



August 30, 2010

Submitted Electronically

The Honorable Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
White Oak Building 1
10903 New Hampshire Avenue
Room 2217
Silver Spring, MD 20993

**RE: Implementation of the Sanitary Food Transportation Act, 75 Fed. Reg. 22713
(April 30, 2010)**

Docket No. FDA-2010-N-0013

Dear Commissioner Hamburg:

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) advance notice of proposed rulemaking (ANPRM) to request data and information on the food transportation industry and its practices. FMI looks forward to working with FDA to implement the Sanitary Food Transportation Act of 2005¹ (SFTA).

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of \$680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

Background

FDA is taking this action as part of its implementation of the SFTA, which requires the Agency to issue regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers and others engaged in food transport.

¹ P.L. 109-59.

HEADQUARTERS:

2345 Crystal Drive, Suite 800
Arlington, VA 22202-4801

T 202.452.8444
F 202.429.4519

WASHINGTON OFFICE:

50 F Street, NW, 6th Floor
Washington, DC 20001-1530

T 202.452.8444
F 202.220.0873

www.fmi.org
fmi@fmi.org

The SFTA amended section 402 of the Federal Food, Drug and Cosmetic Act² (FDCA) to specify that food is adulterated as a matter of law if it is “transported . . . under conditions that are not in compliance with regulations promulgated under section 416.”³ Section 416 directs FDA to issue regulations that require shippers and carriers by motor vehicle among others to “use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated.”⁴

FMI believes if FDA follows the recommendations contained within these comments, it will implement the SFTA in an effective manner.

Effectiveness of Existing Industry Practices

In the supplementary information provided as part of the ANPRM, FDA describes the events the Agency is aware of whereby food became or had the potential to become contaminated during transportation. The Agency cites only six events over the course of 36 years, none of which involve the transportation of food by the supermarket industry. In fact, information the agency cites regarding the 2007 Interstate Food Transportation Assessment Project notes that there were “little or no areas of concern” with large semi-trucks⁵—the mode of transportation used by the supermarket industry.

The fact that no events involving the supermarket industry can be cited by the agency is a testament to the effectiveness of existing industry practices. It is particularly notable in light of the volume of food transported by wholesalers and self-distributing retailers.

A typical distribution center facility ships in excess of 545,000 cases of product every week and more than 47 million pounds of food every four weeks.⁶ More than 600 million pounds of food is shipped out of the typical distribution center facility every year. The industry transports billions of pounds of food across the nation annually.

Existing Laws and Regulations are Working

The few incidents FDA cites in the ANPRM involving issues in the transportation of food are violations of current law and regulations. As such, the development of additional food transportation related guidance clarifying the responsibilities of food transporters already required by the FDCA is the best way to achieve the goals of the SFTA. FDA should work with the industry on such guidance and FMI is willing to help in this effort.

² 21 U.S.C. §§ 301 et seq.

³ 21 U.S.C. § 342.

⁴ 21 U.S.C. §350e.

⁵ Wojtala, G., 2007, Interstate Food Transportation Assessment Project. Presented at the June 16 through 20, 2007, Conference of the Association of Food and Drug Officials, http://www.michigan.gov/documents/mda/truckproj_224450_7.pdf.

⁶ Food Marketing Institute, Distribution Center Benchmarks 2007.

The existing framework of laws and regulations is meeting the purposes of the SFTA. The U.S. Department of Transportation has acknowledged that “taken together, the . . . FDA regulations and implementing guidance adequately address the overarching . . . goal of protecting food and food products from contamination during transportation.”⁷ FDA should not impose new—and unnecessary—regulatory burdens on the food industry.

Commitment to Food Safety

Food safety is the utmost priority for the supermarket industry and the exceptional record of grocers over the decades reflects this. First and foremost, the supermarket industry cares about the customers it serves and is committed to getting foods to consumers in the safest and freshest manner. Secondly, competition in the industry is fierce and supermarkets know that if they fail to provide consumers with fresh and sanitary foods they will not succeed in the marketplace. Food safety issues influence consumer purchasing decisions. In a 2009 FMI sponsored survey, 31 percent of shoppers stopped purchasing a variety of items either short-term or permanently as a result of food safety concerns.⁸ The industry’s dedication to food safety extends beyond store shelves. FMI continues its commitment to the work of the non-profit Partnership for Food Safety Education, a government-industry effort to educate consumers about what they can do to reduce risk of foodborne illness.

Our commitment—and record on food safety—is reflected in the fact that consumers have confidence in the safety of food at their supermarkets. Nine in ten shoppers trust their grocery stores to sell safe produce, canned and boxed goods, meat, poultry and fish and to provide safe food in general.⁹ Consumers trust the grocery stores they shop at. The supermarket industry was rated the most honest and trustworthy industry in America in 2009 and has held this position for six of the past seven years.¹⁰ Trust in a company factors into purchase decisions for most consumers.¹¹ Furthermore, of all major industries in the U.S., supermarkets are the least likely to be cited by the public as needing more government regulation.¹²

Risk-based Approach

FMI believes that FDA must take a risk-based approach in crafting the regulations implementing the SFTA. The risk of microbial contamination to food occurring from the trailer itself during transportation from distribution centers to retail outlets is extremely remote as effectively all products are contained in packaging and are not in direct contact

⁷ 69 Fed. Reg. 76423 (Dec. 21, 2004).

⁸ Food Marketing Institute, 2009 U.S. Grocery Shopper Trends.

⁹ Id.

¹⁰ Harris Interactive, The Harris Poll 2009.

¹¹ Euro RSCG Worldwide, The Value Study 2009.

¹² Harris Interactive, The Harris Poll 2009.

with trailer surfaces. As FDA has pointed out in the Guidance for Industry: Sanitary Transportation of Food, there is already published guidance addressed to numerous industries covering the proper transportation of food.¹³ Current industry practices also make the risk of cross contamination of food and nonfood products very improbable. As such, the Agency should implement the SFTA in a manner which gives the supermarket industry the flexibility to maintain current industry practices which have proven to be effective over many decades.

Responses to FDA Questions

These responses describe the supermarket industry transportation practices involving the transportation of products between and among distribution centers and retail stores. Headings that are italicized reference specific requests for information posed by FDA in the notice.

What types of vehicles or methods are used to transport food by motor vehicle or rail vehicle?

Virtually all shipments of foods are conducted via refrigerated and dry semi tractor-trailers.

What are the amounts and percentages of foods that are transported completely enclosed by packaging?

Effectively all foods transported are in containers and do not come into contact with any surface of the trailer. In dry trailers essentially all foods are completely enclosed by packaging. In refrigerated trailers the vast majority of foods are completely enclosed by packaging.

Industry Standards and Suppliers

Retailers are playing a greater role in ensuring suppliers maintain strict food safety standards. Increasingly, retailers require their suppliers—farmers, processors or wholesalers—to demonstrate through independent audits that food safety practices are being followed. Certification of suppliers, such as FMI's Safe Quality Food recognition, offers greater reassurance that best practices are in place.

Safe Quality Food 2000 Code

The Safe Quality Food (SQF) 2000 Code is a food safety and quality management

¹³ FDA Guidance for Industry: Sanitary Transportation of Food (April 2010)
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm208199.htm>.

certification program. SQF enables suppliers to meet product trace, regulatory, food safety and commercial quality criteria in a structured and cost effective manner. The Code was developed in 1994 with the assistance of experts in quality management, food safety, food regulation, food processing, agriculture production systems, food retailing, food distribution and the Hazard Analysis Critical Control Point (HACCP) Guidelines. FMI acquired the rights to the SQF Program in August 2003 and has established the SQF Institute Division to manage the Program. The SQF 2000 Code is recognized by the Global Food Safety Initiative as a standard that meets its benchmark requirements. SQF's standards on transportation practices are included in Appendix A.

What industry standards exist for the cleaning of food transportation vehicles?

Trailers are frequently swept to remove any debris. Retailers and wholesalers have developed effective methods of ensuring trailers do not pose risks of contaminating foods which meet the needs of their individual supply chain systems. A one-size-fits-all approach to trailer cleaning would be unworkable for the industry. Trailers are visually inspected and assessed for odor. Spills and odors are addressed promptly and thoroughly. Because foods being transported by the industry are enclosed by packaging and not coming into direct contact with trailer surfaces a proscriptive washing regimen determined by FDA is not appropriate or necessary. Excessive washing of trailers results in damage to trailers including corrosion of interior parts. It would not reduce food safety risks and in fact could be counterproductive by introducing excessive moisture into environments and on materials that are designed to be kept dry. Retailers and wholesalers should be given the flexibility to maintain their current practices which have been proven to be effective.

What procedures and practices are in place to ensure temperature control for TCS foods?

Nearly all distributors (97.1%) have a quality control process to check and inspect the temperature of products during unloading activities.¹⁴ 86.8 percent of companies check temperatures of fresh, temperature-sensitive products when making backhaul pick-ups.¹⁵ Nearly 77 percent of firms have implemented policies to record product temperatures en route to the distribution center.

Some fleets run dual-temperature trailers, though the majority operate single-temperature ones. Temperature-controlled products can be shipped in freezer boxes with dry ice. The use of dual or multitemperature refrigeration equipment presents challenges for both loading crews and drivers. Coordinating the loading and unloading of products in multiple temperature zones in one trailer making several stops is difficult.

¹⁴ FMI 2008 Transportation Benchmarks.

¹⁵ Id.

Are food products transported simultaneously or sequentially with nonfood products?

Foods may be transported simultaneously and sequentially with nonfood products. All foods are enclosed by packaging and any risk of cross-contamination from nonfood items is extremely remote. Current industry practices have proven to be very effective in maintaining the freshness and cleanliness of foods. The industry should be granted the flexibility to continue its practices—which are working well. Any requirement to segregate foods from nonfoods would be tremendously costly to the industry and lead to higher prices for consumers. Such a requirement would result in the wasting of vast quantities of fuel, excessive wear and tear on trucks, and a needless increase in greenhouse gases.

What types of records are currently kept by receivers of food? What additional records would be useful or necessary to achieve the goals of 2005 SFTA?

Receivers of food are required to maintain records of the immediate previous source of the food under the FDA Bioterrorism Regulations. Under the Perishable Agricultural Commodities Act¹⁶, retailers are required to keep accounts and records that fully disclose all transactions related to the purchase of produce. These accounts and records include the date of receipt of each lot, kind of produce, number of packages and quantity, price paid, evidence of agreement, or contract of purchase, bills of lading and paid bills. Retailers also must maintain records pursuant to USDA's country of origin regulations which identify the covered commodity and retail supplier. FMI does not believe that any additional records would be useful or necessary to achieve the goals of the SFTA.

FMI notes that Congress is considering comprehensive food safety legislation which addresses food transportation and could be enacted this year. In light of this legislation, FMI believes that FDA should extend the comment period on the ANPRM until December 31, 2010. If the legislation is enacted, FDA should reopen the comment period as part of its rulemaking proceedings to implement the new law.

FMI appreciates the opportunity to comment on this important topic and looks forward to working with FDA to implement the SFTA in an effective manner.

Sincerely,



Erik R. Lieberman
Regulatory Counsel

¹⁶ 7 U.S.C. § 499a et seq.

Appendix A

6.11 Transport and Delivery

6.11.1 Loading, Transport and Unloading Practices

6.11.1.1 The practices applied during loading, transport and unloading of food shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported and unloaded under conditions suitable to prevent cross contamination.

6.11.2 Loading

6.11.2.1 Vehicles (trucks/vans/containers) used for transporting food shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odors or other conditions that may impact negatively on the product.

6.11.2.2 Loading practices shall be designed to minimize unnecessary exposure of product to conditions detrimental to maintaining product and package integrity.

6.11.3 Transport

6.11.3.1 Refrigerated units shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and core product temperatures recorded at regular intervals during loading as appropriate.

Note: Use clean equipment when taking core product temperatures and open outer packaging to access units in the middle of larger cartons. In circumstances where it is difficult to core test product, or if core testing destroys the serviceability of the packaging, alternative methods of determining a products temperature can be used. Prior to loading it is good practice to pre-chill refrigeration units.

6.11.3.2 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals and the storage temperature at regular intervals during transit.

Note: Care should be taken to transport food at its appropriate storage temperature. It is recommended that the refrigeration units air temperatures be recorded at regular intervals during shipment and this can be accomplished by the use of data logger temperature recording devices. Appropriate temperature requirements for chilled food range between 0°C – 4°C (32°F – 40°F) and for frozen foods ≤ -18°C (≤ 0°F).

6.11.4 Unloading

6.11.4.1 Prior to opening the doors the refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently and core product temperatures shall be recorded at the commencement of unloading and at regular intervals during unloading.

Note: Prior to unloading the load is to be checked for signs of temperature abuse (thawing and refreezing), damage or shifting during transport.

6.11 Transport and Delivery.

SQF Requirement	Guidance
6.11.1 Loading, Transport and Unloading Practices	<p>What do I need to do?</p> <p>Proper care for the food packaging safety and quality of your product does not end when the finished product is placed into storage awaiting delivery. Moisture abuse during delivery and transport can damage packaging materials. A Transport and Delivery Protocol will cover those aspects necessary to ensure product is protected during loading, transport and unloading.</p> <p>Loading:</p> <p>Conduct visual inspection for cleanliness, pest infestation, structural conditions, and ability to cool and maintain dry conditions on all outbound trucks/trailers as required. Verify that all trucks/trailers are free of offensive odors. All inspection findings are to be maintained in records.</p> <p>Transport:</p> <p>When using "Hub" delivery systems instead of direct delivery, ensure that the packaging is well protected from the unknown handling that will occur between its pick up and ultimate destination.</p>
6.11.1.1 Practices Documented	
<p>The practices applied during loading, transport and unloading of food shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Foods shall be transported under conditions suitable to prevent cross contamination.</p>	
6.11.2 Loading	
6.11.2.1 Transport Vehicle Condition	
<p>Vehicles (trucks/vans/containers) used for transporting food shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odors or other conditions that may impact negatively on the product.</p>	
6.11.3 Transport- Not applicable to the Guidance	
6.11.4 Unloading- Not applicable to the Guidance	