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

RE: Docket No. FDA–2013–N–0013
Proposed Rule: Sanitary Transportation of Human and Animal Food

The National Grain and Feed Association submits this statement in response to the Food and Drug Administration's (FDA) proposed regulations, published in the February 5, 2014 edition of the ***Federal Register***, to implement the sanitary transportation provisions of the Food Safety Modernization Act by establishing requirements for shippers, carriers and receivers of truck and rail shipments of human and animal food.

The NGFA, established in 1896, consists of more than 1,050 grain, feed, processing, exporting and other grain-related companies that operate more than 7,000 facilities and handle more than 70 percent of all U.S. grains and oilseeds. Its membership includes grain elevators; feed and feed ingredient manufacturers; biofuels companies; grain and oilseed processors and millers; exporters; livestock and poultry integrators; and associated firms that provide goods and services to the nation's grain, feed and processing industry. The NGFA also consists of 26 affiliated State and Regional Grain and Feed Associations, and has strategic alliances with Pet Food Institute and North American Export Grain Association.

The NGFA strongly supports private-sector initiatives and government policies designed to protect the safety of food, feed and agricultural products, and embodies that commitment in the Association's Mission Statement.[1]

The NGFA was involved extensively during the development and consideration by Congress of legislation that resulted in enactment of the Food Safety Modernization Act (FSMA). As such, we provided frequent input and specific legislative language on provisions of FSMA that are the subject of this FDA request for comments, and supported the prevention-, science- and risk-based principles it embodies. The NGFA also joined with the American Farm Bureau Federation and American Meat Institute to help lead a broad-based group of nearly 30 agricultural producer and agribusiness organizations that provided input during the legislative process.

[1] NGFA Mission Statement: 2012. "The NGFA actively promotes a global free-market environment that produces an abundant, safe and high-quality supply of grain, feed, feed ingredients and other grain- and oilseed-based products for consumers. The NGFA focuses on member interests through advocacy, representation, training, education and communication to members, the public and government."

We commend FDA for the extensive public outreach it has undertaken in advance of proposed rulemaking to implement the various provisions of this ground-breaking statute, including the sanitary transportation provisions that are the subject of this rulemaking. We appreciate the time and effort FDA is expending to host public meetings, speak at meetings hosted by public- and private-sector organizations, and conduct smaller group meetings to solicit a wide range of stakeholder input. Such outreach, we believe, is essential to implementing this complex and far-reaching law in a manner that further enhances what already is a safe and wholesome human and animal food supply, without adding unnecessary regulatory burdens and costs that would undermine the industry's ability to provide an abundant and affordable food supply to U.S. and world consumers.

The NGFA previously has submitted several sets of comments with respect to predecessors of this rulemaking, which involved proposals from the U.S. Department of Transportation (DOT) and FDA regarding implementation of the Sanitary Food Transportation Act of 1990 and its successor statutes. Specifically, the NGFA previously submitted comments in October 1993 and January 2005 in response to DOT rulemakings, as well as in August 2010 in response to FDA's advance notice of proposed rulemaking regarding implementation of the Sanitary Food Transportation Act of 2005.

The NGFA has participated actively in the public meetings FDA has hosted concerning implementation of the hazard analysis and risk-based preventive controls provisions of FSMA. And in response to requests for information, the NGFA previously has submitted extensive comments to the agency on implementing the requirements under FSMA that registered facilities identify, evaluate and develop written analyses of "known or reasonably foreseeable hazards" and identify and implement controls to "significantly minimize or prevent" the occurrence of such hazards that could cause human and animal food to be adulterated or misbranded.

The industry segments within the NGFA's membership recognize the paradigm shift FSMA represents in terms of placing the principal focus on prevention of hazards that can pose a risk to human or animal health. The law also codifies a fundamental principle that the grain, feed and grain processing industry has long held – that the industry bears the principal responsibility for producing and distributing safe products.

In that regard, the NGFA in 1994 developed a comprehensive Model Feed Quality Assurance Program, the first such program to be developed by an industry trade association for the commercial feed industry. This program, which is based largely upon good manufacturing practices, has been expanded and updated periodically during ensuing years, and includes a distinct section containing sample feed shipment and delivery best practices to protect the safety of feed and feed ingredients. Included are sample preloading procedures to ensure the conveyance is clean and suitable for transporting feed; loading procedures; delivery procedures at customers' sites; and cleanout procedures for conveyances when warranted, prior to hauling another load.

The NGFA also has engaged in a proactive education/training program for the industry on how to implement the practical and effective steps contained in the model program, including those pertaining to transportation conveyances. These have included more than 20 educational

workshops in all regions of the country that have attracted more than 800 attendees from commercial feed manufacturing and feed ingredient establishments. Participants in the NGFA's Model Feed Quality Assurance Program include large and small medicated and non-medicated feed manufacturers, integrators and allied industries. As part of this ongoing effort, the NGFA followed up in 2000 by producing four feed quality assurance videos to enhance education and training on the model program. In 2010, it launched the first feed industry trade association web-based feed quality assurance program, a self-paced education and training program consisting of six segments, each of which includes a learning-assessment quiz to enable participants and managers to determine the level of knowledge retained.

Further, in 2001, the NGFA established an Animal Protein Transportation Task Force that also consisted of representatives from the National Renderers Association, Association of American Railroads, the Agriculture Transportation Conference of the American Trucking Associations and the National Oilseed Processors Association (NOPA) to develop voluntary best management practices for use by transporters and the feed industry in complying with FDA's regulations designed to prevent the establishment or amplification of BSE in the United States. Those voluntary best management practices, issued in 2002, became the basis for a subsequent video produced by FDA in cooperation with the NGFA and other organizations to provide guidance to transporters on BSE regulatory compliance.

In addition, in early 2004, the NGFA worked with three other organizations – NAEGA, NOPA and the Canadian Oilseed Processors Association – to develop voluntary best management practices to protect against the presence of unknown or unauthorized animal protein residues in conveyances hauling grain-based feed ingredients from Canada to the United States to safeguard against BSE. FDA formally recognized these best management practices, which expedited inspections of U.S.-bound shipments from Canadian facilities utilizing them.

As another example of industry-driven initiatives to protect product safety, the NGFA has had a system of industry Trade Rules in place since the early 1900s (updated on a regular basis to reflect current trade practices) that contain express provisions requiring that shipments be free of objectionable extraneous material. Further, these industry trade rules contain provisions regarding the responsibility of the buyer/receiver to check the condition of inbound shipments to ascertain they conform with contract specifications, including for product safety and wholesomeness. Other NGFA Trade Rule provisions address the rejection of shipments for deficiencies in quality. The NGFA's Trade Rules are incorporated into the vast majority of commercial contracts involving the purchase, sale and shipment of grains, oilseeds, animal feed and feed ingredients, and can be – and are – used by NGFA members and non-members alike.

Finally, the NGFA in September 2009 also finalized an updated version of its ***Facility Risk-Assessment and Security Guide for Grain Elevators, Feed/Ingredient Manufacturers, Grain Millers and Oilseed Processors***. This industry guide, which was developed by the joint NGFA-NAEGA Agroterrorism and Facility Security Committee, with input during the final stages of development from the North American Millers' Association, includes suggested receiving and shipping procedures to protect product safety from potential intentional contamination incidents. The latest edition expands and improves upon an initial facility security guide developed by the NGFA in November 2001 following the September 11, 2001 terrorist attacks.

In other relevant initiatives by the public sector, USDA's Grain Inspection, Packers and Stockyards Administration has established procedures governing stowage examinations of railcars, barges and ocean-going vessels for cleanliness. In addition, for ocean-going vessels, two governmental entities – the National Cargo Bureau (under authority granted by the U.S. Coast Guard) and USDA's Federal Grain Inspection Service – certify that cargo holds are clean and free of injurious insects or other defects prior to loading with grains, oilseeds and other bulk commodities. Among other things, the stowage examinations performed by FGIS inspectors include verification that the cargo hold is substantially clean and free of debris from previous cargo, and fit to be loaded with grains, oilseeds, processed commodities or other agricultural commodities.

In this statement, the NGFA begins by providing insights on the importance of truck and rail transportation to U.S. agriculture, including the grain, feed and grain processing sector and our farmer-customers. Next, we offer general comments and recommendations regarding FDA's proposed rule for sanitary transportation of human and animal food. We then provide comments and recommendations regarding specific aspects of the proposed regulations.

NGFA does believe several sections of FDA's proposed rule require extensive changes, and suggests alternative language for the agency's consideration. As such, we believe it would be prudent for FDA to reissue certain aspects of this proposed rule for sanitary transportation of human and animal food for additional public comment after hopefully making changes reflecting comments submitted in this rulemaking. This would be akin to the agency's announced plans to reissue for public comment certain sections of the proposed rules for hazard analysis and preventive controls for human and animal food, as well as potential additional requirements for which FDA to date has not proposed codified language on which stakeholders could provide comment.

Making available a second draft of sanitary transportation proposed rules would provide stakeholders with another opportunity to offer informed and meaningful comment on the requirements that FDA foresees within its final rule. Given the very significant nature of these regulations, we believe that a second opportunity for stakeholder comment is essential to ensure that the requirements in the final rule are practical, achievable and foster the safe transport and distribution of human and animal food. Further, we believe FDA has the ability and authority to re-propose the regulations and still comply with the court-ordered deadline to publish a final rule by March 31, 2016.

Importance of Truck and Rail Transportation to U.S. Agriculture

At the outset, it is important to emphasize that the already-heavy demand for truck and rail conveyances to transport food and agricultural products is forecast to continue to increase given the growing demand for food, feed and biofuels in domestic and export markets. USDA and DOT, in a major study[2] mandated under the 2008 farm law (P.L. 110-246) and published in April 2010, projected that overall freight demand could double by 2035.

[2] "***Study of Rural Transportation Issues***," U.S. Department of Agriculture and U.S. Department of Transportation. April 2010.

Further, according to data compiled by the U.S. Census Bureau's Commodity Flow Survey conducted every five years, agriculture already is the single largest user of freight transportation in the United States, accounting for 21 percent of all tonnage and 28 percent of total ton miles in 2012. The competition for finite transportation resources is intense, with the U.S. Census Bureau finding that from 2007 to 2012, the value of all transported commodities (agricultural and non-agricultural) expanded by another 15 percent, after growing 41 percent from 2002-07.

The USDA-DOT study stated that "[t]he need for agricultural transportation will continue to increase, based on projected growth in demand for U.S. agricultural products domestically and overseas."[3] The USDA-DOT study's assessment is reinforced by USDA's most recent Agricultural Baseline Projections through 2023, published in February 2014, which predict continuing strong increases in production of U.S. grains, oilseeds, and livestock and poultry products in response to long-term global economic growth and population trends.

Trucks represent the most prevalent mode of transportation for agricultural commodities, amounting to more than 60 percent of the volume hauled. But the U.S. agricultural sector also is a large user of the nation's rail system. In 2011, railroads hauled approximately 28 percent of all commercial movements of whole U.S. grains and oilseeds. While that was down significantly from the 50 percent share hauled by rail at the time of enactment of the Staggers Rail Act of 1980, rail still represents a significant modal share for major agricultural commodities. Rail is the only viable transportation mode available to many agricultural producers and shippers. As examples, nearly all the grains and oilseeds produced in Montana, more than 70 percent of the commodities produced in North Dakota, and more than half of the agricultural commodities produced in Arizona, Oklahoma and South Dakota are transported by railroad.[4] In addition, an average of 72 percent of U.S. wheat moved to domestic and export markets by rail from 2007 to 2011, as did an average 56 percent of U.S barley. For total corn movements during the same five-year period, a still-significant 26 percent moved by rail (compared to 11 percent by barge and 63 percent by truck), while 24 percent of all U.S. soybeans moved by rail (compared to 20 percent by barge and 55 percent by truck).[5]

Many shippers and receivers of agricultural commodities nationwide are captive or potentially captive to a single railroad for service, and have no viable or effective alternative to rail for transportation of outbound product. Further, the cost of transportation typically is borne ultimately by the producer/farmer in the price paid for his or her crop, given the highly competitive marketplace in which the low-margin, high-volume grain-handling business operates.

The strain on the United States' transportation infrastructure and its capacity to serve agriculture has been illustrated graphically by the significant service disruptions that have occurred in the rail sector since the early fall of 2013 – long before the onset of harsh winter weather. Rail service disruptions have been widespread and severe, involving Class I rail carriers operating in both the West and East, as well as in Canada. In the West, shippers served by the BNSF Railway

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[3] Op. Cit. P. 113.

[4] ***Study of Rural Transportation Issues***, U.S. Department of Agriculture and U.S. Department of Transportation (April 2010).

[5] ***Transportation of U.S. Grains, A Modal Share Analysis***, 1978-2011 Update, U.S. Department of Agriculture Agricultural Marketing Service (May 2013).

and Canadian Pacific have been particularly hard hit – especially in areas like North and South Dakota, Montana and parts of Minnesota, where few, if any, viable alternatives to rail exist for moving grain, grain products and fertilizer. Meanwhile, in the Eastern United States, NGFA-member companies served by the Norfolk Southern and the CSX also have reported significant service disruptions.

In the West, the Canadian Pacific has been 60 to 75 days late or later in providing 100-car unit trains, and up to four months late on non-shuttles. Meanwhile, BNSF was two or more months late in providing certificate of transportation – or COT – trains that shippers had paid to have delivered during specific months. The NGFA also has received repeated reports of locomotives being de-linked from trains and cars sitting loaded – but idled – at grain facilities for weeks on end. In the East, there have been sharply reduced turn times on unit trains for domestic and export service, increasing car costs, reducing capacity and causing repeated functional shut-downs of feed mills dependent upon rail deliveries. Likewise, single-car shipments of ingredients for feed in both the East and West have been delayed.

Another repercussion of the serious disruption in rail service is illustrated by the values paid in the secondary rail car freight market, which traded at levels of as great as $6,000 per car on one carrier. That translates to a $1.65-per-bushel just to access rail equipment – not necessarily to receive it – and is a stark reflection in monetary terms of the extent to which service disruptions have affected agricultural shippers. The majority of secondary freight has traded at values of approximately $4,000 per car, equating to $1 per bushel. One NGFA-member company provided the following actual case involving a unit train shipment of soybeans from North Dakota to the Pacific Northwest in March 2014, in which the tariff rate was approximately $5,000 per car and the expense to secure the necessary rail freight from the secondary market amounted to another $4,000 per car. After adding the fuel surcharge, the actual freight cost alone translated to $2.60 per bushel.

It is clear that demands being placed on U.S. rail and truck capacity have reached unprecedented levels – a function of strong and growing demand from: 1) the agricultural sector, given increasing crop production in response to domestic and world demand for food, as well as compressed harvest time periods; 2) the energy sector, including crude oil, coal and ethanol given growing energy demand; and 3) consumer products served by intermodal shipments that involve both truck and rail movements. These trends are projected to continue into the foreseeable future, and raise the specter of significant shortfalls in conveyances available to transport U.S. agricultural products.

For purposes of this rulemaking, these factors point to the absolute necessity of FDA's rules not further exacerbating current truck and rail capacity constraints, or further raising the costs of transportation services.

General Comments and Recommendations

The NGFA wishes to reiterate in this statement the belief expressed in our responses to previous rulemakings on this matter that the single most important principle to retain in any future regulatory framework is the responsibility of those supplying conveyances for transport of

human or animal food to comply with the statutory obligation to provide transport conveyances that are clean, appropriate and in safe condition for transportation of the commodity intended to be shipped. *[See e.g. Texas Gulf Sulphur Co. Terminal Allowance, 288 I.C.C. 315, 320 (1953); Sioux City Term. Ry. Switching, 241 I.C.C. 53, 67 (1940).]* This legal obligation is reasonable because the carrier or other provider of the transportation conveyance is in the best position to monitor the use of transportation conveyances and equipment, know the contents of the previous load(s) hauled, and implement prudent and effective clean-out procedures to protect product safety.

It is extremely important that nothing in FDA's regulations regarding sanitary transportation undermine this fundamental legal responsibility for rail carriers and truck transporters to provide clean conveyances and transportation equipment suitable for the type of human and animal food products being hauled.

The NGFA also offers the following general comments and recommendations regarding FDA's proposal:

- First, we strongly support FDA's stated intent – as articulated in the executive summary and preamble of the proposed rule – to provide shippers, carriers and receivers with the flexibility to continue to utilize appropriate sanitary transportation practices that have evolved over time and been found to be effective in facilitating the safety of human and animal food. This includes the agency's decision not to prescribe specific sanitation practices for clean-out of transportation conveyances and equipment. In so doing, FDA is recognizing that the method used varies, depending upon the conveyance and product transported, and can be carrier-, shipper- or receiver-specific.

- Second, NGFA supports FDA's tentative conclusion to limit application of the proposed rule to truck and rail shipments of human and animal food, rather than also encompassing barge and vessel transportation.

- Third, given our previously articulated comments regarding constrained U.S. transportation capacity and existing severe service-related disruptions, we commend FDA's preamble statement recognizing the diversity in shipping combinations for food and non-food cargoes and strongly support FDA's decision not to restrict access for human and animal food to certain classes or types of rail or truck conveyances or transportation equipment. Specifically, NGFA strongly supports FDA's tentative conclusion that there are "not any specific non-food product(s) that may, under all circumstances, adulterate food subsequently hauled in a bulk vehicle" that would cause the agency to propose a list of such products in the proposed rule. Likewise, we strongly support FDA's tentative conclusion not to identify any specific non-food products that may, under all circumstances, adulterate food subsequently or simultaneously hauled in a non-bulk vehicle…." These conclusions rightfully recognize that clean-out procedures can be utilized that are appropriate and suitable for conveyances transporting food and agricultural products for their intended uses, rather than banning the use of certain conveyances that have dual uses in hauling other non-food products. Further, we concur with FDA's stated intent to develop guidance for the transportation industry on

how the specifics of transportation operations affect the potential for non-food products to adulterate food.

- Fourth, as will be noted subsequently in this statement, it is imperative that FDA recognize that sanitary procedures applied for transporting products intended for use in human food may differ from – and typically may be more stringent than – those appropriate for moving animal food and animal feed ingredients. But it is important to stress that varying procedures have been designed that are appropriate for maintaining the safety of the product to achieve the objective of human and animal health.

Specific Comments and Recommendations

The NGFA offers the following specific comments and recommendations regarding the FDA-proposed rule:

§1.900 – Scope and Exemptions

The NGFA supports FDA's proposal to apply the proposed rules to both interstate and intrastate transportation of human and animal food, as we believe both types of movements are important and relevant to human and animal food safety. We also support the two exemptions proposed by FDA for transportation operations of food that is transshipped through the United States to another country, as well as food that is imported for future export and that is neither consumed nor distributed in the United States.

FDA's preamble also poses the question of whether there are persons other than shippers, carriers and receivers engaged in the transportation of food who should be subject to the rule's requirements. NGFA believes that FDA may wish to consider the degree to which brokers and other third-party logistics operators who arrange for and book freight on behalf of the shipper and/or receiver should be responsible for conveying information to the carrier concerning the transportation requirements of the conveyance to be provided. Alternatively, these third parties could be made responsible for providing carrier contact information to the shipper and/or receiver for which freight is being arranged. Under the FDA-proposed definition of "shipper" and "receiver" in this rule, these third-party transportation brokers and logistics operators currently would not be covered.

Further, the NGFA urges that FDA establish **three additional exemptions** in the final rule, as follows:

- **Transfers of human and animal food between facilities operating under the ownership of the same legal entity, such as the same parent or corporate entity**. In these intra-company transfer situations, the company typically uses a dedicated fleet of trucks and/or rail cars to move agricultural products, animal food and feed ingredients, and other food products between its own facilities, and establishes and implements appropriate clean-out procedures. Further, these transportation-related activities already would be covered under FDA's hazard analysis, preventive control and current good manufacturing requirements for human and animal food being promulgated under FSMA,

and additional regulation and commensurate recordkeeping requirements under the sanitary transportation regulations would be unnecessary, redundant and add undue costs.

A precedent for such an exemption exists within FDA's final regulations implementing the recordkeeping requirements of the Bioterrorism Act of 2002. That exemption provides that records are not required for transfers of agricultural commodities, feed and food between facilities operating under the same legal entity – including vertically integrated companies – ***provided*** the product does not leave the "continuous control" of facilities and transportation conveyances operating under the same corporate ownership. This exemption does not extend to shipments hauled by independent transporters (i.e., transporters not owned by the same corporate entity), even if the movement involves a transfer between two facilities owned by the same company.

For purposes of the sanitary food transportation rule, the NGFA proposes that such an exemption could be accomplished by adding the following language to this section of the proposed rule: *"**Food that is transported between facilities operating under the same legal entity, provided the food does not leave the continuous control of facilities and transportation conveyances operating under the same legal entity**."*

- **Dedicated rail and truck transportation conveyances and transportation equipment used to haul the same type of human or animal food, including raw agricultural commodities and processed products, on a continual basis**. In making this recommendation, the NGFA is cognizant that FDA proposes to grant waivers under the proposed rule for "any class of persons, vehicles, (and) food or nonfood products" if it determines the waiver will not create conditions that would make human and animal food unsafe or be contrary to the public interest. But we believe certain classes of transportation of raw and processed agricultural commodities, as well as feed and feed ingredients, warrant a prima facie exemption to avoid a deluge of waiver petitions and resulting ***Federal Register*** notices and approvals from the agency.

  Good examples of the need for a blanket exemption involve the use of shuttle trains and privately owned railcars that are dedicated exclusively to hauling grains and oilseeds. To enhance efficiency, shippers and receivers have expended extensive capital resources to build additional load-out and receiving capacity to handle 100-plus car unit trains that run a dedicated, circuituitous route (e.g., from North Dakota to Pacific Northwest export ports) hauling the same type of grain continually. Similarly, specific tank car fleets are dedicated solely to hauling vegoils and other food-grade oils for human consumption.

  In addition, animal feed and feed ingredient manufacturers typically use their own dedicated truck fleets to haul large quantities of bulk and bagged products directly to farms and livestock and poultry operations in a continuous fashion. Limited risk exists for cross-contamination of such bulk vehicles because of standard operating procedures for sequencing and clean-out implemented by such firms to comply with FDA's existing regulations for medicated feed.

For these reasons, the NGFA recommends that a specific exemption be created from the sanitary food transportation rule for rail and truck transport conveyances and equipment dedicated to hauling the same type of raw agricultural commodity, animal feed or feed ingredient, and other human and animal food. In addition, we urge FDA to absolve shippers and carriers from the recordkeeping requirements contained in §1.912(a) (b) and (c) of the proposed rule for transportation conveyances and equipment that qualify for this suggested exemption.

To effectuate this exemption, the NGFA offers the following proposed language for FDA's consideration: *"**Food that is transported in bulk vehicles dedicated solely to transporting the same kind of food, and for no other purposes.**"*

- **Transportation of live food animals**. The NGFA supports FDA's tentative conclusion to exempt transport of live food-producing animals from the sanitary food transportation regulations, and suggests adding that specific exemption to this section of the rule. As noted by FDA, the transportation of such live animals is subject to the jurisdiction of the U.S. Department of Agriculture's Food Safety and Inspection Service, and additional regulation under this rule would be duplicative.

  Such an exemption could be implemented by inserting "***Live food-producing animals***" to the list in this section of the rule.

§1.904 – Definitions

- **Issue – Definition of Bulk Vehicle:** FDA proposes to define "bulk vehicle" to mean a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

  NGFA Recommendation: The NGFA believes that in several respects, the definition of bulk vehicle is excessively broad. For instance, the term "hopper bin" can be inferred to mean a grain hopper bottom storage bin that is considered part of the storage facility, not transportation equipment. We recommend that the term "hopper bin" be deleted from the definition of bulk vehicle.

Typical Hopper Bins

- **Issue – Farm Transportation of Raw Agricultural Commodities:** In the preamble, FDA notes that the proposed definition of transportation operations would exclude transportation activities involving raw agricultural commodities that are performed by a farm. FDA also proposes in this rule to expand the definition of "farm" to "include facilities that pack or hold food, regardless of whether all food used in such activities is

grown, raised, or consumed on that farm or another farm under the same ownership." FDA further requests comment on its tentative conclusion that the sanitary transportation practices required under this proposed rule are unnecessary to prevent raw agricultural commodities from becoming adulterated during transportation by farms. "We are not aware of food safety concerns related to the transportation of raw agricultural commodities by farms that could be addressed through the sanitary transportation practices set forth in this rule," FDA states.

NGFA Recommendation: The NGFA notes that the use of truck transportation by farms to transport raw agricultural commodities, such as grains and oilseeds, to country grain elevators, grain processors, feed mills and other first purchasers has become increasingly prevalent and large scale. Many producers now utilize large-volume semitrailer trucks to deliver raw agricultural commodities for further distances than once occurred. For instance, some industry members estimate that more than 80 percent of soybean shipments from farms are transported in semitrailers. In addition, farm trucks frequently can be used to haul treated seed used for planting, as well as fertilizer, other farm inputs and non-agricultural products requiring transportation to or on the farm.

NGFA does not disagree with FDA's conclusion that subjecting farm deliveries of raw agricultural commodities to all of the proposed requirements of the sanitary food transportation rules would be impractical and excessive. However, to minimize the potential for adulteration, NGFA does recommend that the agency develop a guidance document on good transportation practices, as well as user-friendly education materials pertaining to the safe transport of raw agricultural commodities by farms. Such guidance should stress the importance of cleanout procedures in non-dedicated farm transportation conveyances and equipment used to haul raw agricultural commodities and other products, and providing practical, realistic and effective sample clean-out procedures for such conveyances. The guidance also could encourage those delivering raw agricultural commodities from farms to inform the receiver about the previous load hauled in the transportation conveyance used.

- **Issue – Definition of Non-Covered Business:** FDA proposes to exempt shippers, receivers or carriers engaged in transportation operations that have less than $500,000 in total annual sales.

  NGFA Recommendation: Consistent with its comments submitted on FDA's proposed rule for hazard analysis and preventive controls for animal food, NGFA opposes size-based exemptions for sanitary food transportation. It is our belief that sanitary transportation regulations – if practical, cost-effective and appropriately designed – should be applied uniformly across shippers, carriers and receivers involved in the transport of human or animal food, with additional time provided for compliance by smaller entities.

- **Issue – Shelf-Stable Food:** FDA proposes that shelf-stable food be defined as food that can be stored under ambient temperature and humidity conditions, and, if the package integrity is maintained, will not spoil or become unsafe during its storage life.

NGFA Recommendation: The NGFA supports FDA's tentative conclusion that shelf-stable foods that are completely enclosed by a container should be exempt from the proposed rule. However, we urge that the definition be amended to expressly reference the inclusion of canned, packaged and/or bagged animal food, including animal feed, feed ingredients and pet food, as examples of packaging that is considered acceptable, as provided below *(new language bold-faced and underscored; deleted language stricken through)*: "*Shelf stable food means a food that can be stored under ambient temperature and humidity conditions and, if the package integrity is maintained, will not spoil or become unsafe throughout its storage life. Examples of shelf stable* ***human*** *food include canned juice, canned vegetables, canned meat, bottled water and dry food items, such as rice, pasta, flour, sugar, and spices.* ***Examples of shelf stable animal food include canned pet food; bottled nutritional supplements; and bagged or packaged animal feed, feed ingredients, pet food and feed supplements."***

- **Issue – Definition of Shipper:** FDA defines a "shipper" as a person "who initiates" a shipment of food by truck or rail. The definition also uses the term "motor vehicle."

  NGFA Recommendation: The NGFA believes that the phrase "who initiates" is unnecessarily broad and will create confusion as to whether those who arrange for transportation – such as a broker or third-party logistics operator – is considered to be a "shipper" and hence subject to the rule. We believe the definition of "shipper" should be linked to the physical activity of loading a conveyance. In addition, we believe use of the term "motor vehicle" instead of "truck," could be misinterpreted to mean a car or other form of motor vehicle. Further, other portions of the proposed rule use the term "truck" rather than "motor vehicle."

  Therefore, NGFA recommends that the phrase "who initiates" be replaced with "who loads or orders the loading of," and that the phrase "motor vehicle" be replaced with "truck" as provided below *(new language bold-faced and underscored; deleted language stricken through)*: "*Shipper* means a person who ~~initiates~~ **loads** a shipment of food by ~~motor vehicle~~ **truck** or rail vehicle. The shipper is responsible for all functions assigned to a shipper in this subpart even if they are performed by other persons, such as a person who only holds food and physically transfers it onto a vehicle arranged for by the shipper. A shipper also may be a carrier or receiver if the shipper also performs those functions as defined in this subpart."

- **Issue – Definition of Transportation Equipment:** FDA proposes an extremely broad definition of "transportation equipment" that could be interpreted to encompass structures and equipment normally associated with storage, load-out and receiving procedures, not transportation. Specifically, the agency's proposed definition includes "bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems and unloading systems." As currently drafted, this definition could be viewed to include loading bins, spouting and other equipment located within the shipper's or receiver's facility.

NGFA Recommendation: The NGFA believes FDA should revise its proposed definition of "transportation equipment" to clarify that the definition encompasses only such equipment solely associated with the transportation conveyance. Therefore, the NGFA recommends that the definition be modified as follows *(new language bold-faced and underscored; deleted language stricken through)*: "*Transportation equipment* means equipment used in food transportation operations, other than vehicles, e.g., bulk and non-bulk containers, ~~bins,~~ totes and pallets **loaded onto transportation conveyances**, **and** pumps, fittings, hoses, gaskets, loading systems and unloading systems **that are integral and affixed to transportation conveyances**."

- **Issue – Definition of Vehicle:** FDA proposes to define "vehicle" as a "land conveyance that is motorized, e.g., a motor vehicle, or that moves on rails, e.g., a railcar, which is used in transportation operations."

  NGFA Recommendation: NGFA recognizes that FDA's definition of the term "transportation operations" expressly references "activities associated with food transportation that may affect the sanitary condition of food." However, consistent with our previous comment regarding this section of the proposed rule, NGFA believes the definition of "vehicle" as any "land conveyance that is motorized" and the use of the term "motor vehicle" are excessively broad and could be misinterpreted to encompass a wide range of motorized vehicles, including automobiles. Further, we note that there are instances in which railcars, trucks and trailers can be utilized for product storage.

  We thus recommend that the definition be narrowed to read as follows *(new language bold-faced and underscored; deleted language stricken through)*: *"Vehicle* means a ~~land conveyance that is motorized, e.g., a motor vehicle, or that moves on rails, e.g., a~~ **truck or railcar**~~,~~ which is used in transportation operations **and not to hold food**."

§1.908 – Transportation Operations

- **Issue – Requirements Applicable to Shippers to Provide All Necessary Sanitary Requirements to Carriers:** FDA proposes to require that shippers specify to carriers, in writing, all necessary sanitary requirements for the carrier's vehicle and transportation equipment, including any specific design requirements and cleaning procedures to ensure the vehicle is in appropriate sanitary condition for the transportation of food.

  NGFA Recommendation: The NGFA reiterates its previous comment regarding the legal obligation of carriers to provide clean conveyances and transportation equipment suitable for the type of human and animal food products being hauled. We note that the more common current industry practice with respect to raw agricultural commodities and animal food is for the shipper to provide information to the carrier on the type of commodity to be hauled, with the carrier then responsible for providing a conveyance that is appropriate to protect the safety of that type of product. As such, we believe that FDA's proposed language is too prescriptive to apply to all situations involving the transport of all types of food. Further, we believe that language should be included in the

rule stating that a one-time notification from the shipper to the carrier of any additional sanitary transportation requirements should be sufficient for the commodity being hauled.

NGFA therefore recommends that this provision be modified to read as follows *(new language bold-faced and underscored; deleted language stricken through)*: "*Requirements applicable to shippers engaged in transportation operations.* (1) The shipper must specify to the carrier, in writing, ~~all necessary~~ sanitary requirements for the carrier's vehicle and transportation equipment **that exceed the carrier's basic obligation to provide vehicles and transportation equipment that are clean, appropriate and in safe condition for transportation of the commodity intended to be shipped. This shall include** ~~including~~ any specific **additional** design requirements and cleaning procedures to ensure that the vehicle is in appropriate sanitary condition for the transportation of food, e.g., that will prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during the transportation operation. **One-time notification shall be sufficient unless the design requirements and cleaning procedures desired by the shipper change based upon the type of food being transported, in which case the shipper shall so notify the carrier.** The information submitted by the shipper to the carrier is subject to the records requirements of §1.912(a)."

- **Issue – Temperature Controls, Temperature Monitoring, Pre-Cooling and Other Requirements to Protect Against Microbial Spoilage:** Within §1.908, FDA proposes several significant requirements focusing on a broad range of temperature control, temperature monitoring, pre-cooling and other measures to protect food from microbiological contamination during transport.

  NGFA Recommendation: NGFA is aware that other sectors of the human food and transportation industry will be providing extensive comments suggesting major changes to these sections of the proposed rule, and wishes to associate itself in support of those comments. Suffice it to say here that NGFA believes strongly that any such requirements should be directed solely at product safety, not quality, and should recognize and be compatible with the vast array of different human and animal foods being transported by truck and rail. In that regard, NGFA believes FDA's proposed requirements are excessive for animal food, and would add unnecessary regulatory burdens and costs on the animal feed and pet food industries without a commensurate improvement in product safety. In addition, the proposed temperature requirements need to be modified to make it clear that continuous monitoring of temperatures is not required and that, if a deviation occurs, it does not automatically result in the product being deemed adulterated by FDA.

- **Issue – Access to Hand-Washing Facility:** In §1.908(c), FDA proposes an expansive requirement that shippers and receivers engaged in transportation operations provide access to hand-washing facilities for use by vehicle operators who are expected to handle food not completely enclosed by a container during loading and unloading operations.

  NGFA Recommendation: The NGFA believes this requirement is excessive, particularly when applied to raw agricultural commodities, processed grain-based

products or animal food. We are not aware of any data indicating that human handling of either raw agricultural commodities, processed commodities or animal food poses a risk to the safety of such food or to human or animal health. Further, such a requirement would add compliance costs at many facilities where "convenient" hand-washing facilities do not exist.

NGFA instead recommends that any requirement for hand-washing facilities be risk-based, and be linked directly to the effectiveness of hand-washing to reduce or eliminate the risk of human handling causing the food to become adulterated, filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health. As such, we recommend that this provision be modified significantly to read as follows *(new language bold-faced and underscored; deleted language stricken through)*: "*Requirements applicable to shippers and receivers engaged in transportation operations*: (1) Shippers and receivers must provide vehicle operators who are expected to handle food not completely enclosed by a container during loading and unloading operations with access to a hand washing facility **if human contact with the food poses a hazard of causing the food to be adulterated or becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health**. The hand washing facility must be convenient and provide running water to enable vehicle operators to wash their hands and avoid contamination of food."

- **Issue – Identifying Previous Three Loads Hauled for Bulk Vehicles:** In §1.908(c), FDA proposes that carriers providing bulk vehicles for transportation of food provide information to the shipper identifying the three previous loads hauled, unless that requirement is modified by agreement between the shipper and carrier.

  NGFA Recommendation: The NGFA believes that requiring identification of the three previous loads hauled is excessive and unnecessary to accomplish the goal of safe transport. Further, the release by the carrier of information pertaining to multiple previous loads could breach business-sensitive information on multiple competitor-shippers involved. For shippers, what is most important is to know the immediate previous load hauled in the bulk conveyance and information on whether appropriate clean-out procedures have been utilized if needed to ensure the conveyance meets the needs of the shipper based upon the type of food to be loaded. But it should be noted that it can be extremely difficult to obtain last-load hauled information from rail carriers unless the railcars being utilized are owned, leased or controlled by the shipper, or the shipper is the one who is the consignee/consignor or payer of the freight bill. Currently, no consistent or reliable mechanism exists among rail carriers from which to obtain such information. And the degree to which such information can be obtained differs between carriers, sometimes significantly.

  We also believe that the carrier should be responsible for identifying the clean-out procedures, if any, which have been utilized to ensure the bulk vehicle is suitable for transporting the type of food to be loaded and hauled.

For these reasons, NGFA recommends that this provision of the proposed rule be amended to read as follows *(new language bold-faced and underscored; deleted language stricken through)*: "(4) A carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the ~~three~~ **immediate** previous cargo~~es~~ transported in the vehicle**, as well as whether and what type of clean-out procedure was utilized.** The shipper and carrier may agree in writing that the carrier ~~will provide information that identifies fewer than three previous cargoes or that the carrier~~ need not provide any such information if procedures have been established **by the carrier** that would ensure that the bulk vehicle offered will be adequate for the intended transportation operation, e.g., if the carrier by contract, will only offer vehicles dedicated to hauling a single type of **food** product. The written agreement is subject to the records requirements of §1.912(b)."

§1.910 – Training

The NGFA generally agrees with FDA's proposal that carriers provide training to personnel engaged in transportation operations sufficient to make them aware of potential food safety issues that may be involved in the transportation of food being hauled, and carriers' responsibilities to observe sanitary transportation practices. We believe such training should specifically cover when and how to utilize clean-out procedures that are appropriate for conveyances used to haul the types of food and/or non-agricultural products being transported by the carrier. Further, we believe that the scope and format of appropriate employee training by the carrier may vary, and that sufficient flexibility needs to be provided to enable the carrier to provide the type of training necessary for the operator of the conveyance, as well as other carrier personnel involved in providing transportation conveyances used to haul food, given the wide range of products hauled. Therefore, the NGFA believes FDA's regulations should allow carriers to determine the training content and training frequency.

NGFA also urges that FDA work with the transportation sector to develop sample training materials for use by transportation companies. We believe such a need is most pronounced among independent truckers, many of which are extremely small business enterprises.

- **Issue – Electronic Records:** FDA proposes at §1.912(e) to require that electronic records be kept in accordance with 21 CFR part 11 (Part 11). Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The proposed requirement states that all electronic records created to comply with the sanitary food transportation regulations must be Part 11-compliant.

  Requiring electronic records to be Part 11-compliant would mean that current electronic records and recordkeeping systems would have to be recreated and redesigned, which the agency itself determined to be the case in its Bioterrorism Act recordkeeping regulation, and in other cases. In such cases, FDA has not required resulting predicate records to comply with Part 11.

NGFA Recommendation: The NGFA strongly urges FDA not to apply Part 11 to a facility's electronic records in this instance either, because, as with the Bioterrorism Act and other cases, such a requirement is disproportionate to the regulatory need and would impose tremendous burdens and costs on shippers, carriers and receivers. Electronic recordkeeping systems are used widely by shippers and receivers of human and animal food to document and store business-related information. The most efficient and cost-effective manner to establish and maintain such documents and records is with existing electronic recordkeeping systems. The vast majority of such systems do not meet the very stringent provisions detailed in Part 11. As such, shippers, receivers and carriers would be required to recreate and/or redesign their current electronic systems – or, in the case of carriers, create entirely new systems at an enormous cost – or scrap the use of existing systems and create and maintain records in a paper format. Both of these alternatives represent an overwhelming expense and burden that is unnecessary to ensure compliance with recordkeeping requirements for sanitary food transportation.

Alternatively, the NGFA recommends FDA partner with key stakeholders to develop guidance that describes the kinds of practical principles, protocols and systems that may be used to ensure the integrity of electronic records without imposing specific technical requirements that are unnecessary, burdensome and inappropriate.

§1.914 through §1.934 – Waivers

The NGFA reiterates its previous comments in this statement regarding §1.900 that FDA should provide a blanket exemption for dedicated rail and truck transportation conveyances and transportation equipment used to haul the same type of human and animal food, including raw agricultural commodities and animal food, on a continual basis. We believe this type of transportation involving dedicated equipment of raw and processed agricultural commodities, as well as feed and feed ingredients, warrant a prima facie exemption to avoid a deluge of waiver petitions and resulting ***Federal Register*** notices and approvals from the agency.

Further, the NGFA urges FDA to adopt appropriate provisions in its regulations governing waivers to protect against the disclosure of confidential business information of shippers, carriers and receivers.

Conclusion

The NGFA wishes to reiterate its previously expressed view that, given the extensive changes we and others believe are warranted, we believe FDA should reissue significant sections of this proposed rule for sanitary transportation of human and animal food for additional public comment.

Making available a second draft of sanitary transportation proposed rules would provide stakeholders with another opportunity to offer informed and meaningful comment on the requirements that FDA envisions including in its final rule. Given the very significant nature of

these regulations, we believe that a second opportunity for stakeholder comment is essential to ensure that the requirements in the final rule are practical, achievable and foster the safe transport and distribution of human and animal food. Further, we believe FDA has the ability and authority to re-propose the regulations and still comply with the court-ordered deadline to publish a final rule by March 31, 2016.

The NGFA appreciates FDA's consideration of the recommendations expressed in this statement, and looks forward to being a fully engaged and constructive participant in future discussions and rulemakings with the agency to implement the Food Safety Modernization Act.

Sincerely yours,

Randall C. Gordon
President