VIA MAILING

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


Dear Sir/Madam:

The U.S. Chamber of Commerce (the “Chamber”), the world’s largest business federation representing the interests of more than three million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations, and dedicated to promoting, protecting, and defending America’s free enterprise system, is pleased to submit these comments to the Food and Drug Administration (FDA) regarding the proposed rule titled “Sanitary Transport of Human and Animal Food,” FDA Docket Number FDA-2013-N-0013.

The FDA has initiated this proposed rule to adopt regulations for the sanitary transport of human and animal food in order to ensure that food is transported in a sanitary manner. FDA is proposing this rule as part of their implementation of the Food Safety Modernization Act (FSMA). Many of the Chamber’s members are directly involved in the transport of human and animal food and have a strong interest in this proposed rule being implemented in an efficient and effective manner and to ensure that it will not negatively impact commerce.

Specifically, the Chamber’s concerns with the proposed rule involve (1) Concern over Potential Increase in Cargo Claims, (2) Parts of the Proposed Rule
should be Withdrawn and Repurposed, and (3) Errors and Omissions in FDA’s Economic Impact Analysis.

Background

FSMA was signed into law by President Obama on January 4, 2011, to better protect public health by helping to ensure the safety and security of the food supply. FSMA is the statutory basis for the Proposed Rule on Sanitary Transport of Human and Animal Food. FSMA marks the most sweeping change to our nation’s food safety laws since the enactment of the Federal Food, Drug and Cosmetic Act of 1938. FSMA passed with the support of a broad coalition of retailers, producers, and non-governmental advocacy organizations and reflects Congressional intent that administrative flexibility and innovation must be the cornerstones for modernization of the United States food safety regulatory system. The Chamber was supportive of and successfully advocated for passage of FSMA. The Chamber seeks to ensure that FSMA rules are efficient, effective, and within the authority delegated by Congress. Therefore, the Chamber’s comments include constructive criticisms aimed at making improvements to this proposed rule.

On February 5, 2014, FDA published in the Federal Register the proposed rules titled “Sanitary Transport of Human and Animal Food.” FDA’s proposed rule marks the first time that FDA has developed regulations that would govern the sanitary transportation of human and animal food. The proposed rule is the last one of five proposed rulemakings that would lay the cornerstone of a prevention-based, modern food safety system.

The proposed Sanitary Transport of Human and Animal Food rule would establish 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 transportation practices to ensure the safety of food they transport. The goal of the proposed rule is to ensure that transportation practices do not create food safety risks.

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1 P.L 111-353 (2011)
I. Concern Over Potential Increase in Cargo Claims

Motor carriers assume strict liability for the goods they move. Under current law motor carriers are held to the highest legal standard applicable under a bailment agreement/contract.

Under our current system the burden is on the claimant to prove the cargo was damaged during transit prior to liability being imposed on the motor carrier. Most courts have held that a suspicion or unproven belief that damage has occurred does not meet the requirement necessary to establish proof of damage.

The proposed rule directly links failure to adhere to shipper defined standards with adulteration/damage. No longer is the claimant required to prove that the cargo is actually damaged. The claimant would only be required to prove a shipment was not maintained relative to a specified standard.

The proposed rule section 1.902 (a) states:

“Proposed § 1.902(a) would provide that the criteria and definitions of this subpart apply in determining whether food is adulterated within the meaning of section 402(i) of the Federal food, Drug, and Cosmetic Act in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, or receiver engaged in the transportation of food under conditions that are not in compliance with this subpart.

This section clearly states that the shipper is to establish the standard of care with the motor carrier, and under the proposed definition of adulteration, if the motor carrier has not transported the shipment within the specifications outlined by the shipper, the food should be classified as adulterated.

For example, a shipper contracts with a motor carrier for transportation of a full truckload of avocados. The shipper provides instructions to the motor carrier that the full truckload temperature be at 33 degrees during transit. Once the motor carrier delivers the shipment to the consignee and it is tested/probed in multiple places, a couple of readings show 33.5 – 36 degrees. Currently, the burden of proof
to prove damage falls on the claimant, and, in this example, it is unlikely to result in a full claim for the entire load of avocados worth approximately $25,000.

Moving forward and applying the proposed rule to this example, if the temperature in the shipment did register readings above the shipper-specified 33 degrees, then, it is the Chamber’s understanding that the entire load would be declared adulterated regardless of if any spoilage occurred or not.

This proposed rule could dramatically increase the amount of discarded and wasted food. In this day and age we need to ensure that we are not wasteful of food.

It is unclear whether the proposed rule accurately captures FDA’s intent with regards to freight cargo claims. If this is not the case, then FDA needs to clearly and concisely articulate in the proposed rule how this proposed rule will impact freight cargo claims in regards to loads that vary from shipper instructions. The Chamber strongly requests that FDA clarify that this rule does not change nor alter the current cargo claims structure and does not create needless food waste.

II. Parts of the Proposed Rule should be Withdrawn and Repurposed

A. Small Company Exemption

The proposed rule contains an exemption for any shipper, receiver, or carrier engaged in food transportation operations that does less than $500,000 in total annual sales. This exemption is concerning. According to American Trucking Associations, 90.2% of licensed motor carriers operate six or fewer trucks. Therefore, it is likely that as much as 90.2% of the U.S. shipping fleet would be exempted under the proposed rule. Thus, this exemption could potentially cripple 90.2% of the shipping fleet because shippers will use carriers that are compliant with the proposed rule. FDA is drastically shrinking shipping options for no apparent logical reason. The Chamber’s members will be negatively impacted if the shipping fleet is reduced. It’s not clear if this is FDA’s actual intent.

Furthermore, if food safety is the true goal of this proposed rule, then the size of the company should be irrelevant when addressing sanitary transport. FDA’s
approach should be a uniform standard that is risk based. The Chamber supports the legislative intent of the FSMA but, FDA’s proposed rule deviates substantially from Congressional intent.

**B. FDA Should Exempt Alcohol Beverage Facilities That Dispose of Their Spent Grain at Local Farms**

FDA should clarify that they will exempt alcohol beverage facilities that dispose of their spent grains with local farms. Most alcohol beverage facilities either sell or give away at no cost their spent grains to local farms. These local farms use the spent grains as feed for their livestock. The use of spent grains by farmers is a very low risk activity. This arrangement has been mutually beneficial for both the farmers and the brewers.

This is a true recycling success story that FDA needs to encourage and not disrupt. If the alcohol beverage facilities are unable to send their spent grains to local farms, they will most likely have to landfill these materials. This wastes not only a valuable food source but also takes up valuable landfill space.

Under FDA’s proposed rule it could be interpreted that these facilities will have to package their spent grains in accordance with this complex proposed rule and be subject to additional recordkeeping requirements. These actions would impose additional costs without adding value for food safety.

FDA should provide a clear exemption in the final rule that clarifies this issue.

**III. Errors and Omissions in FDA’s Economic Impact Analysis**

The regulatory impact analysis of economic costs and benefits on which FDA’s selection of the proposed rule elements is based is inadequate. The FDA’s estimates of compliance cost of $149.1 million in the initial year and $30.1 million in subsequent years is based on incomplete or erroneous data. FDA relies on assumptions that bias its cost calculations downward.

When a key cost parameter is unknown, good economic analysis practice is to present estimates based on a range of plausible values. Instead, FDA has repeatedly chosen to fill unknown cost parameters with the lowest possible value and failed to
offer reasoning to establish that such value is even remotely plausible. The result is a compliance cost estimate that is likely only a small fraction of the realistic compliance cost for the administratively burdensome regulatory approach proposed.

**A. Concerns With New Paperwork and Record Keeping**

The proposed rulemaking imposes on the existing system of food transportation safety practices a new set of paperwork and recordkeeping burdens without any demonstration that such “red tape” will yield any measurable benefit. FDA’s own Preliminary Regulatory Analysis report admits that “we do not anticipate large scale changes in practices as a result of the requirements of this proposed rule in part because we understand much of the proposed rule to reflect current industry practice.” Thus, FDA recognizes that shippers already routinely and reliably inspect vehicles for cleanliness and appropriate cooling before food cargoes are loaded and provide carriers with instructions regarding temperature requirements, carriers already clean equipment between trips and monitor refrigerated units to ensure maintenance of the proper “cold-chain” conditions during transit, and receivers already routinely inspect cargoes during unloading to confirm cleanliness, to discover any cross-contamination of products, and to confirm that temperature requirements have been observed during transit.

The new elements in the proposed rule are the requirements that shippers, carriers, and recipients engage in a process of written communication, documentation and recordkeeping to document these practices. The cost burden of the proposed rule arises almost entirely from the addition of these “red-tape” requirements to provide a “paper-trail” to prove that shippers, carriers and receivers have done those things that they already engage in.

The result is a proposed rule which is likely to add costs without commensurate benefits, and this is largely why FDA has provided no quantitative analysis of the benefits of the proposed rule: There are none. Indeed, the rudimentary qualitative discussion by FDA admits that the benefits, if any, are likely to be small and much smaller than the costs. FDA should conduct experimental research to evaluate the extent, if any, to which requirements to document vehicle cleaning, provision of temperature requirements information, and temperature tracking logs increases the

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probability that safe practices have been observed and reduces the incidence of food
borne illness.

**B. Concerns with the Unfunded Mandate Impact**

FDA’s analysis of the unfunded mandates impact of its proposed rule on state,
local and tribal governments is particularly inadequate. FDA merely asserts without
detail or rationale that the impact will exceed the current threshold of $141 million to
trigger the analysis requirements of the Unfunded Mandates Act. FDA fails to
conduct the actual analysis required under the Act to identify the particular cost
burdens that state, local and tribal governments will be mandated to absorb in their
budgets if the proposed rule is adopted. A proper analysis in response to the
Unfunded Mandates Act should identify detailed, specific types and amounts of costs
that will be imposed on specific state, local, or tribal government entities.

**C. Concerns With Economic Loss Associated With Food Shipments**

Another issue that FDA has failed to address in its regulatory impact analysis
involves the economic loss associated with food shipments that are deemed to be
adulterated and, therefore, unfit for human (or animal) consumption. Under current
practice, food shipments for which temperature control has failed may be evaluated to
determine whether some safe salvage use may be made. The proposed rule would
effectively outlaw this current practice. FDA should include as an element of the
cost of the proposed rule the economic value of food product that is currently
salvaged but that would be lost under the proposed rule.

FDA has not considered the impact of the proposed rule on food prices,
nutrition, and employment. The proposed rule may have adverse impacts across each
of these dimensions.

The flaws in the economic regulatory impact analysis presented by FDA for
this proposed rule are so pervasive and significant that FDA should withdraw the
current proposal, conduct a new analysis of alternative regulatory approaches’ costs
and benefits, and reconsider its regulatory approach to the proposed rule based on
better research, data and analysis.
Conclusion

The Chamber hopes that FDA will address and correct the issues we have raised and thanks you for allowing us to offer our input on your proposed rule for the Sanitary Transport of Human and Animal Food. I may be reached at (202)463-5533 or wkovacs@uschamber.com.

Sincerely,

William L. Kovacs