July 30, 2014

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

via www.Regulations.gov

Re: Docket No. FDA–2013–N–0013 and RIN 0910–AG98
Sanitary Transportation of Human and Animal Food (79 FR 7006, February 5, 2014)

Dear Food and Drug Administration:

The American Feed Industry Association (AFIA) is the world's largest organization devoted exclusively to representing the business, legislative and regulatory interests of the U.S. animal feed industry and its suppliers. Founded in 1909 as the American Feed Manufacturers Association, the name changed to AFIA in 1985 to recognize one class of members. AFIA is also the recognized leader of international industry developments and holds membership in the International Feed Industry Federation, where AFIA's President, Joel G. Newman, serves as chair of the IFIF Policy Committee.

AFIA membership includes more than 575 domestic and international companies and state, regional and national associations. Member companies are livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, equipment manufacturers and companies that supply other products, services and supplies to feed manufacturers.

The feed industry makes a major contribution to food and feed safety, nutrition and the environment, and plays a critical role in the production of healthy, wholesome meat, milk, fish and eggs. More than 75 percent of the commercial feed in the United States is manufactured by AFIA members. Approximately 70 percent of the non-grain ingredients, including soybean meal, distillers co-products, vitamins, minerals, amino acids, yeast products and other miscellaneous/specialty ingredients are also manufactured by AFIA members.

AFIA's primary founding purposes was to promote and assure feed safety and to harmonize all state feed laws with uniform labeling and regulations. Today, every state except Alaska has a feed law based on the Association of American Feed Control Officials' (AAFCO) Model State Feed Bill. AFIA and its predecessor organizations have had a number of animal food safety

programs. The latest of which is AFIA's Safe Feed/Safe Food Certification Program, described in more detail later.

Several state feed regulators met at AFMA/AFIA's founding meeting in May 1909 and followed up with a meeting in September 1909 where AAFCO was formed. AFIA and AAFCO have an unbroken line of meetings for 105 years. These have resulted in many mutual programs and successes, such as the AAFCO ingredient definitions, the model feed and pet food law and rules, the model Current Good Manufacturing Practices regulations, and checklist and options for feed registration and facility licensing in the AAFCO Model Feed Bill.

Nearly all AFIA members that manufacture, process, pack or hold animal food are registered with FDA under the Bioterrorism Act. For that reason, these facilities are very interested in these proposed rules and must comply with all final rules that FDA issues. Therefore, rules promulgated under the Food Safety Modernization Act impact AFIA members, and these comments represent their views.

AFIA strongly supported development and enactment of FSMA, supports and provides comments to FDA, and belongs to the Food Safety Preventive Controls Alliance's Feed Steering Committee. This committee is reviewing the human food training outline and adjusting it for animal food. AFIA will provide future training workshops based on the FDA-endorsed training outline developed by the Alliance. AFIA has agreed to draft or be involved in a review of domestic guidance documents including those for dry and liquid feed, pet food, vitamin/mineral/specialty ingredients and guides for products derived from plants and animals.

AFIA is committed to a continuing dialogue with FDA on FSMA rules and implementation, and is strongly committed to a full and successful implementation of FSMA across all our varied industries. We greatly appreciate the opportunity to provide feedback in regards to the proposed rule for sanitary transportation for human and animal foods.

Industry Description

The U.S. feed industry is diverse and is authorized to use more than 900 ingredients. There are more than 6,000 animal feed mills that manufacture 158 million tons of ready-to-eat feed annually. These numbers do not include on-farm mixers, which, in most cases, are exempt from Bioterrorism Act facility registration because they fall under the "farm" definition and are exempt from the provisions of FSMA.

AFIA represents many dry dog and cat food firms in the U.S. We also represent numerous specialty pet food manufacturers (as defined in the AAFCO Model Feed Bill found in the AAFCO *2014 Official Publication*). These include facilities that manufacture rabbit, gerbil, hamster, guinea pig, aquarium fish food and other similar specialty pet food.

Some 60 million to 70 million of the total tons used in animal food includes co-products from food, beverage and ethanol production. These co-products provide valuable, cost-effective nutrients to the nation's livestock, poultry and aquaculture industries. Also, the co-product suppliers save considerable resources by providing the ingredients for animal food instead of

disposing of them in the nation's landfills. Providing a market for co-products protects the environment and saves millions of dollars per year.

In 2013, the U.S. feed industry exported more than $9 billion worth of feed and ingredients—most of which was ingredients. Most of the complete feed trade is between the U.S. and Canada. There is also nearly $2 billion worth of feed trade with China, alone. Once FSMA is completely implemented, inspections to facilitate export certifications by both FDA and the U.S. Department of Agriculture's Agricultural Marketing Service will increase, and more exports will be realized. According to USDA's calculations, each billion dollars in agricultural exports results in 6,000 to 7,000 more U.S. jobs.

In 2004, AFIA created its hallmark Safe Feed/Safe Food Certification Program (SF/SF). Since that time, more than 600 facilities have been certified and the program has grown from one basic program to several under the SF/SF umbrella. More information on these programs is available at www.safefeedsafefood.org.

In 2010, AFIA launched its International SF/SF Certification Program in cooperation with the FAMI-QS program launched by the European Union Specialty Feed Ingredients and their Mixtures or FEFANA. The program was developed to provide compliance with the European Union Regulation (EC) 183/2005, which has a mandatory Hazard Analysis and Critical Control Points (HACCP) requirement for all feed, ingredients and pet food. FAMI-QS owns and maintains the standard for the program and provides training. AFIA markets and trains auditors and facilities about the program.

In 2012, AFIA created two new programs for the pet food industry. These are the Pet Food Manufacturing Facility Certification Program and the Pet Food Ingredient Facility Manufacturing Certification Program. Both of these new programs and all the SF/SF programs are designed as hazard identification and preventive control programs based on a facility's feed safety plan. Both pet food programs are different from the basic SF/SF feed programs in that there are microbial control requirements that do not appear in the SF/SF feed programs.

In 2013, AFIA signed an agreement with the Safe Quality Food Institute (SQFI) to operate and manage all the SF/SF programs except the I-SF/SF program, which is owned and maintained by FAMI-QS in the EU.

In late 2013, SQFI announced that the Global Food Safety Initiative (GFSI) has benchmarked the enhanced SF/SF Certification Program (FSC 34) and the PFMFCP/PFIFCP (FSC 32). This allows an assurance that these programs meet the highest standards of food safety on a global basis and can be favorably compared to other food safety programs. These are the only global animal food safety program benchmarked by GFSI.

The development and benchmarking of these programs is consistent with AFIA's highest principles and goals to promote and ensure animal food safety throughout the animal food supply chain. Transportation is an essential component of the animal food industry. Proper processes and control of transportation are important to ensure the safety of ingredients and finished

products during receipt, loading and shipment. Currently, the members of AFIA implement effective controls to ensure the safety of their products during transportation.

General Comments and Recommendations

AFIA has written these comments to provide general comments and, where applicable, we note the specific proposed provision, AFIA's recommended change and the rationale for the change. For the purposes of editing, new language is underlined and deleted language is stricken through.

Cargo Combinations Should Continue to be Permitted

In the preamble, FDA recognizes the diversity in shipping combinations of non-food and food cargoes, concluding there is not any specific non-food product that may, under all circumstances, adulterate food subsequently or simultaneously hauled in a bulk vehicle (79 Fed. Reg. at 7008-7009). AFIA supports the agency's tentative conclusion that will allow industry to continue to use bulk transport equipment in accordance with best practices without limiting industry, by rule, to hauling non-food exclusive of or preceding any food items. AFIA commends FDA for its intent to issue guidance, to help the transportation industry, on how the specifics of transportation operations affect the potential for non-food products to adulterate food products.

FDA Should Expand the Allowable Exemptions

Proposed Rule with AFIA Recommendations

§ 1.900 Who is subject to this subpart?

Except for non-covered businesses as defined in § 1.904, the requirements of this subpart apply to shippers, receivers, and carriers engaged in transportation operations whether or not the food is being offered for or enters interstate commerce. The requirements of this subpart apply in addition to any other requirements of this chapter that are applicable to the transportation of food, e.g., in 21 CFR parts 1, 110, 118, 225, and 589).

The requirements of this subpart do not apply to shippers, receivers, or carriers when they are engaged in transportation operations of:

(1) Food that is transshipped through the United States to another country; or

(2) Food that is imported for future export and that is neither consumed nor distributed in the United States~~.~~; or

(3) Food that is transported from one facility to another within the same company, such as when the shipper and carrier are part of the same corporate-parent ownership; or

(4) Food that is transported only a short haul (as defined by the U.S. Department of Transportation) from the manufacturing facility; or

(5) Food that is transported as finished product or raw agricultural commodities from facilities to farms using dedicated vehicles; or

(6) The transport of live animals.

AFIA Comments

FDA requests comment on whether the provisions of proposed § 1.900 (79 Fed. Reg. at 7010) should be applicable to intrastate activities. AFIA believes the proposed regulations should be applicable to shippers, receivers and carriers engaged in transportation of food—both interstate

and intrastate—that is distributed and consumed within the United States. AFIA supports the intent to ensure the safety of the food supply both within and among all states.

AFIA supports the tentative conclusion of the agency that an exemption should be provided for the transportation of live animals and proposes to add such an exemption as noted above.

However, AFIA is concerned about the undue burden the proposed rule place on shipments of bulk finished animal foods or raw agricultural commodities to farms. Many facilities manufacture and ship large volumes of bulk finished products to farms using dedicated vehicles for transporting these materials. Thus, a "closed loop" is maintained with repeated shipments from a manufacturing facility to a farm using the same vehicle. AFIA recommends these shipments be exempt from the proposed sanitary transportation requirements. The exemption is justified through the limited risk for contamination that comes with the use of these dedicated vehicles for shipments to the farms. Additionally, as the transportation vehicles are dedicated, the chance of outside contamination occurring is at minimal, to nonexistent levels, after the hatches or entry ports are secured.

Similarly, AFIA also supports an exemption for intra-company and short haul shipments. Shipments within a single company where firms maintain control of the transported product following an internal standard operating procedure should be adequate, rather than developing additional documentation that would be unnecessary and overly burdensome. FDA should not establish a definition of "short haul" in the regulation for sanitary transportation, as the U.S. Department of Transportation already has such a definition established in their regulations. Utilizing an already established definition that is well understood in the transportation industry would provide consistency and be easily implemented. The proposed rules should be amended to reference this DOT definition.

<u>The Proposed Rule Covers the Applicable Segments of the Transportation Industry</u>
FDA requests comment on whether any other persons should be subject to this proposed rule, as the Federal Food Drug and Cosmetic Act explicitly states the regulation should address "other persons" engaged in the transportation of food (79 Fed. Reg. at 7010). FDA tentatively concluded there are not "other persons" engaged in the transportation of food to which the rule should apply. AFIA supports this conclusion, acknowledging a shipper, receiver and carrier, as defined in § 1.904, are responsible for ensuring the safety of food during transport.

<u>Changes to § 1.904 Definitions are Needed</u>

Proposed Definition

> *Animal food* means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

AFIA Comments
As noted in our comments on the animal food preventive control proposed rule, AFIA is concerned with the addition of "raw materials" in this proposed definition for a number of reasons. Currently, the Association of American Feed Control Officials (AAFCO) Model Regulations exempt raw materials (such as meat scraps or the initially mined material) from

regulation as they are not suitable for feed without further processing. If FDA expects the firms producing raw materials for animal food to register, create animal food safety plans and now institute sanitary transportation measures beyond what is practiced today, we believe many of these firms will merely dispose of these "raw materials" in landfills due to the high cost of developing and maintaining such plans.

The term "raw materials" may be interpreted to cover the ingredients used to safely manufacture feed ingredients (such as amino acids, vitamins, minerals, technical additives, enzymes and additives) that assure the safety and usefulness of agricultural-based products. These same raw materials are used in the manufacturing of many non-food products, for example drugs, plastics, solutions and building materials. It is costly and ill-conceived to require raw materials to be covered under these regulations.

FDA should seriously consider exempting many of the low risk raw material industries, as the processing of these materials into feed ingredients will remove many, if not all of the hazards associated with the transportation of raw materials.

Proposed Definition with AFIA Recommendation

> *Non-covered business* means a shipper, receiver, or carrier engaged in transportation operations that has less than ~~$500,000~~ $10,000 in total annual sales, adjusted for inflation.

AFIA Comments

FDA requests comment on whether the proposed rule should be limited in some way to a business engaged in transportation operations with less than $500,000 in total annual sales, called a "non-covered business" as defined in proposed § 1.904. Consistent with AFIA's comments submitted regarding exemptions within the proposed rule Current Good Manufacturing Practices and Hazard Analysis Risk-Based Preventive Controls for Food for Animals (Docket No. 2011-N-0922 and RIN 0910-AG10), AFIA believes that no firm, regardless of annual sales volume, should be exempt if they are engaged in transportation operations of food, and recommends the level for exemption be set at less than $10,000. The exemption should be similar to that which is established for other rules for FSMA therefore, we are proposing the edit above.

Proposed Definition with AFIA Recommendation

> *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 food include canned juice, canned vegetables, canned meat, bottled water and dry food items such as rice, pasta, flour, sugar, ~~and~~ spices, canned and packaged animal food (such as sewn or sealed bags) and bottled animal nutritional supplements.

AFIA Comments

FDA cites it is not aware of safety concerns related to transportation of food in sealed containers, compressed food gases and live food animals (79 Fed. Reg. at 7015). AFIA supports the intent to exempt shelf stable food, as defined in proposed § 1.904, from the scope of this proposed rule.

The definition provided by the agency for "shelf stable food" does not include any examples for animal food. AFIA recommends the agency include examples for animal food, such as packaged animal food.

Proposed Temperature Control Requirements are Excessive for Animal Food Safety

AFIA urges FDA to revise the proposed temperature monitoring requirements to better align with the risks in the animal food industry, and current industry practices that are adequate to ensure food safety. AFIA believes that temperature control requirements are not appropriate across the animal food industry. To mandate temperature requirements across the animal food industry would induce unnecessary cost on the industry without improving the safety of animal food products. At the very least, FDA should revise the language in the final rule to make it clear that continuous temperature monitoring is not required for animal food. Currently, temperature control shipments in the animal food industry do not involve the use of continuous time/temperature recording devices for most temperature-controlled shipments as the risk level for animal food safety does not require this practice.

Hand Washing Facilities Should not be a Requirement for Handling Animal Food

Proposed Rule with AFIA Recommendation

~~§ 1.908(c)(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. The hand washing facility must be convenient and provide running water to enable vehicle operators to wash their hands and avoid contamination of food.~~

AFIA Comments

AFIA does not believe this proposed provision should be a requirement for animal food. AFIA is not aware of any data to support this requirement for animal food. Without scientific justification, to make this a blanket requirement across the entire animal food industry would place an additional financial burden upon facilities to add such "convenient" hand washing facilities and, in many cases, may be completely unfeasible to attain in our current animal food facilities.

Information on a Single Previous Cargo is Adequate for Food Safety

Proposed Rule with AFIA Recommendations

§ 1.908(d)(4) A carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the ~~three previous cargoes~~ last (single) cargo load transported in the vehicle immediately prior to the current food cargo. The shipper and carrier may agree in writing that the carrier will provide information that identifies ~~fewer than three~~ previous cargo~~es~~ load or that the carrier need not provide any such information if procedures have been established 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 product. The written agreement is subject to the records requirements of § 1.912(b).

AFIA Comments
FDA notes that identification of three previous cargoes transported in the vehicle is consistent with its understanding of current industry practice (79 Fed. Reg. at 7025). While this may be true in certain segments of food handling operations, it is incorrect to suggest it is current practice across the entire food industry. Food safety efforts currently in place—and widely accepted—within the animal food industry are effective and practical in that it is common to ascertain the single previous cargo hauled on a bulk transport vehicle. The proposed language is overly prescriptive and unnecessary. AFIA recommends this section to be rewritten as indicated above.

To require three previous cargoes, with exception by written agreement, is overly burdensome and unnecessary. The shipper, in accordance with FSMA rules, would maintain written procedures as part of the food safety plan to ensure adequate cleanout of vehicles is performed and documented. This written plan should suffice in lieu of any additional documentation required to support compliance to the rule.

In addition to the excessive burden, providing information on the three previous cargoes could create a breach in confidentiality among suppliers and facilities, as the shipment of materials to other facilities (such as competitors) would be exposed. Thus, some businesses could request shippers not provide materials to certain businesses, limiting the ability of shippers to provide materials to a variety of facilities.

The tracking of three previous cargoes becomes almost impossible on a consistent basis, certainly impractical, as the attachment of trailers to tractors (transport vehicles) is continually changing. Rarely are trailers pulled by the same tractor (transport vehicle). The request for three previous cargoes is also impractical for less-than-truckload (LTL) shipments where tractors hauling trailers with packaged goods may stop at multiple locations for shipments. It is virtually impossible to maintain and track such information for LTL.

<u>Part 11 Should Not be Mandated for Records Required as part of this Proposed Rule</u>

Proposed Rule with AFIA Recommendations

§ 1.912(e) All records required by this subpart must be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records~~, which must be kept in accordance with part 11 of this chapter~~.

AFIA Comments
FDA's acceptance of electronic records for satisfaction of records requirements is appreciated. However, AFIA believes that compliance with 21 CFR Part 11 will be a significant burden to the industry and is unnecessary. The spirit, and in some places, the language of FSMA, encourages FDA not to require new business practices or specific requirements with respect to records. The industry currently has many types of records that will support FSMA requirements but do not meet the requirements of Part 11. Part 11 is very complex and few, if any, facilities would be able to meet the requirements for the rule proposed here without lasting and significant costs. The industry-wide cost of compliance would outweigh any benefit. Therefore, we are urging its removal from (e).

AFIA appreciates the opportunity to provide feedback regarding the proposed rule for sanitary transportation of human and animal foods. AFIA will continue reviewing the proposed rules and filing comments throughout the year. Our goal is to continue to provide FDA with the best information on the animal food industry, develop non-prescriptive rules that promote innovation and push FDA to reduce the costs and to better approximate the benefits.

Sincerely,

Leah Wilkinson
Director, Ingredients, Pet Food and State Affairs