THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

July 30, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Sanitary Transportation of Human and Animal Food Proposed Rule

Dear Sir or Madam:

On February 5, 2014, the Food and Drug Administration (FDA or the Agency) published in the *Federal Register* a proposed rule entitled Sanitary Transportation of Human and Animal Food ("Proposed Rule").1 The Proposed Rule establishes requirements for shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary food transportation practices to ensure the safety of the food they transport. The Proposed Rule is being issued to implement the Sanitary Food Transportation Act (SFTA) as required by the Food Safety Modernization Act (FSMA).

The Food Marketing Institute (FMI) proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost $770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

FMI appreciates the opportunity to comment on this important matter.

Summary of Key Points

1. **Intracorporate transportation should be exempt from the Proposed Rule**

1 79 Fed. Reg. 7006 (February 5, 2014).

2. **Temperature conditions shippers are required to communicate to carriers under the Proposed Rule should be based on critical, rather than operational limits**
    a. **FMI requests that food temperature controlled for quality not fall under the same guidelines as food that is temperature controlled for safety**
3. **The Agency should provide flexibility regarding what constitutes "convenient access" to handwashing facilities in distribution centers**
4. **Greater clarity is needed as to when food is rendered adulterated under the Proposed Rule**
5. **FMI supports the waiver FDA is proposing to issue concurrently with the Final Rule exempting food establishments when they are engaged in certain activities**
6. **Greater clarity is needed as to the applicability of the Proposed Rule to foreign exporters**
7. **FMI supports the Agency's position that food transporters routinely safely transport food and non-food items in the same load**
8. **FMI disagrees with an exemption for non-covered businesses**
9. **FDA should exempt short haul transportation from the Proposed Rule**
10. **Inspections and enforcement should be clear and consistent**

Introduction

FDA is taking this action as part of its implementation of 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.

SFTA amended section 402 of the Federal Food, Drug and Cosmetic Act 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." 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."

Section 111 of FSMA required FDA to implement SFTA not later than 18 months after the date of enactment of FSMA.

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

Effectiveness of existing industry practices

In the supplementary information provided as part of the Advance Notice of Proposed Rulemaking on SFTA that the Agency issued in April 2010 (ANPRM) and cites in the Proposed Rule, 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-trucks —the mode of transportation most commonly used by the supermarket industry. The Proposed Rule reiterates this point about large semi-trucks.

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. 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.2

Existing laws and regulations are working and burdensome new rules are not justified

The few incidents FDA cites in the ANPRM, and by reference, in the Proposed Rule, involving issues in the transportation of food are violations of current law and regulations. These limited incidents do not justify the establishment of a complex new regulatory regime that would impose significant costs on industry. With an average annual profit margin of less than 1 percent, it is inevitable that many of these costs are passed down to consumers. The existing framework of laws and regulations has met 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."3 FDA should not impose a costly new regulatory regime for the transportation of food in the absence of a public health problem for the retail food industry.

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2 Food Marketing Institute, Distribution Center Benchmarks 2007.
3 69 Fed. Reg. 76425 (Dec. 21, 2004).

That said, FMI acknowledges that Congress required FDA in FSMA to promulgate a regulation implementing SFTA. As such, it should be promulgated in a risk-based, flexible manner, while serving the policy goal of protecting public health. FMI believes FDA has strived to do this in the regulation, and commends them for their effort. With the changes to the Proposed Rule outlined in these comments, FMI believes FDA can strike the right balance between providing regulatory flexibility and protecting public health.

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 safe foods they will not succeed in the marketplace. Food safety issues influence consumer purchasing decisions. In FMI's 2013 U.S. Grocery Shopper Trends study, 19 percent of shoppers stopped purchasing one or more items as a result of food safety concerns. 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 ensure that their food is safe.4

Risk-based approach

FMI believes that FDA must take a risk-based approach in crafting the regulations implementing 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 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. Current industry practices also make the risk of cross contamination of food and nonfood products very improbable. As such, the Agency should craft the Proposed Rule in a manner which gives the supermarket industry the flexibility to maintain current industry practices which have proven to be effective over many decades.

4 Food Marketing Institute 2013 U.S. Grocery Shopper Trends Data Tables.

Key Issues

Intracorporate transportation should be exempt from the Proposed Rule

Under the Proposed Rule, the shipper is required to specify in writing to the carrier all necessary sanitary requirements for the carrier's vehicle and transportation equipment. This information is subject to record retention requirements. For foods that require time/temperature control for safety (TCS) or are subject to microbial spoilage in the absence of temperature control, shippers are required to specify in writing to carriers[5] the temperature conditions necessary during the transportation operation to ensure the food remains safe and does not spoil. FMI believes that imposing these regulatory requirements on intracorporate transportation would not serve to enhance public health, but would impose significant, and unnecessary, regulatory costs.

The Agency defines the terms shipper, carrier and receiver in the Proposed Rule in a manner whereby a single person can play all three roles. In the supermarket industry this is a common occurrence. For example, a retailer may arrange to ship products from their central bakery to a retail owned distribution center or from a distribution center to their corporate owned retail store. In some cases, the vehicles are owned by the company, and in other cases, the vehicles are owned by common carriers under contract with the company. In both instances, the shipper and receiver would be the same entity responsible for loading goods onto trailers from the distribution center or manufacturing facility and for unloading and inspecting products as the receiver. Regardless of whether a third party carrier or a company owned vehicle is used, the retailer retains complete control of the product from the moment it enters the supply chain at the company-owned distribution center to the point of sale. Under proposed § 1.908(d)(2) FDA requires the carrier, and if contractually obligated, the shipper, to demonstrate to the receiver that temperature was maintained throughout the movement of the product. In the situation described above, the shipper and receiver would be the same entity and thus the information transfer requirement is unnecessary.

FMI does not see a public policy justification for regulation of intracorporate transportation. Retailers have no incentive to transport food they purchase or manufacture in a manner which would make it unsafe for their customers or reduce shelf-life. For example, a retailer who ships products from the distribution center to the retail establishment has every incentive to ensure the utmost quality and safety standards. FMI believes that intracorporatetransfers should be exempt from the recordkeeping requirements under the Proposed Rule and subject only to good transportation and sanitation practices. In situations where the shipper and receiver are the same corporate entity and the carrier is under control via a third party contract, FDA

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[5] Except carriers that transport food in a thermally insulated tank.

should require flexible recordkeeping requirements such as submission of standard operating procedures (SOPs) and good sanitation practices.

FDA is contemplating exempting intracorporate imports from the supplier verification requirements of the Foreign Supplier Verification Program Rule. We believe that the Agency should similarly consider such an exemption for intracorporate transportation under the Proposed Rule and ultimately adopt that approach. Doing so would reduce the overall burden of the regulation significantly.

FMI notes that FDA did not impose duplicative recordkeeping requirements on distribution centers and the stores they serve under the Bioterrorism Act of 2002.

FMI strongly believes that FDA should exempt intracorporate transportation from the scope of the Proposed Rule. Of particular concern are the duplicative information transfer and recordkeeping requirements that would be imposed by the Proposed Rule on self-distributing retailers in the absence of such an exemption. In the alternative, FMI suggests the following flexible recordkeeping standards for intracorporate transportation.

(1) Completely exempt intracorporate transportation entirely from the scope of the Proposed Rule; or
(2) Exempt intracorporate transportation from the information transfer and related requirements

Under option 1, FMI suggests the following changes to the regulatory language.

In § 1.904 add a new definition of intracorporate transportation:

Intracorporate transportation means transportation conducted between or among facilities and establishments under the same corporate ownership via a carrier under the same such ownership or a carrier contractually obligated to adhere to the corporate owner's food safety operating procedures using a common supply-chain management system.

And change the definition of transportation operations by adding at the end:

Transportation operations do not include intracorporate transportation.

Under option 2, FMI suggests the following changes to the regulatory language:

In § 1.904 add a new definition of intracorporate transportation:

Intracorporate transportation means transportation conducted between or among facilities and establishments under the same corporate ownership via a carrier under the same such ownership or a carrier contractually obligated to adhere to the corporate owner's food safety operating procedures using a common supply-chain management system.

In § 1.908 add at the end the following:

(e)*Intracorporate transportation*
§ 1908(b)(1), (b)(3), (b)(4), (b)(5), and (D)(1)-(5) do not apply to intracorporate transportation.

Greater clarity is needed as to when food is rendered adulterated under the Proposed Rule

Food that has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, or receiver engaged in transportation operations under conditions that violate the Proposed Rule is rendered adulterated by law6. FMI sees the potential for many circumstances where food is legally adulterated because of a minor violation (i.e. paperwork) of the Proposed Rule, but is not unsafe or otherwise unfit for human consumption. FMI is concerned that this could lead to increased cargo claims and disruptions to the supply chain. Furthermore, we have significant concerns relating to how retailers and wholesalers are to proceed in such circumstances where a minor violation occurs but food is not in reality rendered unsafe or unfit. Must retailers and wholesalers reject the load? Who is responsible for disposing of the product and how is it to be disposed of?

Food waste is a significant concern for the industry and the Agency should be cognizant of this issue in promulgating the Proposed Rule. The Agency should also consider this issue in the context of food that is donated to food banks. According to a 2012 report "Decades of Donations"7, 99% of retailers donate product to food banks. Local grocery stores are a very important part of the food stream for food banks contributing 894 million pounds of food annually.8 If product is considered adulterated because of

6 21 USC §342(i).
7 Food Marketing Institute and Feeding America. 2012. Decades of Donations: The 2012 Survey of the Food Retail Industry's Support of Food Banks.
8 Id.

recordkeeping violations or minor quality variations, this could significantly affect the amount of product that is available to food banks.

FMI requests that food temperature controlled for quality not fall under the same guidelines as food that is temperature controlled for safety

FDA states under proposed § 1.908(a)(3)(iii), that "persons engaged in transportation operations that result in the transportation of non-TCS food subject to microbial spoilage e.g. pasteurized juice, under conditions of inadequate temperature control, would not meet the requirements of proposed § 1.908(a)(3)(iii), and may deem the food adulterated under section 402(i) of the FD&C Act for food transported under conditions not in compliance with the sanitary food transportation regulations." FMI is concerned that the new provision could be interpreted to mean any deviation from temperature specifications results in adulterated food. FMI requests that food temperature controlled for quality not fall under the same guidelines as food that is temperature controlled for safety. The goal, as stated by FDA, is to ensure food is transported in a way that keeps it from becoming adulterated, not less fresh. FDA should recognize that a deviation from the temperature specified by the shipper does not necessarily mean that the food is unsafe for human or animal consumption.

If a food fails to meet a temperature limit for quality, but meets temperature requirements for safety under the FDA Food Code that food should not be considered adulterated. Retailers frequently set stringent quality requirements for food and current industry practices are working well.

FMI furthermore urges the Agency to contemplate issues regarding rejections of produce shipments for quality reasons pursuant to the Perishable Agricultural Commodities Act (PACA)9 in crafting a Final Rule. Under PACA sellers and buyers must legally ship and accept the quantity and quality of produce specified in their contracts. Under PACA, receivers must accept produce that is damaged and decayed up to a certain percentage depending on the product's grade standards. FMI can imagine a situation where a receiver would be required to accept produce under PACA, and would be required to reject it under SFTA for deviation from quality standards set by the shipper.

Temperature requirements should be based on critical limits, rather than operational limits

FMI believes FDA should specify that the requirements under § 1.908(b)(3) for shippers to specify to carriers the temperature conditions necessary during the transportation

9 The Perishable Agricultural Commodities Act ("PACA"), 7 U.S.C. §§ 499a-499t

operation, including the pre-cooling phase, to ensure that the operation will maintain the temperature conditions and ensure that the food will not become filthy, putrid, decomposed, or otherwise unfit for food or become unsafe are critical limits as understood pursuant to a Hazard Analysis and Critical Control Points (HACCP) system. FMI believes this change can be achieved by creating and defining the term “necessary temperature conditions”.

FMI suggests the following change to the regulatory language:

In § 1.904 add a new definition of necessary temperature conditions:

Necessary temperature conditions means critical time/temperature limits, which if breached, are reasonably likely to render a food injurious to health or make it filthy, putrid, decomposed or otherwise unfit for human consumption.

FMI is concerned that failing to provide a clearer meaning of the phrase “temperature conditions necessary” in § 1.908(b)(3) will lead to increased cargo claims and disruptions in the supply chain, particularly because food transported in violation of the Proposed Rule is rendered adulterated. The critical temperatures outlined in the FDA model Food Code serve as a well-established reference for identifying the critical safety limits for food products

The Agency should provide flexibility regarding what constitutes “convenient access” to hand washing facilities in distribution centers

FMI is concerned that this requirement could necessitate the installation of additional sinks in virtually all distribution centers at great cost to the industry. Distribution centers are constructed in a manner with thick concrete floors where installation of new plumbing is very costly and difficult. FMI urges the Agency to not require the addition of new sinks next to delivery bays in distribution centers. Rather, FDA should provide flexibility within the regulation so hand washing facilities located away from bay doors can meet this requirement. In addition, FMI notes that in supermarket distribution centers, vehicle operators very rarely ever directly touch unpackaged food. FDA should further clarify the term “handle.” Does it mean directly touch a food, or merely pick up a box or carton with unpackaged food inside of it? FMI believes the Agency should define “handle” to mean directly touch a food, rather than merely touch a vented box or crate holding unpackaged food inside.

FMI supports the waiver FDA is proposing to issue concurrently with the final rule exempting food establishments when they are engaged in certain activities

FMI strongly supports the waiver FDA is proposing to issue concurrently with the final SFTA rule to exempt food establishments holding valid permits only when engaged in transportation operations as receivers, or as shippers or carriers in operations in which food is relinquished to consumers after transportation from the establishment. The Food Code waiver will exempt the vast majority of retail supermarket establishments even if such establishments engage in home delivery services. This waiver will significantly reduce the burdens of the Proposed Rule on the supermarket industry.

FMI urges FDA to contemplate that home grocery delivery services may also originate from distribution centers. Under these circumstances the transportation of the food from the distribution center to the consumer would be regulated under the Proposed Rule (i.e. subject to the requirements for a carrier); however, there would be no receiver for purposes of the Proposed Rule. The definition of receiver explicitly excludes consumers. FDA should craft the final SFTA rule in such a manner as to not create unnecessary regulatory challenges for home grocery deliveries originating at locations other than food establishments.

Greater clarity is needed as to the applicability of the Proposed Rule to foreign exporters

FDA states in the preamble of the Proposed Rule that the rule applies to foreign exporters who ship food to the U.S. in an international freight container by oceangoing vessel or in an air freight container, and arrange for the transfer of the intact container in the U.S. onto a motor vehicle or rail vehicle for transportation in U.S. commerce, if that food will be consumed or distributed in the U.S. The Agency further states that if the shipper fails to comply with the requirements of the Proposed Rule, and FDA determines that food shipped to the U.S. by that shipper may as a result be adulterated, such shipments of food would be subject to refusal of admission when offered for entry into the U.S.

FMI seeks further clarity regarding the applicability of the Proposed Rule to foreign inland transportation. FDA has made clear that the foreign inland transporter is not regulated as a carrier under the Proposed Rule; however, if the necessary temperature conditions the shipper has communicated to the U.S. carrier are violated by the foreign inland carrier is the food rendered adulterated by law? Does the foreign shipper have any obligations to communicate to foreign inland carriers necessary sanitary requirements for vehicles and transportation equipment or temperature conditions for

foods? Are foreign shippers subject to the requirements of SFTA as applied to the packing of containers in certain circumstances?

FMI supports the Agency's position that food transporters routinely safely transport food and non-food items in the same load

FDA stated that the transportation of food and non-food items in the same load can be safely accomplished as long as appropriate practices, such as those that the industry has developed to ensure that food is adequately protected from contamination by non-food items on the same load, are consistently followed.

Current supermarket industry practices have proven to be very effective in maintaining the freshness and cleanliness of foods. FMI appreciates that the Agency has granted the industry the flexibility to continue its practices—which are working well. Any requirement to segregate foods from nonfoods would have been tremendously costly to the industry and led to higher prices for consumers. Such a requirement would have resulted in the wasting of vast quantities of fuel, excessive wear and tear on trucks, and a needless increase in greenhouse gases.

FMI disagrees with an exemption for non-covered business

FDA is not statutorily required to provide an exemption from the Proposed Rule for small businesses as it has done in completely exempting non-covered business.10 FDA has defined a non-covered business as a shipper, receiver, or carrier engaged in transportation operations that has less than $500,000 in total annual sales. This exclusion is not science or risk-based and as FDA notes in the supplementary information provided as part of the ANPRM on SFTA issued in April 2010, "most of the specific instances where food transportation problems were found involved small box trucks and transporters of ethnic food; there were "little or no areas of concern" identified with larger (semi-tractor-trailer) trucks inspected during the survey. Under FDA's proposed exemption many operators of these small box trucks and transporters of ethnic food would be exempt.

Similarly, FMI notes that there are no size exemptions for cGMP requirements for manufacturers or warehouses. FMI believes the exemption is inconsistent with the risk-based approach under FSMA.

As crafted the Proposed Rule imposes interdependent obligations on the shipper and carrier. FMI seeks clarification on the expectations when some entities involved in transportation are exempt while others are covered. For example, what would be the

standard if a shipper is exempt, but the carrier and receiver are subject to the Proposed Rule?

FDA should exempt short haul transportation from the Proposed Rule

FDA should develop modified requirements for short-haul shipments in the Proposed Rule. In FDA's Fish and Fishery Products Hazard and Controls Guidance Document, in-transit temperature recording is not required for products that have been transported for 4 hours or less.[11] FMI encourages FDA to exempt or establish modified requirements for short-haul transportation under 4 hours where temperature fluctuations are unlikely to affect the safety of the product. Modified requirements for short-haul transportation is consistent with FDA's current Seafood HACCP requirements and would reduce the overall regulatory burden on industry.

Inspections and enforcement should be clear and consistent

FDA has indicated they will work with the Department of Transportation, the United States Department of Agriculture and State agencies on inspections and enforcement of the regulation and to establish procedures for transportation safety inspections. How will FDA coordinate across multiple agencies? FMI strongly suggests making inspection criteria clear and transparent so that the regulation is implemented and enforced consistently across jurisdictions. We appreciate the willingness of the agency to work with the wide range of stakeholders and regulated industries on this proposed regulation in order to develop a final rule that is consistent with the law and protects public health. We welcome the opportunity to comment on this important matter. If you have questions about these comments or would like additional information, please feel free to contact Stephanie Barnes at sbarnes@fmi.org or 202-220-0614.

Sincerely,

Stephanie Barnes
Regulatory Counsel

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