



July 30, 2014

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

**Re: Docket No 2013–N–0013 and RIN 0910–AG98, Food and Drug Administration; Sanitary Transportation of Human and Animal Food; Proposed Rule; 79 *Fed. Reg.* 7006 (Feb. 5, 2014).**

Dear Sir/Madam:

The American Meat Institute (AMI) and the North American Meat Association (NAMA) (hereinafter the organizations) respectfully submit the following comments concerning the above-referenced proposed rule.

AMI is the nation's oldest and largest meat packing and processing industry trade association. AMI members slaughter and process more than 90 percent of the nation's beef, pork, lamb, veal, and a majority of the turkey produced in the United States. In addition, some AMI members operate beef facilities in Brazil, Australia, and Canada, and many members import beef. Finally, approximately 80 percent of AMI member companies are small or very small based on Small Business Administration standards.

Organized in 1942 NAMA is a trade association with more than 400 member companies in the United States, Canada, and Mexico, representing every segment of the meat industry. Since its inception NAMA has provided its members with regulatory advocacy, educational opportunities, and informational resources. NAMA members have a profound interest in safe transportation of the products they produce.

The safety of the meat and poultry products the organizations' members produce is their top priority. Failing to transport food safely negates the extraordinary measures that meat and poultry companies employ to produce safe food and undercuts consumer confidence in those products. Because the meat and poultry industry already implements robust practices related to the safe transportation of food, any final rule should mirror current industry practices.

The Food and Drug Administration's (FDA or the agency) proposed rule (the proposal) would directly affect Food Safety and Inspection Service (FSIS) inspected establishments by imposing new and unnecessary regulations upon those facilities and the carriers with which they work. For that reason, the organizations have a vested interest in the above-referenced proposed rule and submit the following comments.

**There is No Demonstrated Food Safety Problem Related to the Transportation of Food.**

It is well established there are no systemic food safety issues related to the sanitary transport of food. Indeed, FDA is unable to quantify the benefits from the proposed rule.<sup>1</sup> Although there have been isolated occurrences of food safety issues related to food transportation, such occurrences are rare, limited in scope, and do not justify the proposed prescriptive and rigid requirements. In fact, the preamble to the proposal cites only one instance in which a foodborne illness was epidemiologically attributed to food transportation and that incident occurred more than 20 years ago. The four other instances of food being transported under potentially unsanitary conditions were never linked to a specific foodborne illness.<sup>2</sup> In short, one incident that borders on ancient history and a handful of other incidents with no connection to foodborne illness does not justify the burdensome changes proposed.

FDA relies on the findings of the Interstate Food Transportation Assessment Project to support the proposal.<sup>3</sup> This study thoroughly analyzed the state of food safety practices for in-transit food in interstate commerce and found that large semi-trailer trucks are of little concern with respect to food safety. Yet, the proposal would require additional practices for semi-trailer trucks, imposing additional and unnecessary costs. In short, FDA has proposed a solution in search of a problem.

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<sup>1</sup> 79 *Fed. Reg.* at 7007 (“[FDA] lack[s] sufficient data to quantify the potential benefits of the proposed rule” and, “[FDA is] unable to estimate the effectiveness of the requirements of the proposed rule to reduce potential adverse health effects in humans or animals.”).

<sup>2</sup> 79 *Fed. Reg.* at 7007

<sup>3</sup> *Id.*

## **The Food and Drug Administration Lacks Jurisdiction over Federally Inspected Meat and Poultry Establishments.**

Through the proposal, FDA seeks to impose new regulatory requirements on federally inspected establishments that produce meat and poultry products. FDA's own policies, however, preclude the agency from promulgating such regulations.

FDA Compliance Policy Guide Section 565.100 discusses the scope of the agency's jurisdiction regarding meat and poultry.<sup>4</sup> Specifically, section 565.100 provides, in pertinent part, that

With respect to adulteration and misbranding, Section 902(b) of the Federal Food, Drug, and Cosmetic Act states meat and meat products are exempt to the extent they are covered by the Meat Inspection Act. This had been construed since 1938 as meaning that USDA has exclusive jurisdiction up to the time a meat or meat product leaves a USDA inspected plant. Thereafter, FDA asserts its jurisdiction which, until 1967, was also exclusive. The Wholesome Meat Act of 1967 extended USDA jurisdiction over meat and meat products beyond the plant, to include their subsequent adulteration and misbranding (comparable to FDA jurisdiction over all other foods). ... In an opinion letter dated August 17, 1972 to the Secretary of Agriculture, the Attorney General has set out the legislative history showing that Congress intended to give USDA and FDA concurrent jurisdiction over misbranding and adulteration of meat products after inspection.<sup>5</sup>

Section 565.100 provides a stark delineation of where FDA's purported jurisdiction begins with respect to meat and poultry. Although FDA asserts concurrent jurisdiction over such products in interstate commerce, USDA has "exclusive jurisdiction up to the time a meat or meat product leaves a USDA inspected plant." The proposed rule suggests that failure to comply with the proposed regulatory requirement could render a product adulterated. But FDA lacks jurisdiction over meat and poultry products until those products leave the plant. For that reason, although FDA may be positioned to impose requirements on the carrier as it transports a food product and receivers of that product FDA cannot promulgate regulations imposing requirements on federally inspected establishments where the product originates nor can FDA impose requirements on the receiver if it is a federally inspected establishment.

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<sup>4</sup> <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074588.htm>

<sup>5</sup> *Id.* (Emphasis added.)

**This New Layer of Regulation is Unnecessary for the Meat and Poultry Industry.**

Even if FDA can assert jurisdiction the proposal is unnecessary for the meat and poultry industry for several reasons. First, federally inspected meat and poultry establishments are already subject to regulations developed and administered by FSIS and those regulations apply to the transportation of meat and poultry products. FSIS regulations, 9 CFR Part 325 and 9 CFR Part 381, Subpart S, address many transportation issues unique to meat and poultry products. In addition, FSIS has a regulation that is directly on point for purposes of the proposal. Specifically, 9 CFR 416.4(d) establishes a performance standard providing that:

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

This language is intentionally general and allows necessary flexibility to regulated establishments. Indeed, less than eight months ago FSIS affirmed that it intended not to be prescriptive with respect to ensuring that product is not adulterated during shipment. Responding to an askFSIS question FSIS stated:

“Are there any specific procedures that must be used to protect product during storage and shipment?”

No. Product should be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation by the official establishment. The regulation in 9 CFR 416.4(d) is not prescriptive; thus the establishment decides what procedures it will follow to meet the performance standard.”<sup>6</sup>

Although not prescriptive, that lack of specificity does not obviate an establishment’s obligation to ensure the sanitary condition of the product during transportation.

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<sup>6</sup> [http://askfsis.custhelp.com/app/answers/detail/a\\_id/108/~protection-of-product-during-storage-and-transport](http://askfsis.custhelp.com/app/answers/detail/a_id/108/~protection-of-product-during-storage-and-transport). “Protection of Product During Storage and Transport,” Updated December 18, 2013.

In addition, the FSIS Hazard Analysis and Critical Control Point (HACCP) regulations impose a duty on federally inspected establishments to conduct a hazard analysis, which

shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.<sup>7</sup>

Through this provision FSIS compels inspected establishments to consider and address the hazards that could present themselves even after the inspected product leaves the facility – including hazards presented during loading, transport, and unloading of the product.<sup>8</sup>

As a means of complying with the FSIS existing regulatory requirements, the meat and poultry industry, working as part of and with the food transportation industry, developed guidelines and best practices addressing the issues identified by FDA, including vehicle dedication and cleaning, the cold chain, loading and unloading, training, and record keeping. Records kept by meat and poultry companies include vehicle inspection and wash records, loading records, seal verification records, bill of lading verification records, employee training records, and audit reports.

Measured against the long-standing regulatory requirements established by FSIS, FDA's own analysis of the limits of its jurisdiction, and the industry's compliance with same regarding the safe transportation of meat and poultry products FDA offers the proposed rule but is unable to quantify in a meaningful way any benefits the proposal, if finalized, would afford to consumers or the industry, particularly the meat and poultry industry. Indeed, in the preamble to the proposal FDA states

We lack sufficient data to quantify the potential benefits of the proposed rule. The causal chain from inadequate food transportation to human and animal health and welfare can be specified but not quantified. Because no complete data exists to precisely quantify the

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<sup>7</sup> 9 CFR 417.2(a)(1).

<sup>8</sup> For example, in September 2005 FSIS published the Meat and Poultry Hazards and Controls Guide, which identifies hazards along the production and distribution chain. See page 28. [http://www.fsis.usda.gov/wps/wcm/connect/3cd0a6a5-fcff-4809-a298-030f3cd711a9/Meat\\_and\\_Poultry\\_Hazards\\_Controls\\_Guide\\_10042005.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/3cd0a6a5-fcff-4809-a298-030f3cd711a9/Meat_and_Poultry_Hazards_Controls_Guide_10042005.pdf?MOD=AJPERES)

likelihood of food becoming adulterated during its transport, we are unable to estimate the effectiveness of the requirements of the proposed rule to reduce potential adverse health effects in humans or animals.<sup>9</sup> (Emphasis added)

This admission calls into question not only the prescriptive nature of the proposal but the necessity of the proposal at all, and certainly with respect to products and practices already regulated by FSIS.

**The Economic Analysis is Lacking and Underestimates the Proposed Rule's Cost.**

The proposed rule is estimated to cover nearly 84,000 entities, a number that includes carriers engaged in food transportation and food and animal facilities. There are more than 50 million truck-related food shipments annually as well as more than 3 million railcar loads of food. The implementation costs almost certainly will exceed FDA's \$1,784 per firm estimate. In addition, FDA's recurring cost estimate of \$360 per firm also is low.

But costs of the rule are not limited solely to food transportation because the costs are not limited to the number of moving units that will be regulated. The costs also will be incurred at the points of origin and destination of the product.

The proposal's approach to temperature control is not aligned with current industry practices and has significant cost implications. Currently, it is not a routine practice for carriers to demonstrate to shippers (or receivers) that the shipment met the shipper's temperature requirements. Rather, such records generally are only provided if there is an indication of a problem (*i.e.*, signs of temperature abuse) upon receipt of the load.

The proposal would require that "transportation equipment used for the transport of food that can support the rapid growth of undesirable microorganisms must be equipped with an indicating thermometer, temperature-measuring device or temperature-recording device so installed as to show the temperature accurately within the compartment."<sup>10</sup> Moreover, proposed section 1.908(d)(2)(i) provides that the carrier's demonstration can be provided through methods "such as the carrier presenting printouts of a time/temperature recording device or a log of temperature measurements taken at various times during the shipment."<sup>11</sup>

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<sup>9</sup> 79 *Fed. Reg.* 7007, (Feb. 5, 2014).

<sup>10</sup> Proposed section 1.906, 79 *Fed. Reg.* at 7034-35.

<sup>11</sup> Proposed section 1.908, 79 *Fed. Reg.* at 7035-36.

There are many different methods for monitoring and recording temperatures during shipment. Those methods range from very sophisticated to more manual methods of temperature monitoring and recording. All methods, however, involve some costs and challenges and requiring routine demonstration of temperature records could be unrealistic and costly in addition to being unnecessary to ensure food safety.

If the intent of the proposal is to require the carrier to routinely demonstrate compliance with the shipper's temperature requirements during transportation, then many, if not most, carriers will need to purchase new equipment and implement new systems so this information can be retrieved in a timely manner. Those purchases will have a significant impact on the proposal's implementation costs. In the Preliminary Regulatory Impact Analysis (PRIA), FDA estimated the implementation costs of equipment associated with the proposed temperature provision in section 1.906(d) and that cost was \$14.25.<sup>12</sup> This estimate cannot include any type of automated device that measures and records time versus temperature data.<sup>13</sup>

In addition, FDA apparently assumed that only one percent of the refrigerated trucks subject to the rule would need to be equipped with temperature monitoring devices based on the assumption that 99 percent of the trucks already have devices that enable the carrier to demonstrate adherence to the shipper's temperature specifications. Currently, the majority of carriers only provide temperature data in cases where temperature abuse is suspected. The reality is that if routine demonstration of temperature compliance is required, more than one percent of the industry would most likely have to upgrade their systems and methods of gathering temperature data so this information could be more easily accessed and downloaded in a timely manner. Although most carriers have temperature data on temperature controlled shipments, this data is not readily available and easily retrievable without incurring significant costs and burdens.

In addition to implementation costs, the proposal would impose recurring costs on the industry and FDA's estimates of those costs are significantly under-valued. Specifically, routine and continuous temperature monitoring, coupled with demonstrating such monitoring, is required for temperature controlled shipments, significant recurring costs would be incurred. Indeed, one large meat and poultry

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<sup>12</sup> See Preliminary Regulatory Impact Analysis at 33.

<sup>13</sup> A basic thermometer with no recording device attached would require the use of manual recording of temperature during transit to demonstrate adherence to proposed section 1.908(d)(2)(i), which is not practical. Unless the thermometer was connected to a readout device inside the truck cab or on the outside of the trailer, manually measuring the temperature inside the container would require the driver to stop the truck and enter the container to obtain each measurement. Additionally, the seal on the container would have to be broken, creating a food defense concern. In addition, by opening the container for a manual temperature measurement, the controlled air inside the container would be released to the environment which contrary to the goal of maintaining and controlling the temperature of the shipment.

processor conservatively estimated that its annual recurring costs will exceed \$2 million. In another example, a large domestic carrier of refrigerated foods calculated the cost of maintaining telematic devices to be approximately \$793,800 annually.<sup>14</sup> Although all of this carrier's containers are equipped with telematic devices for temperature monitoring, that is not the industry standard. It is not the norm that containers are equipped with telematic devices for purposes of demonstrating continuous adherence to temperature specifications. Rather, if temperature abuse is suspected, the temperature data is manually downloaded from the refrigeration unit, typically by a third party provider, with the cost per data download per shipment estimated at \$50-150.

Not only are there direct costs associated with downloading the data, but conducting that exercise would remove the trailer/container from service for several hours so the data can be downloaded by a third-party, also adding costs. Removing a container from service, even for a few hours, disrupts the supply chain and adds cost with respect to labor, lost efficiency, lost revenue for both the company and the driver, and delays in delivering the product to the customer.<sup>15</sup> None of these cost factors appear to have been part of the PRIA.

Given the absence of meaningful evidence linking temperature deviations during transportation and foodborne illness outbreaks and because routine demonstration of continuous temperature monitoring has significant financial and economic implications that were not adequately considered in the PRIA this provision should not be included in any final rule.

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<sup>14</sup> The cost of telematic devices, which continuously monitor, record and transmit temperature data, not only involves the initial cost of the equipment but also the recurring monthly cost of the data plan since telematics involve data sent and received through Wi-Fi and cellular signals. The carrier quoted a data fee per telematic device per container of approximately \$9.45 per month. This particular carrier currently operates approximately 7,000 refrigerated trailers/containers.

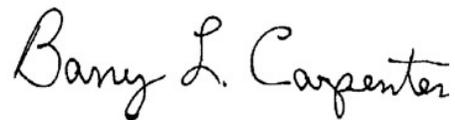
<sup>15</sup> If trucks and the corresponding cargo has to be removed from service so that temperature data can be manually downloaded from the microprocessor of the unit, this will result in an increased time that product reaches the consumer or end-user. Hence, this process can result in back-orders in the supply chain.

**Summary**

The absence of epidemiological data linking transportation to foodborne illness outbreaks suggests strongly that the sanitary transportation practices compelled by FSIS through the existing regulatory requirements applicable to the meat and poultry industry ensure that meat and poultry products remain safe while in transit. Accordingly, there is no need or reason to impose on the industry an additional, prescriptive set of regulatory requirements. For the foregoing reasons FDA should exempt federally inspected establishments from the proposed regulations.

AMI and NAMA appreciate the opportunity to submit these comments. If you have any questions regarding these comments or anything else regarding this matter, please contact Mark Dopp at (202) 587-4229 or [mdopp@meatami.com](mailto:mdopp@meatami.com) or Barry Carpenter at (202) 640 5323 or [barry@meatami.com](mailto:barry@meatami.com).

Respectfully submitted,



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