The waiver becomes effective on the date it is published in the Federal Register.

The FDA may deny the waiver if the regulated party fails to provide adequate information in their petition or if the FDA determines that the waiver would result in transportation conditions that are unsafe for human health or against the public interest. If the waiver is denied, the FDA will inform the petitioner, in writing, of the reason for the denial.

The FDA has announced its intention to grant waivers to specific categories of regulated parties, if the rules are finalized in their proposed form. These categories include the following:
Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade “A” Milk Safety Program, only when engaged in transportation operations involving Grade A milk and milk products.

Food establishments holding valid permits, only when engaged in transportation operations as receivers, or as shippers and carriers in operations in which food is relinquished to consumers after transportation from the establishment. A food establishment is an operation that “[s]tores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption,” e.g., restaurants, markets, and catering operations. These operations are generally regulated by state and local authorities. These authorities have adopted food safety programs patterned on the model Food Code, published by the FDA. The FDA indicated that these programs adequately address the transport concerns related to food establishments exempted from the proposed regulations.

Can the FDA revoke or modify a waiver?

The FDA can revoke or modify a waiver if it determines that the waiver will result in food transport conditions that are unsafe for human health or that the waiver is contrary to the public interest. If the FDA takes this action, the agency will provide the affected party with written notification mailed to the address provided in their initial request for a waiver. The FDA will also publish notice of the modification or revocation in the Federal Register. The date of publication will be the effective date of the modification or revocation.

Is there Judicial Review?

The regulations do not specifically provide for judicial review for the denial, modification, or revocation of a waiver. However, since the petition requesting a waiver is made under 21 C.F.R. § 10.30, it is subject to judicial review in the federal district courts once certain steps have been taken.

What are the penalties for failing to comply with this section of FSMA?

Failure to comply with the provisions of this section is a violation of the Food Drug and Cosmetics Act and may result in an injunction, incarceration, and/or fines. Currently, a violation of this provision can result in up to a year in prison and/or a $1,000 fine. However, if the violation was committed with the intent to defraud or mislead, or was committed after the conviction for a separate violation of the Act, the penalty is increased to up to 3 years in prison and/or a $10,000 fine.

What are the potential economic impacts of Section 111 and the proposed regulations?

The FDA estimates that proposed regulations will cover 83,609 entities. The agency also estimates that the initial cost to industry will be $149.1 million in the first year, and $30.08 million annually thereafter. However, the FDA does not quantify the potential benefits of the regulations. The agency states that

We lack sufficient data to quantify the potential benefits of the proposed rule. The causal chain for inadequate food transportation to human and animal health and welfare can be specified but not quantified. Because no complete data exists to precisely quantify the likelihood of food becoming adulterated during transport, we are unable to estimate the effectiveness of the requirements of the proposed rule to reduce the potential adverse health effects in human or animals.

Concerns Expressed Regarding Proposed Regulations

The proposed transport regulations have not generated the same level of controversy as other FSMA provisions. At last review, the FDA has received only 107 comments regarding the proposed sanitary transport rules. A few of the public’s concerns are discussed below.
(1) **Non-covered businesses exemption:** Some commenters believe that exempting small transport companies, through the non-covered business exemption, creates a threat to public health. The proposed regulations would not apply to transportation companies that have less than $500,000 in annual sales. This concern appears to be supported by a survey discussed in the preamble to the proposed regulations. The Interstate Food Transportation Project, released in 2007, was conducted to determine “the current state of food safety and food defense in the context of in-transit food in interstate commerce.” The project revealed that most of the food transportation problems were found to involve smaller box trucks and that there were very few problems identified with larger (semi-tractor trailer) trucks. The relevant, and logical, assumption is that smaller exempt companies would be parties that utilize these smaller box trucks. In his comments, Anthony S. Gilliam, the Director of Food Protection Programs for the Indiana State Department of Health, reinforces this line of reasoning by stating that “with this exemption you have effectively [exempted] the most problematic group of transporters.” Mr. Gilliam supports this statement with a brief discussion of his experience as a public health official.

(2) **Live animal exemption:** The regulations exempt the transport of live animals from the proposed sanitary transport requirements. However, shellfish present an interesting situation, as highlighted by comments of the Shellfish Growers of Virginia (“SGV”). The SGV points out that their product, oysters and hard clams, are often consumed live. They also discuss how raw shellfish have been implicated in several foodborne illness outbreaks and require temperature control measures during transport to prevent the proliferation of naturally occurring bacteria. As a result, SGV requested that the FDA revise the live animal exemption so that shellfish are subject to the sanitary transport standards. It is important to note that shellfish are not regulated by the USDA’s FSIS, which focuses on meat, poultry, and egg products. In the preamble to the regulations, the FDA justifies the exemption of live animal transport, in part, on the belief that the FSIS provides adequate safety oversight of live animals.

**Additional Resources**

1. [Proposed Rule on Sanitary Transportation of Human and Animal Food](#)
2. [FSMA Facts: Proposed Rule on Sanitary Transportation of Human and Animal Food](#)

**SUPPORTERS**

The Network for Public Health Law is a national initiative of the Robert Wood Johnson Foundation with direction and technical assistance by the Public Health Law Center at William Mitchell College of Law.

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5 Id.
6 Id.
8 Id.
10 Id.
17 Id.
20 Id.
22 Id.
27 Id.
28 See Sanitary Transportation of Human and Animal Food, 79 Fed. Reg. 7006, 7010 (Feb. 5, 2014) (stating that the FDA has tentatively “concluded that section 416 of the FD&C Act is not intended to apply to the transportation of food that is neither consumed nor distributed in the United States”).
30 Id.
33 Id.
34 Id.
35 Id.
37 Id.
38 Id.
39 Id.
40 Id.
42 Id.
43 Id.
44 Id.
45 Id.
46 Id.
47 Id.
50 Id.
52 Id.
53 Id.
54 Id.
55 Id.
56 Id.
57 Id.
59 Id.
60 Id.
62 Id.
63 Id.
64 Id.
65 Id.
66 Id.
70 21 C.F.R. § 10.30(b)(1,2).
72 Id.

21 C.F.R. § 10.30(b)(3).

Id.

See Sanitary Transportation of Human and Animal Food, 79 Fed. Reg. 7006, 7037 (Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1.922) (the regulations also allow the Director or Deputy Directors of the Center for Veterinary Medicine (CVM) and the Director, Office of Surveillance and Compliance, CVM, to review petitions, however, this is presumably for requests relating to the transportation of animal food. This primer focuses only on the requirements related to transport of human food).

21 C.F.R. § 10.30(h).


Id.


Id.

Id.


Id.

See 21 U.S.C. § 10.45 (describing the requirements for a judicial review of an administrative action).


Id.


Id.


Id.


Id.

Id.