Journal of Food Law & Policy

Volume 10 | Number 2 Article 7

Paradise Found? Food Transportation Regulation: A Detour Through Regulatory Purgatory

William Nash
McGuire Woods

PARADISE FOUND? FOOD TRANSPORTATION REGULATION: A DETOUR THROUGH REGULATORY PURGATORY

*William Nash**

I. INTRODUCTION

On January 31, 2014, the Food and Drug Administration ("FDA") issued a Notice of Proposed Rulemaking ("NPRM") that would set requirements for shippers, carriers and receivers of food transported in intrastate and interstate commerce.[1] The NPRM marks a potentially

* Mr. Nash graduated from Harvard Law School in 2014 and currently is an Associate Attorney at McGuireWoods where his practice focuses on healthcare law including a range of transactional, regulatory and corporate matters.

important step in a long history of the (non-)regulation of food transportation.[2] In Parts I and II, this paper will provide some context of the history of food transportation, as well as the major incidents that placed the food transportation industry on the regulatory map. In Parts III and IV, the paper will consider the history of food transportation regulation from the Food, Drug and Cosmetics Act ("FDCA") to the most recent NPRM.[3] Finally, in Part V, the paper will consider the potential efficacy of the NPRM from the standpoint of its ability to correct market failures.[4]

II. A BRIEF HISTORY OF FOOD TRANSPORTATION

Food transportation is nothing new. For thousands of years, merchants have sought to satisfy consumers' desire for new foods, with demand being fueled by consumers' willingness to pay for better nutrition and new tastes, as well as experiencing different cultures.[5] Archeological evidence suggests that fish paste was shipped between Spain and Britannia over two thousand years ago.[6] Transporting food presents a number of challenges, which may not be as significant when shipping other goods, mainly because food has the tendency to spoil and is frequently unstable due to its irregular shape.[7] From the beginning, people have devised innovative methods to allow for the shipment of a greater variety of foods in greater quantities over greater distances.[8] For example, around the same time that the fish paste was being transported, Romans were importing Spanish olive oil in massive quantities.[9] One estimate was that the Romans imported 1.6 billion gallons of oil during this period.[10] The quantity and efficiency of the operation was due to a container designed for easy carrying which also fit the contour of a ship.[11]

---

1. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1).
2. *Id.*
3. Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 (2012); Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. at 7006.
4. *See* Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. at 7006.
5. *See generally* Lynne Olver, *Food Timeline FAQs: Mesopotamia through Shakespeare*, THE FOOD TIMELINE, http://www.foodtimeline.org/foodfaq3.html#venice (Jan. 3, 2015).
6. SARAH MURRAY, MOVEABLE FEASTS x (2007).
7. *Id.*
8. *Id.* at ix-x.
9. *Id.* at 6-8.
10. *Id.* at 8.
11. Murray, *supra* note 6, at 10.

The modern revolution in food transportation was made possible by the popularization of refrigeration.[12] To achieve ubiquity, the icebox first fought against a number of countervailing cultural forces.[13] Individuals were accustomed to purchasing food for immediate or near immediate consumption.[14] Further, the use of refrigeration was initially viewed with skepticism.[15] Some believed that merchants used refrigeration to control the food supply and artificially inflate prices.[16] However, in the United States, the ice men had cometh by the early twentieth century.[17] Household refrigeration increased consumer demand for imported fresh food.[18] And as the transportation industry developed, suppliers sought innovative ways to satisfy this demand, such as through refrigerated steamships[19] and faster modes of transport.[20] However, with increased transportation came increased concerns about food safety.[21] Early efforts focused mainly on stamping out methods used to make spoiled food appear palatable.[22] However, as our understanding of food borne illnesses developed, state and federal governments began identifying new areas of concern, such as microorganisms, cross-contamination[23] and bioterrorism.[24]

12. SUSANNE FREIDBERG, FRESH A PERISHABLE HISTORY 19 (2009).
13. *Id.* at 29.
14. *Id.*
15. *Id.* at 19.
16. *Id.* at 29.
17. Freidberg, *supra* note 12, at 19.
18. *Id.* at 47.
19. *See generally* Murray, *supra* note 6, at 109.
20. *Id.*
21. *See* SANDRA HOFFMAN, FOOD SAFETY POLICY & ECONOMICS: A REVIEW OF THE LITERATURE 1 (2010), *available at* http://www.rff.org/documents/RFF-DP-10-36.pdf.
22. *Id.*
23. The FDA has defined cross-contamination or "cross-contact" to be "the unintentional incorporation of a food allergen into a food." Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3643, 3693 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 117).
24. *See, e.g.*, Gerald Wojtala, *Interstate Food Transportation Assessment Project*, MICH. DEP'T OF AGRIC. & RURAL DEV. (June 16-20, 2007), https://www.michigan.gov/documents/mda/truckproj_224450_7.pdf.

III. A SERIES OF INCIDENTS PLACES THE FOOD TRANSPORTATION INDUSTRY ON THE FEDERAL REGULATORY RADAR

Modern food regulation has been a largely reactive enterprise,[25] and public health crises move the regulatory agenda.[26] In food transportation, the trend has been no different.[27] Although there is significant concern of adulteration during transport, it has generally been difficult to isolate incidents that occur while the food is being transported from those that originate during production or preparation.[28] Perhaps as a result, the number of public health issues that can be directly linked to food transportation is relatively low.[29] Further, nearly all the documented incidents involve cross-contamination.[30] This is not surprising. In such cases, the adulteration can generally be traced to a specific substance that either left residue in a vehicle that was later used to transport food or that accompanied the food on its journey.[31]

One of the first incidents that placed food transportation on the national radar involved pet food.[32] In 1974, approximately 800 dogs died after eating Dad's Dog Food.[33] The FDA conducted an investigation and was able to determine that one of the ingredients used in the food, corn gluten, was transported in a railcar that previously housed lead monoxide.[34] As a result, the manufacturer issued a Class I recall and the FDA prosecuted the company responsible.[35] In a memo approving the prosecution, the FDA concluded that the company, Corn Products International ("CPC"), did not even employ "minimal controls" to prevent contamination.[36] Specifically, CPC only did a "cursory" inspection of the rail hopper at night using a flashlight.[37] Further,

---

25. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22714 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

26. *See id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. *See* Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22714 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1)

31. *See id.*

32. *Id.*

33. Memorandum from the FDA Bureau of Veterinary Medicine to General Counsel (June 9, 1975) (on file with author).

34. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. at 22714.

35. *Id.*

36. Memorandum from the FDA Bureau of Veterinary Medicine, *supra* note 33.

37. *Id.*

the FDA pointed out that the firm failed to follow its own inspection procedures as provided to the FDA at the Notice of Hearing.[38]

In 1989, a somewhat similar situation arose when animal feed was contaminated by a hull previously used to transport barium carbonate, a highly toxic chemical used in rat poison.[39] The incident led to the death of a number of dairy cows.[40] And the FDA found the manufacturer, Purina Mills, had failed to property inspect the railcar prior to mixing the feed.[41] The FDA worked with the manufacturer to voluntarily recall the adulterated feed.[42] Perhaps because neither incident sparked significant public outcry, the FDA did not immediately pursue a regulatory response. However, at the close of its memo detailing the cow feed incident, the FDA stated that "[w]ith the current interest in the suitability of the transportation vehicles for food transport, this case merits further review."[43]

Not long after the feed incident, the food transportation industry faced its first crisis of confidence.[44] The popular press ran a number of reports that food trucks were being used to haul garbage on return trips.[45] The practice allegedly developed because New York was a net importer of food from the Midwest and a net exporter of garbage.[46] In a practice known as "backhauling," the press detailed incidents where transporters used food trucks to transport garbage from New York.[47] Although no specific public health incident was tied to the apparent practice of backhauling, the press reports hit Americans in their stomachs.[48] The Government Accounting Office ("GAO") was commissioned to conduct an investigation of the

---

38. *Id.*

39. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22714 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

40. *Id.*

41. Memorandum from the Dep't. of Health & Human Servs. Case Guidance Branch to Tura L. King, Supervising Consumer Safety Officer of the New Orleans District Office (Nov. 5, 1989) (on file with author).

42. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. at 22714.

43. Memorandum from the Dep't. of Health & Human Servs. Case Guidance Branch, *supra* note 41.

44. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22714 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

45. Matthew Purdy, *Trash in Food Trucks Appalls Lawmakers*, INQUIRER WASHINGTON BUREAU (Aug. 3, 1989), http://articles.philly.com/1989-08-03/news/26147296_1_food-trucks-haul-garbage-food-science-professor.

46. *Id.*

47. *Id.*

48. U.S. GOV'T ACCOUNTABILITY OFFICE, RCED-90-161, TRUCK TRANSPORT: LITTLE IS KNOWN ABOUT HAULING GARBAGE & FOOD IN THE SAME VEHICLES, 2 (1990).

practice, but only found "anecdotal" evidence.[49] The GAO was unable to reach firm conclusions, in part because of a lack of recordkeeping requirements in food transportation.[50] But it highlighted a number of gaps in both knowledge and the regulatory regime;[51] one finding was that little research had been done about the public health risks associated with food transportation.[52] Additionally, the GAO pointed out that the FDA did not have regulations requiring specific truck cleaning procedures.[53] Finally, the report provided that the FDA was not conducting inspections on trucks because of the lack of health incidents tied to food transportation as well as the costs associated with setting up an inspection regime.[54] Although the GAO's conclusions were far from clear, sufficient public concern was engendered to spur Congress to pass the Sanitary Food Transportation Act of 1990 ("1990 SFTA").[55]

As much as food trucks transporting garbage made good headlines, the watershed moment in food transportation regulation occurred in 1994.[56] The Minnesota Department of Health traced an increase in salmonella enteritidis infections to Schwan's ice cream.[57] After investigating the plant and tanker trailers, it was determined that ice cream premix was contaminated by residue left in three tanker trailers from non-pasteurized liquid eggs.[58] The premix was then used to produce a significant amount of ice cream.[59] The Minnesota Department of Health linked the consumption of the contaminated ice cream to 150 cases of salmonella in Minnesota.[60] An investigation published in the New England Journal of Medicine, extrapolated from the confirmed cases to estimate that 29,100 Minnesotans and 224,000 people nationwide contracted salmonella from the contaminated ice cream.[61] The outbreak led the FDA and the Food Safety and Inspections Service ("FSIS") to issue a joint advance notice of proposed rulemaking ("ANPRM") in 1996 requesting comments on approaches to transportation

---

49. *Id.*
50. *Id.* at 3.
51. *Id.*
52. *Id.*
53. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 48, at 3.
54. *Id.*
55. *See id.*; Sanitary Food Transportation Act of 1990, Pub. L. No. 101-500, § 1, 104 Stat. 1213 (1990).
56. Thomas W. Hennessy et al., *A National Outbreak of Salmonella Enteritidis Infections From Ice Cream*, 334 NEW ENG. J. MED. 1281 (1996).
57. *Id.* at 1283-84.
58. *Id.*
59. *Id.*
60. *Id.* at 1282.
61. Hennessy et al., *supra* note 56, at 1283.

and storage of "potentially hazardous foods."[62] The ANPRM highlighted a number of regulations issued by the FDA, FSIS and the Department of Transportation ("DOT") both before and after the GAO report.[63] However, the ANPRM indicated that the agencies had not devoted significant resources to the problem and empirical data was still lacking.[64] Although the FDA collected industry data and responses, no specific action was taken on the ANPRM.[65]

In rulemaking actions taken after 1994, the FDA cites the salmonella outbreak as an example of the potential public health impact of procedural failures in food transportation.[66] Arguably labelled as having committed the original sin, the dairy industry has reacted defensively to subsequent FDA actions.[67] For example, the dairy industry submitted comments in response to the FDA's 2010 ANPRM, over fifteen years after the outbreak.[68] In its comments, the International Dairy Foods Association ("IDFA") sought to "clarify" FDA's characterization of the outbreak.[69] The IDFA said another outbreak was "highly unlikely" given that the industry had worked with the FDA to implement procedures to pasteurize its products at the plant of final packaging and to eliminate possible sources of cross-contamination.[70] However, the 1994 incident remains the paradigmatic example of improper food transportation.[71]

Given that the most significant food transportation incidents involved cross-contamination, FDA actions have continued to emphasize the importance of industry inspection and cleaning procedures.[72] For example, in a 2010 warning letter, the FDA investigated contaminants in shipments of cottonseed, which is used in animal feed.[73] The investigator found shredded tire intermingled with the cottonseed.[74] The transport company was using

---

62. Transportation and Storage Requirements for Potentially Hazardous Foods, 61 Fed. Reg. 59372 (proposed Nov. 22, 1996) (to be codified at 21 C.F.R. pt. 110).

63. *Id.*

64. *Id.* at 59376.

65. *See id.*

66. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22715 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

67. Letter from Clay Detlefsen, representing the International Dairy Foods Association, to the FDA, regarding Docket No. FDA-2010-N-0013 (Aug. 30, 2010).

68. *See id.*

69. *Id.*

70. *Id.*

71. Hennessy et al., *supra* note 56, at 1283-84.

72. Letter from John R. Gridley, Dist. Dir., Dep't of Health & Human Serv., to C. Michael Chewning (May 12, 2010), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm219966.htm.

73. *Id.*

74. *Id.*

the same trailer to ship both seed and tire remains.[75] Although the company claimed that the driver was responsible for ensuring the trailer was cleaned between shipments, the FDA found no procedures in place for ensuring this was done.[76]

Since 1994, there have been instances where food transportation was implicated, but was not tied to a specific outbreak.[77] For example, in July 1999, approximately 300 people in the United States and Canada were confirmed to have contracted salmonella muenchen from contaminated orange juice.[78] The outbreak was not linked to a specific issue in transportation.[79] However, the FDA expressed concern that containers housing the affected juice could contaminate future shipments.[80] Similarly, in 2009, the FDA reiterated this concern after an outbreak of salmonella typhimurium was caused by contaminated peanuts.[81] The FDA's stance after these incidents made it clear that the agency believes the regulation of food transportation is important not only to prevent outbreaks, but also to limit its scope.[82]

Additionally, the FDA was alerted to potential issues as a result of incidents outside of food transportation.[83] In 2010, Johnson & Johnson ("J&J") issued a large recall of Tylenol after reports of consumers feeling sick from "odd odor."[84] J&J blamed chemically-treated wood pallets for the incident.[85] Concerns were also raised about the potential contamination of food from wood pallets.[86] Small scale local tests of wood pallets revealed that ten percent were contaminated with E. Coli and three percent with Listeria.[87] In its 2010 ANPRM, the FDA noted a study finding that pallet

---

75. *Id.*

76. *Id.*

77. *Outbreak of Salmonella Serotype Muenchen Infections Associated with Unpasteurized Orange Juice*, CDC (July 16, 1999), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4827a2.htm.

78. *Id.*

79. *Id.*

80. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22715 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

81. *Id.*

82. *Id.*

83. *Tylenol Pain Caplets Recalled for Odd Odor,* NBC NEWS (Dec. 29, 2009), http://www.nbcnews.com/id/34620367/ns/health-arthritis/t/tylenol-pain-caplets-recalled-odd-odor/.

84. *Id.*

85. *Id.*

86. Joel Grover & Matt Goldberg, *Can Shipping Pallets Contaminate Your Food?*, NBCLA (June 16, 2010), http://www.nbclosangelees.com/news/local/Food-Safety-Concern-96519224.html.

87. *Id.*

quality was a food safety concern.[88] In its comment to the 2010 ANPRM, the National Wooden Pallet and Container Association largely placed blame on improper handling.[89] Nonetheless, because of its ubiquity and tendency to degrade, the FDA tagged wood pallets as a potential area of food transportation regulation.[90]

Finally, the FDA also looked to state enforcement to evaluate the potential scope of food transportation contamination.[91] Based on anecdotal evidence and available state inspection data, it is not uncommon for the state police to pull over trucks and discover violations. For example, an Indiana police officer recently pulled over a truck leaking "brown liquid" to discover raw chicken stacked on open containers of vegetables.[92] In 2006, the Michigan Department of Agriculture & Rural Development ("MDARD") made a concerted effort to "determine the current state of food safety and defense of in-transit food in interstate commerce."[93] The study included data from 615 inspections of food trucks traveling between Michigan, Ohio, Illinois and Indiana.[94] The study found 22 violations resulting from improper or no refrigeration, cross-contamination and insanitary conditions in trucks.[95] Further, the study cited low levels of food safety awareness among drivers.[96] The MDARD concluded that nearly all violations were small box trucks and ethnic food trucks.[97] Recommendations included encouraging better law enforcement surveillance and coordination, as well as educating food truck drivers on food safety issues.[98] The MDARD's approach was, therefore, to increase industry compliance through some combination of industry best practice and state enforcement efforts.[99]

---

88. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22720 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

89. Bruce N. Scholnick, *Industry Wake Up Call,* NATIONAL WOODEN PALLET AND CONTAINER ASSOCIATION (Sept. 2010), *available at* www.palletcentral.com.

90. *See id.*

91. *200 Pounds of contaminated food headed to central Indiana restaurants in semi destroyed*, THEINDYCHANNEL.COM (Mar. 18, 2013), http://www.theindychannel.com/news/local-news/200-pounds-of-contaminated-food-headed-to-central-indiana-restaurants-in-semi-destroyed.

92. *Id.*

93. Wojtala, *supra* note 24.

94. *Id.*

95. *Id.*

96. *Id.*

97. *Id.*

98. Wojtala, *supra* note 24.

99. *Id.*

The FDA has cited the MDARD study, as evidence of the extent of food transportation violations.[100] However, it is difficult to draw firm conclusions from a study limited to 615 inspections conducted in a single year in four states.[101] Although the study called for greater interagency and interstate coordination,[102] there is no indication that either state or federal agencies have taken up the call for a more systematic effort to document violations. Perhaps this is at least partially explained by its results; the majority of the offending shipments contained food bound for a handful of restaurants.[103] Presumably, such shipments are less likely to cross state lines. The FDA may have determined that rather than devoting significant federal resources, local authorities should be left to deal with what appears to be largely a local issue.

IV. THE HISTORY OF FDA FOOD TRANSPORTATION REGULATION

As previously alluded to, the FDA shares responsibility for the regulation of food transportation with the United States Department of Agriculture ("USDA"), the DOT and state and local authorities.[104] Congressional actions have generally provided for some coordination between relevant agencies.[105] This paper will focus on the role of the FDA and its regulations promulgated under the relevant statutes. Particular attention will be devoted toward assessing the FDA's most recent notice of proposed rulemaking ("NPRM"), which was published in the Federal Register on February 5, 2014, as required under the FDA Food Safety Modernization Act ("FSMA").[106]

A. *Pre-1990 Food Transportation Regulation*

Prior to 1990, the FDA's sole authority for the regulation of food transportation was the Food, Drug and Cosmetics Act of 1938 (the "Act" or "FDCA").[107] The FDA first promulgated food transportation regulations

100. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22715 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).
101. Wojtala, *supra* note 24.
102. *Id.*
103. *Id.*
104. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22715 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).
105. *See id.*
106. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1); Food Safety & Modernization Act, Pub. L. No. 111-353, § 418, 124 Stat. 3885, 3894 (2011).
107. Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 (2012).

under the Act's provision on adulterated drugs and devices.[108] Specifically, the FDA sought to regulate the contamination of animal feed under the Act's section on adequate controls on manufacture, which provides that drugs must conform to "current good manufacturing practice" ("CGMP").[109] In 1976, the FDA promulgated a series of CGMPs, which included a section on medicated animal feeds.[110] The specific section may have been partially motivated by the pet food contamination incident two years prior.[111] A relatively short section of the regulation was specific to feed transportation,[112] and it regulated equipment cleanout procedures and provided that any equipment housing medicated feed shall be cleaned using physical means (such as washing), flushing or "equally effective measures."[113] The section's stated purpose was to "avoid unsafe contamination of feeds with drugs."[114] Other than this relatively narrow provision, the FDA did not have regulations specific to food transportation and, therefore, had to rely on the Act's sections covering adulterated food.[115]

B. *The 1990 Sanitary Food Transportation Act*

Although the GAO report on food trucks hauling garbage was largely devoid of empirical evidence, it did highlight potential regulatory gaps.[116] Specifically, the GAO pointed out that the FDA did not have standard procedures to regulate the separation of food from potential contaminants or specific recordkeeping requirements for vehicles hauling food.[117] Not surprisingly, the 1990 SFTA attempted to remedy these perceived deficiencies.[118]

The 1990 SFTA provided responsibility to the DOT to issue regulations covering motor and rail vehicles which transport food and "nonfood products" (including refuse) that might render the food unsafe to humans or

---

108. 21 U.S.C. § 351 (2012).
109. 21 U.S.C. § 351(a)(2)(B) (2012).
110. 21 C.F.R. § 225.1 (2014).
111. Memorandum from the FDA Bureau of Veterinary Medicine to General Counsel, *supra* note 33.
112. 21 C.F.R. § 225.65 (2014).
113. *Id.*
114. *Id.*
115. *See* 21 U.S.C. § 342 (2012).
116. U.S. GENERAL ACCOUNTING OFFICE, RCED-90-161, TRUCK TRANSPORT: LITTLE IS KNOWN ABOUT HAULING GARBAGE & FOOD IN THE SAME VEHICLE 1, 3 (June 1990).
117. *Id.*
118. Sanitary Food Transportation Act of 1990, Pub. L. No. 101-500, § 2, 104 Stat. 1213 (1990).

animals.[119] Under the 1990 SFTA, the DOT was required to consult with the Department of Health and Human Services ("HHS", the FDA's parent agency) and the Environmental Protection Agency ("EPA").[120] The 1990 SFTA mandated that the DOT provide a two-track system of regulatory prohibitions governing the transportation of "nonfood" products with foods.[121] For tank vehicles, which includes "tank truck(s), rail tank car(s) or cargo tank(s)," the FDA was required to publish and maintain a list of "acceptable nonfood products" that would not be subject to the prohibition.[122] For motor and rail vehicles, the DOT was required to publish a list of unacceptable nonfood products.[123] The statute also provided that trucks hauling "extremely dangerous products," such as asbestos and refuse, could never be used to transport food "despite any decontamination."[124] The DOT was also expected to promulgate a list of products meriting the "extremely dangerous" designation.[125] Inspection authority was also vested in the DOT, which included assisting states in carrying out compatible laws.[126] The DOT had the authority to seek assistance from other agencies and the states in carrying out inspections as well as training inspectors.[127] Further, the 1990 SFTA attempted to address the paucity of available information by requiring the DOT to promulgate recordkeeping provisions.[128]

What followed after the 1990 SFTA cannot be described as model for administrative efficiency. The delays and ultimate lack of action can be described as characteristics of food transportation regulation as a whole. The 1990 SFTA required the DOT to promulgate the relevant regulations by July 31, 1991.[129] The DOT issued an ANPRM on February 20, 1991.[130]

---

119. Sanitary Food Transportation Act § 4, 104 Stat. at 1214.
120. *Id.*
121. Sanitary Food Transportation Act §§ 5-6, 104 Stat. at 1215-16.
122. Sanitary Food Transportation Act § 5, 104 Stat. at 1215.
123. Sanitary Food Transportation Act of 1990, Pub. L. No. 101-500, § 6, 104 Stat. 1213, 1216 (1990).
124. Sanitary Food Transportation Act § 7, 104 Stat. at 1216.
125. *Id.*
126. Sanitary Food Transportation Act § 9, 104 Stat. at 1217.
127. *Id.*
128. Sanitary Food Transportation Act § 4, 104 Stat. at 1214.
129. Safeguarding Food From Contamination During Transportation, 69 Fed. Reg. 76423-24 (proposed Dec. 21, 2004) (to be codified at 49 C.F.R. pt. 121); DEPT. OF TRANSPORTATION, OFFICE OF INSPECTOR GENERAL AUDIT REPORT, REVIEW OF DEPARTMENTAL ACTIONS CONCERNING THE SANITARY FOOD TRANSPORTATION ACT OF 1990, TR-1998-100 (Mar. 27, 2008).
130. *Safeguarding Food From Contamination During Transportation,* FEDERAL REGISTER (2004), http://www.federalregister.gov/regulations/2137-ac00/safeguarding-food-from-contamination-during-transportation.

Approximately a month later, the agency extended the comment period until April 29, 1991.[131] The 1990 SFTA deadline passed and nearly two years of radio silence followed.[132] Finally, on May 21, 1993, the DOT issued an NPRM.[133] In the NPRM, the DOT refused to provide a list of acceptable nonfood products to be transported with food in tank vehicles because they found that there were no qualifying products.[134] The DOT did provide a list of nonfoods deemed unacceptable for transportation with food products in motor or rail vehicles.[135] Unacceptable substances included those meeting the DOT's definitions of poisonous materials, infectious substances, hazardous waste or solid waste.[136] The DOT did not define any additional "extremely dangerous" products requiring dedicated trucks.[137] Finally, the DOT found that elaborate recordkeeping procedures were not justified and proposed to limit shipping disclosures to cargo tanks.[138]

After accepting comments, the DOT again went into regulatory silence.[139] In 1998, the Office of Inspector General wrote an audit report assessing whether the DOT was fulfilling its requirements under the 1990 SFTA.[140] The report found that the DOT did not fulfill its deadlines, failed to develop the required lists of acceptable and unacceptable nonfood products, and had not consulted with the other agencies on how to implement the act.[141] The Inspector General concluded the DOT lacked the expertise required to implement the 1990 SFTA and that inspections required under the act may have been incompatible with the DOT's existing safety inspections.[142] Specifically, the report found that the DOT: i) frequently inspected vehicles prior to the attachment of any food containers or tanks; ii) did not conduct inspections at "critical control points" as would be required to catch contaminants during final shipment to the distributor; and iii) lacked

131. *Id.*
132. *See id.*
133. Safeguarding Food from Contamination During Transportation, 58 Fed. Reg. 29698 (proposed May 21, 1993) (to be codified at 49 C.F.R. pts. 106, 107, 108, 110, 212, 171, 178 and 180).
134. *Id.*
135. *Id.*
136. *Id.*
137. *Id.* at 29701.
138. Safeguarding Food From Contamination During Transportation, 58 Fed. Reg. 29698, 29702 (proposed May 21, 1993) (to be codified at 49 C.F.R. pts. 106, 107, 108, 110, 212, 171, 178 and 180).
139. DEPT. OF TRANSPORTATION, OFFICE OF INSPECTOR GENERAL AUDIT REPORT, REVIEW OF DEPARTMENTAL ACTIONS CONCERNING THE SANITARY FOOD TRANSPORTATION ACT OF 1990, TR-1998-100 (Mar. 27, 2008).
140. *Id.* at 1.
141. *Id.* at 1-2.
142. *Id.* at 6.

the training and equipment to conduct inspections.[143] The report concluded that the regulatory authority should be moved to the FDA and the USDA given the agencies' expertise and tradition of food safety oversight.[144] Six more years of regulatory silence followed.[145] On December 21, 2004, the DOT issued a supplemental notice of proposed rulemaking ("SNPRM").[146] In the SNPRM, the DOT reiterated the stance of the Inspector General, saying that regulatory authority should be vested in the FDA and USDA.[147] Further, the DOT concluded that FDA and USDA regulations and guidelines issued after the 1990 SFTA "adequately address the overarching SFTA goal of protecting food and food products from contamination during transportation."[148] The DOT, therefore, requested comment on incorporating USDA and FDA regulations and developing procedures to ensure coordination between the agencies.[149] Again, no final rule was published.[150] Finally, and perhaps mercifully, a year later the DOT withdrew its 1993 NPRM and SNPRM citing the Sanitary Food Transportation Act of 2005, which transferred authority from the DOT to the HHS.[151]

C. *FDA Actions Between 1990 and 2005*

Although the 1990 SFTA vested primary regulatory authority with the DOT, the FDA continued to promulgate regulations and put out guidance impacting food transportation.[152] After the 1994 salmonella outbreak, the FDA and FSIS issued a 1996 ANPRM that sought comment on across the board regulation of "potentially hazardous foods."[153] However, ultimately the FDA did not take action on the 1996 ANPRM and opted for a more industry-specific approach involving binding regulations and nonbinding

143. *Id.* at 6-7.

144. DEPT. OF TRANSPORTATION, OFFICE OF THE INSPECTOR GENERAL AUDIT REPORT, *supra* note 129, at 6-7.

145. The previously discussed audit report was issued in 1998; no known action was taken again until 2004 with the DOT's issuance of a supplemental notice of proposed rulemaking. Safeguarding Food from Contamination During Transportation, 69 Fed. Reg. 76423 (proposed Dec. 21, 2004) (to be codified at 49 C.F.R. pt. 121).

146. Safeguarding Food from Contamination During Transportation, 69 Fed. Reg. 76423, 76424 (proposed Dec. 21, 2004) (to be codified at 49 C.F.R. pt. 121).

147. *Id.* at 76425.

148. *Id.*

149. *Id.* at 76424.

150. To date, there is no record of such a rule being published.

151. Safeguarding Food from Contamination During Transportation, 70 Fed. Reg. 76228 (proposed Dec. 23, 2005) (to be codified at 49 C.F.R. Ch. I, Subch. B).

152. Transportation & Storage Requirements for Potentially Hazardous Foods, 61 Fed. Reg. 59372, 59374 (proposed Nov. 22, 1996).

153. *Id.* at 59372.

guidance.[154] An exhaustive examination of these regulations and guidance is beyond the scope of this paper. However, the trend during this period was for the FDA to identify particular risk industries and prescribe or recommend various procedures to minimize risk.[155] For example, the 2001 Hazard Analysis & Critical Control Points ("HACCP") regulation focused on juice as a carrier of various bacteria-related infections.[156] The regulation prescribed a 5-log reduction process, which is a set of performance standard requirements.[157] The 5-log process must achieve a 100,000 fold decrease in "pertinent pathogens."[158] The process must be applied after any transportation of juice or juice products to the plant of final packaging.[159] The FDA stated that the regulation was designed to allow processors flexibility to determine how to meet these requirements.[160]

Outside of such targeted regulation and guidance, it seems that food transportation practice developed with little or no regulatory oversight and food industries began putting out their own best practice guides.[161] Industries were likely motivated by a desire for standardization as well as to stay off the FDA's regulatory agenda. For example, the North American Produce Transportation Working Group released a best practice guide which included recommended produce storage temperatures and a series of checklists for use between the shipper, transportation provider and receiver.[162] It is worth considering the impact of long regulatory lulls and the FDA's targeted, flexible regulation on the food transportation industry as a whole. It should not be a surprise that the industry now largely relies on procedures that it has developed.[163] Erik Lieberman, of the Regulatory

---

154. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22716 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

155. *See generally* Hazard Analysis & Critical Control Point; Procedures for the Safe & Sanitary Processing & Importing of Juice, 66 Fed. Reg. 6138 (Jan. 19. 2001) (to be codified at 21 C.F.R. pt. 120) (providing an example of such measures taken by the FDA).

156. *Id.*

157. *Id.* at 6139.

158. *Id.* at 6169, 6174.

159. *Id.* at 6139-40.

160. Hazard Analysis & Critical Control Point; Procedures for the Safe & Sanitary Processing & Importing of Juice, 66 Fed. Reg. at 6140.

161. *Produce Transportation Best Practices*, NORTH AMERICAN PRODUCE TRANSPORTATION WORKING GROUP (2012), http://www.hortcouncil.ca/uploads/file/naptwg_produce_trans_best_practices.pdf

162. *Id.*

163. Erik R. Lieberman, *Sanitary Food Transportation: What's in Store for the Food Industry?*, FOOD SAFETY SUMMIT EXPO & CONFERENCE (Apr. 19, 2012), http://www.fmi.org/docs/regulatory-documents/sanitaryfoodtransportation041912.pdf?sfvrsn=2.

Counsel for the Food Marketing Institute ("FMI"), made a case for retaining the current regulatory regime at the 2012 Food Safety Summit.[164] Anticipating FDA rulemaking, Lieberman cited the industry's long history of self-regulation without significant incidents.[165] Rather than a new regulatory regime, Lieberman preferred a flexible, guidance-based approach.[166] Lieberman cited a number of industry best practices and quality control processes that, in his view, rendered further regulation unnecessary.[167]

D. *2005 Sanitary Food Transportation Act Amendments*

The 1998 DOT Inspector General report made it clear the DOT was not meeting its obligations under the 1990 SFTA and recommended a reallocation of agency authority.[168] However, likely because of a lack of serious public health incidents that could be traced to food transportation, congressional action was not forthcoming.[169] Although reform was deprioritized, the issue occasionally resurfaced when the FDA and public health organizations pointed to the potential role of food transportation in exacerbating outbreaks.[170] When Congress passed the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users ("SAFETEA-LU"), they took the opportunity to revise the 1990 SFTA.[171] SAFETEA-LU was passed in 2005 to "shape[] the highway program to meet the Nation's changing transportation needs."[172] The bill authorized funding for a number of highway infrastructure initiatives.[173] Of its 836 pages, approximately three were devoted to food transportation.[174] The subtitle of the relevant section was the Sanitary Food Transportation Act of 2005 ("2005 SFTA").[175]

---

164. *Id.*
165. *Id.*
166. *Id.*
167. *Id.*
168. Lieberman, *supra* note 163.
169. *Id.*
170. *Id.*
171. FEDERAL HIGHWAY ADMINISTRATION, SAFETEA-LU, A SUMMARY OF HIGHWAY PROVISIONS (Aug. 25, 2005), http://www.fhwa.dot.gov/safetealu/safetea-lu_summary.pdf.
172. *Id.*
173. *Id.*
174. Sanitary Food Transportation Act of 2005, Pub. L. No. 109-59, § 7201-04, 119 Stat.1144, 1911 (Aug. 10, 2005).
175. Sanitary Food Transportation Act § 7201, 119 Stat. at 1911.

Much of the substance of the 1990 SFTA was retained in the 2005 version.[176] The purpose, as provided in the Conference Report of the Committee of Conference of H.R. 3, was to "reallocate responsibilities for food transportation" among the relevant agencies.[177] As recommended in the 1998 DOT Inspector General report, the 2005 SFTA shifted much of the regulatory authority from the DOT to the FDA.[178] Specifically, the 2005 SFTA amended Section 342 of the FDCA by deeming food adulterated if it is not in compliance with the new Section 416.[179] The 2005 SFTA then delegated authority under Section 416(b) to the HHS Secretary to establish "sanitary transportation practices."[180] The Secretary was required to regulate food sanitation, packaging, vehicle limitations, disclosure and recordkeeping.[181] Like the 1990 SFTA, the 2005 SFTA also distinguished between bulk and motor or rail vehicles.[182] However, the 2005 SFTA discarded the 1990 SFTA requirement to list "acceptable" nonfoods for bulk vehicles and "unacceptable" nonfoods for motor or rail vehicles.[183] Instead, the 2005 SFTA made the lists consistent by requiring that the FDA maintain lists of unacceptable foods for each vehicle type.[184] This may have been a reaction to the DOT's refusal to list any acceptable nonfoods for transportation with foods in bulk vehicles.

The 2005 SFTA also provided for specific recordkeeping requirements, which may have been Congress's way of responding to the DOT's 1993 NPRM, which largely found recordkeeping requirements unjustified by their costs.[185] Compared to the 1990 SFTA, the 2005 SFTA provided the HHS Secretary with more robust enforcement mechanisms, for instance the 2005 SFTA required that shippers and carriers produce records at the Secretary's request.[186] Failure to do was a "prohibited act" under Section 331 of the Act,[187] which carried the potential imposition of fines and criminal penalties.[188] Despite the DOT Inspector General's statement that food safety inspections may be incompatible with its existing safety inspections,

176. *Id.*
177. H.R. REP. NO. 109-201, at 1088 (2005).
178. Lieberman, *supra* note 163.
179. Sanitary Food Transportation Act of 2005, Pub. L. No. 109-59, § 7202-04, 119 Stat. 1144, 1911 (2005).
180. *Id.*
181. *Id.*
182. *Id.*
183. *Id.*
184. Sanitary Food Transportation Act § 7202, 119 Stat. at 1911.
185. *Id.*
186. *Id.*
187. *Id.*
188. 21 U.S.C. § 333 (2012).

Congress largely left inspection authority with the DOT.[189] However, perhaps recognizing that prior agency coordination had been nonexistent, Congress required that the DOT notify the HHS of "any instances of potential food contamination or adulteration" identified during safety inspections.[190] Given the lengthy periods of regulatory neglect, one might have expected that Congress would have imposed strict deadlines to promulgate regulations. However, the 2005 SFTA contained no specific timeframes.[191] Perhaps because over a decade had passed since the last significant public health food transportation incident, Congress chose to proceed with caution. As a result, the stage was set for another period of food transportation regulation remission.

E. *2005–2010: The FDA Continues the DOT's Prior Tradition of Regulatory Inaction*

Despite being granted broad regulatory authority, the FDA initially seemed content to continue to regulate specific industries using both guidance and regulations.[192] For example, in 2007, the FDA provided a model standard for training and evaluation criteria to be met by transporters of milk; in 2008, the FDA provided guidance for transporting fresh-cut vegetables to prevent physical, chemical and microbiological contamination; and, also in 2008, the FDA, responding to concerns about mad cow disease, promulgated regulations requiring dedicated equipment in transporting "cattle materials" prohibited for use in animal feed.[193] The agency did not pursue any specific action under the 2005 SFTA until 2010.[194]

During this period the FDA did, however, take steps to attempt to remedy the dearth of information about the scope of the potential problem.[195] Prior regulatory efforts had demonstrated the difficulty in estimating the

189. Sanitary Food Transportation Act of 2005, Pub. L. No. 109-59, § 7203, 119 Stat. 1144, 1914 (2005).

190. *Id.*

191. *See generally* Sanitary Food Transportation Act § 7202, 119 Stat. at 1911.

192. *See* Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

193. Implementation of Sanitary Food Transportation, 75 Fed. Reg. at 22719.

194. Implementation of Sanitary Food Transportation, 75 Fed. Reg. at 22713.

195. *Sanitation & Transportation Guidance Documents & Regulatory Information*, FDA.GOV. (Aug. 20, 2014), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/default.htm.

potential benefits of regulation.[196] For example, the DOT, in its 1993 NPRM, estimated that the benefits of the regulation would outweigh its costs.[197] It may be argued that much of this conclusion rested on the estimated benefits from reducing consumption of contaminated food. However, based on the analysis thus far, it seems that the DOT's difficulty was putting a number on benefits without specific data on the number of illnesses caused by food contaminated during transportation. Food safety incidents may not be reported. Further, it may be impossible to know whether contamination occurred during transportation or elsewhere in the distribution chain. The 1993 NPRM would have required incident reporting to "evaluate the extent of the problem, the effectiveness of the regulatory program, and the need for any legislative or regulatory changes."[198] However, there is no record of the DOT issuing a final rule based on the 1993 NPRM. The FDA had some industry data in response to its 1996 ANPRM, but by the time of the 2005 SFTA, the FDA considered this information "dated."[199] Therefore, in 2009, the FDA contracted the Eastern Research Group, Inc. ("ERG"), to provide a study of the current methods employed in food transportation and to identify particular risks.[200]

The ERG report begins by stating that "[t]here is currently very little information on the state of food transportation . . . in the United States."[201] Given that specific industry data was lacking, the ERG's findings were largely based on scientific literature and a survey of industry experts.[202] An industry survey found the biggest concern among companies and carriers was insufficient capacity and driver shortages.[203] Food safety, on the other hand, was sixth on the list.[204] However, the ERG cautioned that issues with capacity could lead to more dangerous practices, such as the type of backhauling discussed in Section II, of this article.[205] Additionally, driver

196. *See generally* Safeguarding Food from Contamination during Transportation, 58 Fed. Reg. 29698 (proposed May 21, 1993) (to be codified at 49 C.F.R. pts. 106, 107, 108, 110, 212, 171, 178, and 180).

197. *Id.*

198. Safeguarding Food from Contamination during Transportation, 58 Fed. Reg. at 29703.

199. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22719 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

200. Nyssa Ackerley & Aylin Sertkaya, Eastern Research Group, *Characteristics of Current Food Transportation & Holding Practices for Food Commodities* i (ERG Task No. 0193.16.001.001, March 6, 2009).

201. *Id.*

202. *Id.*

203. *Id.* at 2-1.

204. *Id.*

205. Ackerley et al., *supra* note 200, at 2-2.

shortages could place pressure on companies to employ individuals with less knowledge of food safety or to invest less money in training.[206] ERG was unable to provide data on the specific costs associated with contamination.[207] The report cited to a 2003 article which speculated that the food transportation "failures" may account for costs of two billion dollars annually.[208] However, the article does not provide the methodology used to derive this figure.[209] The ERG report concluded that the size of the problem is likely significant given the amount of food shipped, 200 billion metric tons per year globally, as well as the variety of foods and techniques employed to transport it.[210]

Based on the available scientific literature and expert opinions, the ERG identified fifteen problem areas where contamination may occur.[211] The list largely tracked the problems identified in food transportation incidents that have occurred over the last forty years: improper packing including cross-contamination, refrigeration, handling, materials including pallets, sanitation of vehicles and containers, pests and insufficient driver knowledge.[212] The report then considered how industry and HACCP best practices address potential risks.[213] However, the ERG did not engage in a granular approach to identify potential gaps between the problems identified by scientific literature and those addressed by best practices.[214] One way to do this would be to determine whether problems are prioritized differently by the literature and best practices. Given the lack of empirical data, such a comparison would be difficult. However, it might be possible to identify some areas in which best practices have not developed in response to emerging risks. For example, post-9/11 literature discussed the food supply as a potential target for bioterrorism.[215] Although regulations were passed to address potential vulnerabilities, there is evidence that less than half of all food transportation trucks are properly locked.[216] A comparative approach

206. *Id.* at 3-4.
207. *Id.* at A-45.
208. Larry Keener, *Transportation: the Squeaky Wheel of the Food Safety System*, FOOD SAFETY MAG. (Oct./Nov. 2003), http://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2003/transportation-the-squeaky-wheel-of-the-food-safety-system.
209. *Id.*
210. Ackerley et al., *supra* note 200, at 2-1.
211. *Id.* at i-ii.
212. *Id.*
213. *Id.* 2-14:2-21.
214. *See generally id.*
215. Dina Solodoukhina, *Food Safety and Bioterrorism from Public Health Perspective, in* ADVANCES IN FOOD PROTECTION 17, 19 (Magdy Hefnawy ed., 2011).
216. Wojtala, *supra* note 24.

of the literature and empirical data could guide the FDA's allocation of resources by assessing whether resources are being allocated according to current food safety concerns.

Although the ERG report contained data from nearly 50 studies, it only provided general information about the degree and nature of food transportation risks.[217] In order to better understand the problem and exigency of devising particular regulatory solutions to supplement or replace existing methods, the FDA attempted to obtain more information through a 2010 ANPRM.[218] The FDA requested data on current industry practice as well as on specific incidents of contamination and "associated outbreaks."[219] The agency's stated purpose was to "obtain data and information that would be more current and of greater relevance than the data and information [the agency] received in response to the 1996 joint ANPRM and to augment the more current information in the ERG report."[220]

The specific questions posed to industry can be classified under the headings of i) quantitative shipping data; ii) public health incident data; iii) current industry best practices; iv) current recordkeeping practices; v) data on the shipping of nonfoods with foods; vi) grounds for waiver of potential regulatory requirements; vii) information on relevant state and local food transportation regulations; and viii) general information on the potential benefits and costs of regulation.[221] In response, the FDA received 52 comments, the majority of which were submitted by various industry associations, institutes and councils.[222] Industry responses generally pointed out the benefits of retaining current best practices.[223] For example, the National Grain and Feed Association wanted the flexibility to use existing cleanout procedures given the expected increases in demand for its products.[224] The Independent Bakers Association took the tack of pointing out the sufficiency of its procedures given the relatively low risk nature of

217. Ackerley et al., *supra* note 200, at A-1:A-61.

218. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22720 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

219. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. at 22713-14.

220. *Id.* at 22720.

221. *Id.* at 22720-22.

222. *Implementation of the Sanitary Food Transportation Act of 2005*, REGULATIONS.GOV (2010), http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=FDA-2010-N-0013.

223. Randall C. Gordon, National Grain & Feed Association, Docket No. FDA-2010-N-0013, 5 (Aug. 20, 2010).

224. *Id.* at 3.

its products.[225] It was argued the FDA did not receive meaningful data on the potential scale of the problem,[226] and most comments either did not address this question or said data was unavailable.[227] When addressed, the American Meat Institute's response is characteristic of the industry's tone: "[T]he number of instances which transportation of food has been implicated as the cause for contamination is negligible."[228]

On the same day that the ANPRM was published, April 20, 2010, the FDA released guidance on the sanitary transportation of food.[229] The guidance was more significant as an indication of FDA's willingness to promulgate regulations applying across industries than for its specific content. The FDA provided that the guidance "differs from prior regulations and guidance in that it provides all sectors of the food industry with broadly applicable recommendations."[230] The document highlighted a number of ERG's findings, including problem areas that posed the greatest risk to food safety.[231] Based on this evidence, the FDA recommended that the food transportation industry focus on: i) appropriate temperature control; ii) sanitation which includes vehicle conditions, pests and loading/unloading conditions; iii) packing materials; iv) communication between the shipper, transporter and receiver; and v) employee awareness and training.[232] The FDA stated it would revisit the need for guidance once final regulations were issued.[233] Because the guidance is nonbinding and extremely general, it is unclear what effect it has had, if any, on the food transportation industry.

In response to the 2010 ANPRM and guidance, some food transportation consultants and experts questioned whether the FDA's findings justified a change in its current approach to issuing industry and process-specific guidance and regulations.[234] Terry Levee, Food Safety Manager for Deloitte & Touche LLP, took issue with the paucity of the

225. Nicholas A. Pyle, Independent Bakers Association, Docket No. FDA-2010-N-0013, 2 (Aug. 30, 2010).

226. *Id.*

227. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22720-22 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

228. Ashley B. Peterson, American Meat Institute, Docket No. FDA-2010-N-0013, 8 (Aug. 30, 2010).

229. *Guidance for Industry: Sanitary Transportation of Food*, FDA.GOV (Apr. 2010), http://fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitationtransportation/ucm208199.htm.

230. *Id.*

231. *Id.*

232. *Id.*

233. *Id.*

234. *See* Terry Levee, *Sanitary Food Transportation Act: What's the Food Industry to Expect?*, DELOITTE & TOUCHE, LLP (June 13, 2010), *available at* http://www.afdo.org.

FDA's evidence, saying the agency had cited a only a "handful" of events over the last 35 years.[235] Levee questioned whether regulation was needed in light of the DOT's conclusion just six years earlier that FDA regulations and guidance sufficiently protected the food supply during transportation.[236] Similarly, FMI's Lieberman responded to the 2010 ANPRM by stressing the food transportation industry's relatively unblemished incident record.[237] Further, he pointed out that all of the incidents FDA cited are now violations of current law and regulations.[238] His proposed solution was for the FDA to develop guidance to ensure food transporters understood their current obligations under the Act.[239] All signs pointed to another regulatory lull: the FDA lacked data, no significant incidents had occurred, Congress had not imposed deadlines and the industry was resistant to change.

However, rather than waiting to see whether the FDA would act, Congress forced the agency's hand and on January 4, 2011 passed the Food Safety Modernization Act ("FSMA"), which the FDA describes as "the most sweeping reform of our food safety laws in more than 70 years."[240] The FSMA focuses on improving food safety and security through provisions: i) requiring industry to institute greater procedural controls such as hazard analysis, recordkeeping and tracing systems; ii) providing the FDA with greater inspection and enforcement authority; and iii) instituting new requirements for imported foods.[241] The original version of the FSMA introduced in 2009 did not have a particular provision specific to food transportation.[242] The final version, however, contained Section 111, "Sanitary Transportation of Food."[243] Of the bill's 89 pages, this section occupies less than half a page.[244] In substance, Section 111 requires the FDA to promulgate regulations under the 2005 SFTA within eighteen months of the enactment of the FSMA.[245] Recognizing the persistent shortage of data, the Section also required the HHS Secretary to conduct a food transportation study which includes data about food safety in "rural and frontier areas."[246]

---

235. *Id.*
236. *Id.*
237. Erik R. Lieberman, Food Marketing Institute, Docket No. FDA-2010-N-0013, 2 (Aug. 30, 2010).
238. *Id.*
239. *Id.*
240. *Food Safety Modernization Act (FSMA)*, FDA.gov (2014), http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm.
241. Food Safety Modernization Act, Pub. L. No. 111-353, § 1, 124 Stat. 3885 (2011).
242. Food Safety Modernization Act, H.R. 875, 111th Cong. (1st Sess. 2009).
243. Food Safety Modernization Act § 111, 124 Stat. 3916.
244. *Id.*
245. *Id.*
246. *Id.*

The legislative history does not provide any specific discussion of why Section 111 was added to the bill; however, speaking on behalf of the bill, Texas Representative Sheila Jackson Lee recounted how a "single tainted pepper" had spread salmonella to 1,251.[247] Although the outbreak was not tied to improper food transportation, it is reasonable to think that such incidents made Congress more aware of the potential for food transportation to exacerbate public health crises. Regardless, the FDA was required to promulgate regulations under the 2005 SFTA within eighteen months of its enactment.[248]

V. THE 2014 NOTICE OF PROPOSED RULEMAKING

The FDA met the FSMA deadline by issuing a NPRM on schedule.[249] The stated goal of the proposed rule is "to ensure that transportation practices do not create food safety risks."[250] The proposed rule sets out requirements under five general headings: vehicles and transportation equipment, transportation operations, training, records and waivers.[251] Each is addressed below.

The proposed rule would cover both intrastate and interstate shipment of food.[252] The proposed rule tracks the problem areas identified in the ERG report relatively closely.[253] However, a notable exception is that the proposed rule would exempt shippers, receivers or carriers with less than $500,000 in total annual sales.[254] The proposed rule would also exempt fully packaged shelf-stable foods, live food animals and raw agricultural commodities when transported by farms.[255] Further, the proposed rule would not apply to food transported into the United States by means other than motor or rail.[256] Nor would the proposed rule cover foods transported in the United States but not for domestic consumption or distribution.[257]

---

247. H.R. Rep. No. 111-H8861, at § 510 (2010).
248. Food Safety Modernization Act, Pub. L. No. 111-353, § 111, 124 Stat. 3885, 3916 (2011).
249. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1).
250. *Id.*
251. *Id.*
252. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. at 7010.
253. *Id.* at 7008.
254. *Id.* at 7006.
255. *Id.*
256. *Id.* at 7010.
257. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006, 7010 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1).

Notably, like the DOT before it, the FDA refused to promulgate a list of nonfoods prohibited for transportation with food.[258] The FDA stated that such a list was impractical given that the likelihood of contamination depended on case specific factors such as packaging, vehicle construction, concentration of nonfoods and cleaning, and sanitation procedures.[259] Instead, the FDA indicated that, after publication of the final rule, it would provide guidance on procedures to prevent contamination of food by nonfoods during transport.[260]

Based on its statements under the various provisions of the proposed rule, the FDA appears to have attempted to minimize costs imposed upon industry. The FDA points out that many of the provisions have been designed in light of industry best practice.[261] Further, the FDA provides a table which compares proposed provisions against current good manufacturing practice ("CGMP").[262] The FDA concludes that seven provisions have CGMP analogues and that, therefore, "many firms are likely to already be in compliance with the proposed provisions of this rule."[263] The FDA estimates that the proposed rule would impose a first year cost of $149.1 million.[264] The agency determined that 83,609 firms would be covered by the rule at a cost of $1,784 per firm.[265] The FDA, unlike the DOT before it, did not attempt to provide an estimate of benefits.[266] In its Preliminary Regulatory Impact Analysis, the FDA notes that it is difficult to link an outbreak to a specific issue in transportation.[267] Further, intrastate transportation data is generally unavailable to the agency.[268] The FDA candidly admits that it is "unable to estimate the effectiveness of the requirements of the proposed rule to reduce potential adverse health effects in humans or animals."[269] Although the FDA expects some changes in behavior, the changes are anticipated to be small scale because the proposed rule largely adheres to industry best practice.[270] The potential benefits that

258. *Id.* at 7009.
259. *Id.*
260. *Id.*
261. *Id.* at 7006.
262. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. at 7011-12.
263. *Id.*
264. *Id.* at 7007.
265. *Id.*
266. *Id.*
267. *Preliminary Regulatory Impact Analysis*, REGULATIONS.GOV 3 (2014), http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0013-0001.
268. *Id.* at 4.
269. Sanitary Transportation of Human and Animal Food, 79 Fed. Reg. 7006, 7007 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1).
270. *Id.*

may result from the rule include a reduction in recalls, adverse health effects and losses resulting from contaminated human and animal food.[271]

The proposed rule would be placed in 21 C.F.R. 1, subpart O under the title "Sanitary Transportation of Human and Animal Food."[272] The provisions under the rule would span from Sections 1.900 to 1.934.[273]

A. *Section 1.906, Vehicle and Transportation Equipment*

The provisions under Section 1.906 would set out a number of general requirements for the design and maintenance of vehicles and transportation equipment.[274] The provisions would require that vehicles and equipment be: designed to allow for adequate cleaning, 1.906(a); maintained in sanitary condition, 1.906(b); designed to maintain temperatures, 1.906(c); equipped with thermometers in refrigerated compartments containing foods that can support microbial growth, 1.906(d); and stored as to prevent pest infestation or other conditions that would result in adulteration, 1.906(e).[275] Section 1.906 does not appear to impose requirements beyond existing regulations and industry best practices.[276] The FDA indicated that 1.906(a) is consistent with best practices as provided in response to the 2010 ANPRM.[277] Additionally, Sections 1.906(b)-(e) have nearly equivalent provisions in the FDA's CGMP.[278]

B. *Section 1.908, Transportation Operations*

Section 1.908(a) would set out general procedures to prevent food adulteration during transportation.[279] Specific provisions would require effective measures to: i) ensure foods are not contaminated by nonfoods when transported in the same load, 1.908(a)(3)(i); ii) prevent cross-contamination of foods in the same load, 1.908(a)(3)(ii); and iii) ensure appropriate conditions, including temperature control, for foods that can support microbial growth, 1.908(a)(3)(iii).[280] Section 1.908(b) would set out a number of requirements for shippers, including i) providing the carrier with

271. *Id.*
272. *Id.* at 7009.
273. *Id.* at 7033.
274. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. at 7016.
275. *Id.* at 7016-18.
276. *See id.*
277. *Id.* at 7017.
278. *Id.* at 7011-12.
279. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006, 7018 (proposed Feb. 5. 2014) (to be codified at 21 C.F.R. pt. 1).
280. *Id.* at 7018-19.

sanitation requirements for vehicles and equipment, 1.908(b)(1); ii) inspecting the carrier's vehicle or transportation equipment before loading any food not "fully enclosed" in a container, 1.908(b)(2); iii) providing the carrier with transportation conditions in writing for foods that can support microbial growth, 1.908(b)(3); and iv) verifying the precooling of refrigerated compartments that will contain foods that can support microbial growth, 1.908(b)(4).[281] Section 1.908(c) would apply to both shippers and receivers and includes requirements for provision of hand washing facilities, 1.908(c)(1), and conditions for loading and unloading of foods that can support microbial growth, 1.908(c)(2).[282] Finally, Section 1.908(d) would apply to carriers and largely tracks the same requirements outlined above, including with regards to vehicle and equipment conditions, 1.908(d)(1), temperature maintenance, 1.908(d)(2), and precooling, 1.908(d)(3).[283]

The Section would also impose a number of recordkeeping requirements on carriers, such as offering the shipper information about the last three cargoes, 1.908(d)(4),and the most recent cleaning, 1.908(d)(6).[284] Additionally, the carrier is required to have written procedures for cleaning practices, 1.908(d)(6)(i), and temperature control, 1.908(d)(6)(ii).[285] The FDA points out that most of the provisions would mirror existing CGMP and industry best practice.[286] However, the FDA cites a few instances where the regulations may require additional compliance for some entities.[287] For example, the FDA states that it has received comments indicating that temperature control procedures are not always followed during loading and loading, 1.908(c)(2),[288] and carriers do not always provide information about the previous three cargoes in all sectors of food transportation, 1.908(d)(4).[289]

C. *Sections 1.910–1.914, Training, Recordkeeping and Waiver*

The proposed rule would require carriers to train "personnel engaged in transportation operations" in food safety awareness and practices upon hiring and as needed, 1.910(a).[290] As outlined above, a number of Sections

281. *Id.* at 7020-22.
282. *Id.* at 7022-23.
283. *Id.* at 7023-24.
284. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. at 7025-26.
285. *Id.* at 7026.
286. *See id.* at 7018-26.
287. *Id.* at 7023.
288. *Id.* at 7023.
289. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006, 7026 (proposed Feb. 5, 1990) (to be codified at 21 C.F.R. pt. 1).
290. *Id.* at 7027.

of the proposed rule mandate recordkeeping.[291] Section 1.912 would establish specific recordkeeping requirements for the relevant provisions of the proposed rule, such as how long documents must be kept, when documents must be produced, and the format of and when the documents must be disclosed, 1.1912(a)-(g).[292] Finally, the proposed rule would provide the FDA with the ability to waive any provision for "any class of persons, vehicles, food or nonfood products" as long as the result would not be "unsafe for human or animal health and the waiver [would] not be contrary to the public interest," 1.914.[293]

VI. A LONG OVERDUE SOLUTION OR A REGULATION IN SEARCH OF A PROBLEM?

The road to food transportation regulation is littered with detours, delays and failed attempts. The problems are many and varied: overlapping agency mandates, federalism, uncertainty and cost. The FDA, seeing the 1990 SFTA languishing in regulatory purgatory, pursued a fractured approach to regulation.[294] During the decade that followed the 1990 SFTA, the agency issued guidelines and regulations specific to industries, procedures and products.[295] This was at least partially enabled by a lack of significant public health crises that would have shifted attention to the industry. Even the most serious incident, the contamination of ice cream estimated to have caused 224,000 cases of salmonella,[296] did not provide sufficient political pressure for meaningful regulatory change. The regulatory response to the 1994 incident was an ANPRM in 1996 that was eventually abandoned.[297] The FDA's solution was like many that pre and postdated it; the agency worked directly with the dairy industry to develop procedures to prevent a recurrence.[298]

As the 1994 incident has receded into the rearview mirror, the food transportation industry has effectively staved off efforts to regulate. Arguably, the DOT proved to be somewhat of a combination of unable and unwilling to regulate during the 1990s and the FDA did not fill the regulatory

291. *See generally id.* at 7006.
292. *Id.* at 7027-28.
293. *Id.* at 7028.
294. *See* Sanitary Food Transportation Act of 1990, Pub. L. No. 101-500, § 1, 104 Stat. 1213 (1990).
295. Transportation & Storage Requirements for Potentially Hazardous Foods, 61 Fed. Reg. 59372 (proposed Nov. 22, 1996).
296. Hennessy et al., *supra* note 56, at 1281.
297. Transportation & Storage Requirements for Potentially Hazardous Foods, 61 Fed. Reg. at 59372.
298. Letter from Clay Detlefsen, *supra* note 67, at 1-2.

void. Although the Act provided the FDA with relatively broad powers to regulate across industries, the agency chose a targeted approach.[299] Further, it may be argued that regulation was hampered by an enforcement gap. The most logical agency to conduct inspections, the DOT, could not easily wrap food truck inspections into its existing efforts. Further, the off cited but rarely practiced coordination between agencies and state and local officials did not materialize to any large degree.

During this period, industries took up the mantle to develop food transportation best practices.[300] One can reasonably ask to what degree the industries' decision was motivated by food safety and/or a desire to preempt more stringent regulations. Regardless, the food transportation industry could cite its own practices and a relatively unblemished safety record to justify the status quo. What was not mentioned, however, was that the industry appeared to benefit from a high degree of empirical uncertainty. When food safety incidents occurred, it was generally difficult to isolate the cause to transportation. Unless the incident could be traced to a previous substance in a vehicle, the contamination could have as easily occurred in the factory or point of distribution. Additionally, few studies specifically looked at the potential role of transportation in food contamination. Uneven recordkeeping practices also made tracing incidents difficult. It is notable in this regard that the FDA continues to cite the 2006 Michigan MDARD study,[301] which was small scale, regional and temporally limited, as evidence of the role of food transportation in contamination.[302] The FDA's own effort to gain a better empirical foothold, the 2009 ERG study, pointed to potential vulnerabilities in food transportation procedures.[303] However, the study did not provide a real sense of the scale of the problem.[304]

In light of this history, recent efforts seem to be a departure from what could be called the laissez-faire approach of the 1980s and 1990s. The 2005 SFTA attempted to address the jurisdictional issues by largely vesting power in the FDA.[305] The FDA's 2010 ANPRM sought to obtain evidence of the magnitude of the problem.[306] Although the industry's response may be categorized as pleading the fifth, Congress would not be deterred. Instead

299. 21 U.S.C. § 301 (2012).
300. Lieberman, *supra* note 163.
301. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006, 7007 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1).
302. *Id.*
303. *See* Ackerley et al., *supra* note 200.
304. *Id.*
305. Sanitary Food Transportation Act of 2005, Pub. L. No. 101-59, § 7201, 119 Stat. 1911 (2005).
306. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).

of allowing the FDA to continue a tradition of inaction based on uncertainty, Congress included a provision in the 2011 FSMA to require the FDA to issue regulations under the 2005 SFTA within eighteen months, as well as to conduct a food transportation study.[307] Notably this all occurred without having been prompted by a specific public health crisis. However, the question remains as to whether the FDA's 2014 NPRM addresses significant regulatory gaps or if time has made the proposed rule largely redundant.[308]

A. *Market Failure Analysis of the 2014 Notice of Proposed Rulemaking*

A useful way to analyze the 2014 NPRM[309] is to consider the extent to which it addresses potential market failures. Diana Crumley provides a framework for analysis in her 2012 article, "Achieving Optimal Deterrence in Food Safety Regulation."[310] She lists imperfect information and externalities as primary food safety market failures.[311]

Food safety suffers from the familiar "lemons" problem in the used car market. The individual purchasing food can only verify its lack of contamination at great expense. Therefore, purchasers are forced to rely on individuals up the supply chain ("providers"). Providers have the incentive to only spend resources up to the point that the food is likely to be rejected by the purchaser or that they will be held responsible for negative health effects. Responsibility could be in the form of legal liability, fines, imprisonment or reputational damage.

Under this model, food carriers would be expected to calculate how much to spend on safety based on the probability of having food rejected or being required to bear the costs of public health effects. There are reasons to think the current market is less than efficient. The first reason is underreporting and under-identification of public health incidents.[312] Particularly if the health impact is not serious enough to require hospitalization, carriers would not be responsible for unidentified, but potentially significant, public health impacts. The likelihood of reporting would also be a function of shipment size. Larger shipments would impact more individuals and increase the probability that public officials would

307. Food Safety Modernization Act, Pub. L. No. 111-353, § 111, 124 Stat. 3885, 3916 (2011).
308. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1).
309. *Id.*
310. Diana Crumley, *Achieving Optimal Deterrence in Food Safety Regulation*, 31 REV. LITIG. 353 (2012).
311. *Id.* at 370-71.
312. Keener, *supra* note 208.

identify and attempt to determine the source of an outbreak. Another reason for market inefficiency is the number of actors in the supply chain. Even when a public health incident is identified, there could be difficulty in meting out blame to the shipper, carrier, receiver or consumer. To the extent that such issues are intractable, the carrier would have a lower probability of facing ramifications.

Under-enforcement of regulations may also contribute to lower levels of compliance. Even discounting the aforementioned factors, companies may reasonably believe the FDA is unlikely to bring enforcement actions. Because of limited resources, the agency is unable to pursue every identified issue and generally allows companies an opportunity to comply prior to bringing an enforcement action.[313] Further, penalties may be too low to encourage efficient behavior. The issue of the appropriate penalty is particularly significant given the difficulty in aggregating potentially large and dispersed public health impacts. For example, should Schwan's have been held responsible for the 150 confirmed cases of salmonella or the 224,000 estimated cases?[314] And how should damages be calculated? Missed work and hospital bills, or some measure of suffering and inconvenience? Depending on the answers to these questions, the range of damages could be minimal to crushing. To the extent that carriers would not be held responsible for the public health impacts of contamination they cause, this would impose an externality on society.

Many of the market inefficiencies identified may be at least partially mitigated by market forces exerting pressure in the opposite direction. The costs associated with recalls and their reputational damage provide companies with a strong incentive to prevent contamination. For example, a salmonella outbreak in 2009 from tainted peanut butter led to a massive recall and ultimately the bankruptcy of the company responsible, the Peanut Corporation of America.[315] In fact, entire industries may have incentives to encourage individual companies to adhere to food safety measures. One can be sure that the impact of the peanut butter recall spread to brands not associated with the outbreak. The month after the recall, overall sales of peanut butter were estimated to have declined by twenty-five percent.[316]

---

313. *See* Letter from John R. Gridley, *supra* note 72.

314. Hennessy et al., *supra* note 56, at 1281-83.

315. Phil Wahba & Emily Chasan, *Salmonella-hit peanut company files for bankruptcy*, REUTERS (Feb. 13, 2009), http://www.reuters.com/article/2009/02/13/us-peanutcorp-bankruptcy-idUSTRE51C67C20090213.

316. Andrew Martin & Liz Robbins, *Fallout Widens as Buyers Shun Peanut Butter*, N. Y. TIMES (Feb. 6, 2009), http://www.nytimes.com/2009/02/07/business/07peanut.html?_r=1&hp=&adxnnl=1&adxnnlx=1394327012-xih3ZVs7xx1lFz8zeufOPQ&.

Even the best case scenario is costly. Schwan's handling of the ice cream contamination is cited as a model of successful crisis management.[317] However, to survive the crisis, Schwan's was compelled to shutdown sales and production, invite in state and FDA officials to investigate, and conduct customer outreach.[318] Although the brand recovered, it took approximately two years for ice cream sales to return to their 1994 levels.[319]

Given the importance of brand recognition for large food producers, the incentive provided by the desire to preserve brand integrity likely dwarfs that provided by possible regulatory reprisal. However, for smaller producers and producers not reliant on brand recognition, reputational concerns will not induce the same degree of compliance. In the case of independent carriers, the incentive is further attenuated. Carriers are not public brands. Their incentive is not necessarily to ensure that food is not contaminated during transport. Instead their primary concern is to secure business, which may involve demonstrating a safety record as well as entering into a contract requiring that certain measures be taken. The shipper/carrier situation is a classic agency problem. Although shippers can take measures to align interests, incentives will not be perfectly matched because carriers will not suffer the full measure of reputational harms.

B. *Comparison of the Efficacy of Current Regulations and the Proposed Rule in Correcting Market Failures*

In order to gauge the success of the 2014 NPRM[320] in addressing market inefficiencies, one must consider how well they are being addressed by the status quo web of best practices, nonbinding guidance and regulations. The FDA has the ability to conduct inspections and charge violators under Section 331 of the Act.[321] For example, a carrier that did not sufficiently clean out a vehicle before loading food could render the food adulterated under Section 342[322] and be subject to penalty under Section 333.[323] Additionally, as outlined above, the FDA has issued regulations governing a number of specific issues, including cleanout procedures for vehicles used

317. ARCHIE CARROLL & ANN BUCHOLTZ, BUSINESS AND SOCIETY: ETHICS AND STAKEHOLDER MANAGEMENT 172 (8th ed. 2011).
318. *Id.*
319. The Schwan Food Company, *International Directory of Company Histories*, ENCYCLOPEDIA.COM (2007), http://www.encyclopedia.com/doc/1G2-3479900080.html.
320. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1).
321. 21 U.S.C. § 331 (2012).
322. 21 U.S.C. § 342 (2012).
323. 21 U.S.C. § 333 (2012).

to transport medicated animal feeds, treatment requirements for juice processing, and record retention and production requirements.[324]

Despite these legal bases, there are a number of reasons to doubt that the FDA's regulations are having a large independent impact on industry behavior. First, the agency has limited resources to conduct inspections. It seems likely that any efforts the FDA conducts are in response to specific reports from other agencies, state or local officials or the industry itself. Second, given the relatively broad language of the Act's adulteration provisions, the FDA may not have a regulation addressing a particular behavior. Therefore, the agency may balk at bringing resources to bear on an action that is not clearly a prohibited act under Section 331.[325]

Third, the likelihood of significant penalties is low. The industry is aware that the FDA generally issues warning letters to allow companies to remedy behavior before bringing any legal action. Further, a $1000 fine under Section 333[326] is unlikely to be a significant deterrent. The Act does allow for imprisonment for up to one year.[327] Although not spelled out in the Act, this would presumably be reserved for particularly egregious behavior. The FDA has said the type of action to be taken against a violator depends on "public health concern[s], [a]gency policy, previous history of violations by the firm, and other factors."[328]

Finally, existing regulations do not address the incentive deficit of smaller companies and carriers. As outlined above, such companies have less to lose in brand reputation and, therefore, are less likely to devote resources to ensuring food safety. In sum, although market pressures may induce compliance, the legal regime does not appear to have the content or the authority to be a strong independent source of preventing food transportation contamination.

To determine the efficacy of the 2014 NPRM,[329] it is worth considering the extent to which it would address the market inefficiencies identified above. The NPRM does not contain any provisions directly addressing the issue of underreporting.[330] However, the NPRM would require relatively extensive recordkeeping requirements, which may allow for better

---

324. Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713, 22717-18 (proposed Apr. 30, 2010) (to be codified at 21 C.F.R. pt. 1).
325. 21 U.S.C. § 331 (2012).
326. 21 U.S.C. § 333 (2012).
327. *Id.*
328. *Types of FDA Regulatory Actions*, FDA.GOV (June 25, 2014), http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm268127.htm.
329. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1).
330. *Id.*

identification of the cause of contamination.[331] It should not be a surprise that the NPRM does not contain specific provisions to encourage reporting since this issue is not specific to food transportation and involves coordination with other agencies and state and local officials.[332]

The NPRM does not call for greater enforcement efforts or penalties.[333] However, the NPRM would allow the FDA to better respond to conduct likely to cause contamination during transport.[334] The greater specificity of the provisions of the NPRM would provide the FDA with a stronger basis for bringing enforcement actions for behavior that is currently not a clear violation of the Act.[335] The efficacy of these new provisions in shaping conduct would depend on the degree to which they are enforced. It is not clear yet whether the FDA would devote significant resources to upholding the terms of any final rule. Additionally, the NPRM would not increase penalties for violations.[336] A violation of a provision of the NPRM would be labeled a prohibited act under Section 331 of the Act and carry the same penalties as outlined above.[337]

The NPRM does not appear to specifically target entities with lower market-based incentives to adopt food safety measures.[338] As detailed above, carriers have less incentive to ensure food safety given their lower reliance on brand recognition. To some degree the NPRM may address this through imposing greater requirements on carriers.[339] Again, whether these provisions shape behavior would depend on the degree to which they are enforced. However, most problematic is the fact that the NPRM would exempt shippers, carriers and receivers with less than $500,000 in annual revenues.[340] As outlined above, these are precisely the entities with a greater incentive to cut food safety corners. Such entities would not be recognized brands nor have a great deal of assets to protect. The data that is available supports this conclusion. The Michigan MDARD study found that large semi trucks, which would be more likely to carry large brand name food products, "had little or no areas of concern."[341] Conversely, most of the

331. *See id.*
332. *Id.*
333. *Id.*
334. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. at 7006.
335. *Id.*
336. *See id.*
337. *Id.*; 21 U.S.C. § 331 (2012).
338. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1).
339. *See id.*
340. *Id.* at 7007.
341. Wojtala, *supra* note 24.

problems identified in the study were in small box and ethnic food trucks.[342] The FDA provides that the exemption addresses the requirement under the Regulatory Flexibility Act ("RFA") that agencies "analyze" options to minimize the impact on small entities.[343] Further, the agency notes that smaller entities would still be covered under the Act.[344] However, as important as ensuring the viability of small entities may be, this does not appear to justify wholesale exemption. The FDA could impose variable standards to reduce burdens according to annual revenues. By exempting the entities most likely to pose a threat to public health, the FDA would undermine the purposes of the proposed rule.

Overall, the NPRM would take a few small steps in the right direction. The proposed rule would enable the FDA to better target specific conduct deemed to create the greatest public health risks. However, the efficacy of the rule will largely depend on considerations outside the scope of its terms. Specifically, the agency would need to devote more attention to identifying public health incidents, conduct greater enforcement efforts and potentially raise the penalties for noncompliance, or at least reduce its reliance on warning letters. Further, much of the potential benefit of the NPRM would be lost by exempting entities with annual revenues of less than $500,000. The FDA should consider eliminating this provision or, at minimum, scaling the NPRM's burdens according to an entity's annual revenue.

VII. CONCLUSION

The road to food transportation regulation has been bumpy. Food transportation has provided enormous benefits to society; however, a number of incidents point to its public health risks. Further, there is reason to think identified incidents may only be the tip of the iceberg. Despite a growing awareness of the dangers associated with food transportation, regulation has not been forthcoming. Amongst other factors, regulation has been hindered by empirical uncertainty, a lack of agency coordination and the cost of setting up a more robust enforcement regime. Recent events have provided more hope for a broader, more consistent regulatory approach. Specifically, Congress vested regulatory authority in the FDA in the 2005 SFTA and put a deadline on the agency to promulgate regulations in the 2011 FSMA.[345] The result was the 2014 NPRM, which does take some important steps in

342. *Id.*

343. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. at 7031.

344. *Id.* at 7014.

345. Sanitary Food Transportation Act of 2005, Pub. L. No. 109-59, § 7201, 119 Stat. 1911 (2005); Food Safety Modernization Act, Pub. L. No. 111-353, § 1, 124 Stat. 3885 (2011).

providing consistent regulations across industries.[346] However, there are reasons to believe that the NPRM will not solve many of the risks associated with food transportation. The FDA could go a long way toward reducing public health dangers by devoting more attention to identifying incidents, conducting greater enforcement efforts, increasing penalties for violators and removing, or at least scaling back, exemptions for small entities. Only time will tell whether the 2014 NPRM[347] becomes a milestone in food transportation regulation or another agency action left abandoned by the side of the road.

346. Sanitary Transportation of Human & Animal Food, 79 Fed. Reg. 7006 (proposed Feb. 5, 2014) (to be codified at 21 C.F.R. pt. 1).
347. *Id.*