July 30, 2014

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

Re:  Sanitary Transportation of Human and Animal Food, Proposed Rule
[Docket No. FDA-2013–N–0013]

To Whom It May Concern:

On behalf of our members, the Produce Marketing Association (PMA) respectfully submits the following comments as per the Food and Drug Administration's (FDA) request for comments regarding the “Sanitary Transportation of Human and Animal Food” proposed rule [Docket No. FDA-2013–N–0013]. In addition to this executive summary, PMA submits the attached document that provides specific, detailed comments on the proposal. PMA is the largest trade association representing companies in the fresh fruits and vegetables industry globally. Our association represents more than 2,700 member companies located in 45 countries. In the U.S., our members operate at every level in the supply chain from growing to shipping, processing/manufacturing, distribution, wholesaling, retail and foodservice. Collectively, our members handle more than 90 percent of fresh produce sold to domestic consumers. Regardless of member size or scope of operations, our members are committed at every level in the supply chain to food safety.

The overarching objective for PMA is to increase the consumption of fresh fruits and vegetables on a global basis. PMA serves its members by providing a forum to make business connections and by providing them with the information they need to make informed decisions that will enhance their businesses and deliver fresh fruits and vegetables to consumers. It is in this role of educator that PMA’s food safety and technology efforts are focused. During the initial discussions on the Food Safety Modernization Act (FSMA), PMA provided industry expertise to congressional staff and FDA to help inform them of current science and industry practices. PMA is also a strong supporter of the development of fresh produce-based science as demonstrated by the association’s founding support of the Center for Produce Safety (CPS). CPS is a unique research foundation focused exclusively on produce-related food safety research in
collaboration with industry and government. CPS provides open access to scientific research results that are actionable and necessary to continually enhance the safety of produce. Companies of all sizes and locations benefit from CPS research.

In developing these comments regarding the FDA proposed rule for “Sanitary Transportation of Human and Animal Food”, PMA staff has relied on numerous in-depth discussions with its members to gather feedback on issues of significance regarding this FSMA proposed rule. We also engaged the PMA Science and Technology committee on several occasions to get their input and guidance. This committee is composed of industry experts from around the industry: small producers to very large, technology vendors, growers, processors, retailers and foodservice representatives. Their insights have proven to be invaluable in sorting through this proposal and developing comments based on their collective experience. We have also participated as speakers in regional forums and events on FSMA and have met individually with PMA members and non-members alike to discuss the impacts of this proposal.

Executive Summary

Assuring the safety of produce at all steps from farm to fork continuum including during transport is a top priority for the global produce industry. Implications of this proposal are important to PMA members’ businesses and to the industry overall. PMA strongly supports advancing food safety in ways that are meaningful and that focus industry efforts to protect public health. PMA supports the implementation of science-based and risk-based regulations throughout the supply chain that use appropriate preventive controls to address hazards associated with the commodity, practices and procedures employed during the production, handling and holding of fresh produce. PMA believes that FDA has done an admirable job in drafting the FSMA proposed rule for the “Sanitary Transportation of Human and Animal Food.”

Key issues from the perspective of PMA members regarding FDA’s Sanitary Transportation of Human and Animal Food” proposed rule are as follows:

- **Bulk Vehicle Requirements:** PMA believes that FDA’s proposed definition of “bulk vehicle” is overly broad in scope and should not include the transport of fruit and vegetable RACs.
- **Definition of “Farm”:** PMA strongly supports FDA’s departure from the definition of Farm” definition found in 21 CFR §1.227 (b)(3) as the new proposed definition is more closely aligned with the practical meaning of farming operations. However, further amendments are suggested.
• **Raw Agricultural Commodities Do Not Require Time/Temperature Control for Safety:** PMA supports FDA’s tentative conclusion in the preamble discussion of this rule that: “FDA would not consider bananas and other foods that are similar in this regard and typically transported under temperature control solely for marketability purposes to be food that can support the rapid growth of undesirable microorganisms in the absence of temperature control and these foods therefore would not be subject to proposed § 1.908(a)(3)(iii).”

• **Defining Foods Requiring Time/Temperature Control for Safety:** PMA comments request clarification regarding what is meant by “a food that requires time/temperature for safety to limit pathogenic microorganism growth or toxin formation”? in that how will FDA in practical terms make this determination and is there a quantitative measure of “growth”?

• **Farm Transport Operations:** PMA has concerns regarding FDA’s proposed definition of “transport operations” specifically that, “transportation operations do not include any transportation activities for raw agricultural commodities that are performed by a farm.” It is suggested that all transportation activities for raw agricultural commodities before they are sold and placed into commerce, irrespective of whom performs this activity, would not be considered transportation operations for the purposes of this rule.

PMA has participated in the congressional debate about FSMA and has provided comment to FDA at every opportunity in the development of the proposed rules and policies. We greatly appreciate those earlier opportunities and the opportunity here to provide detailed comments on this FSMA proposal. PMA would like to continue to offer input and expertise to the Agency beyond the comment period. We are always available for additional stakeholder meetings with the Agency and PMA welcomes the opportunity to continue the dialogue beyond our attached formal written comments.

Thank you for the opportunity.

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The Food and Drug Administration’s (FDA) “Sanitary Transportation of Human and Animal Food” proposes to establish requirements for shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, to use sanitary transportation practices to ensure the safety of the food they transport. The Produce Marketing Association’s (PMA) comments below fall into two categories: General Comments and Comments Regarding Specific Proposed Criteria.

**General Comments:**

**Shipper Control Transport Safety**

Significant quantities of perishable fresh produce are transported by motor and rail carriers, annually within the United States. The majority of domestically grown fresh perishable produce is shipped freight on board (FOB), which indicates that the buyer assumes all risk of damage and delay in transit not caused by the seller irrespective of how the shipment is filled. FOB means that the produce quoted or sold is to be placed free on board the boat, car, trailer, container or other agency of the through land transportation at shipping point, in suitable shipping condition. Specific terms of shipping agreements vary widely, but agreements generally stipulate which party (shipper or receiver) pays for transportation of the shipment and who is responsible for the goods once they are placed in the carrier transportation vehicle. This last distinction regarding responsibility of the load is important for determining not only liability for perishable goods but who is responsible for assuring the safety of produce in-transit. It is a very common business practice in the perishable produce industry that the receiver will actually arrange and pay for a contract carrier to transport produce from a grower/shipper to the receiver’s facility, with the carrier being specifically under contract by the receiver. This gives very little control to the shipper regarding the quality and performance of transport, as the transportation entity is usually chosen and contracted by the receiver. As per the proposed FDA rule regarding Sanitary Transportation of Human and Animal Food, it would be difficult for perishable produce shippers to control and monitor the actions and performance of carriers, which they have not chosen and to be sure they conform to written product specifications for the transport of the products they are shipping. Many of the provisions of the proposed Sanitary Transportation of
Human and Animal Food rule pre-suppose that shippers have a greater amount of control over carriers than they actually have.

As such PMA suggests that FDA consider the contractual allocation of compliance responsibilities to the Sanitary Transportation of Human and Animal Food Regulation. The current proposed rule explicitly and rigidly lays out the responsibilities for shippers, carriers and receivers by restrictive definitions and explicit roles and responsibilities. These restrictive definitions of roles and responsibilities, if implemented, will adversely affect how operations are conducted. The current industry practice is to contractually define and allocate these roles and responsibilities to the party for whom it makes the most sense to be responsible. PMA suggests that FDA consider allowing for sufficient flexibility for shippers, carriers and receivers to contractually allocate responsibilities for the safe transportation of food among themselves. It is suggested that the proposed rule currently establish practices regarding the contractual (legal) terms between shippers, receivers and carriers.

**Implementation and Compliance Verification**

The Sanitary Transportation of Human and Animal Food regulation will affect how many entities conduct business in the future as well as how they interact with international, Federal, State and local government agencies (e.g. U.S. DOT, USDA FSIS, U.S. EPA, State and Local regulatory authorities). PMA recommends that FDA consider providing stakeholders with opportunity to constructively comment and provide input on the Agency's proposed implementation, compliance and enforcement strategy. In the proposed FDA implementation, compliance and enforcement strategy should clearly articulate how the Agency will coordinate implementation, compliance and enforcement activities among these partner agencies and with stakeholders. PMA suggests that FDA consider development of an interagency coordinating body that will clearly identify and delineate the roles and responsibilities of FDA, other Federal, State and local regulatory authorities, regarding the implementation, compliance and enforcement of this rule.
Comments Regarding Specific FDA Proposed Criteria:

Subpart O—Sanitary Transportation of Human and Animal Food General Provisions

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Subpart O—Sanitary Transportation of Human and Animal Food General Provisions

§ 1.900 Who is subject to this subpart?

(a) 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).

(b) 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.

PMA Comment: PMA requests clarification from FDA as to how foods intended solely for export will be covered or not covered by this regulation and specifically what actions need to be taken by the food facility to assure compliance when food product is intended exclusively for export markets. PMA contends that food intended for export should not be covered by this regulation, as the food is neither consumed nor distributed in the United States. It is suggested that FDA clarify the scope of the proposed rule with regard to trans-national shipment of foods and provide clear guidance to industry that addresses the complex relations/issues involved in international shipments.

§ 1.902 How do the criteria and definitions in this subpart apply under the Federal Food, Drug, and Cosmetic Act?

(a) 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 (21 U.S.C. 342(i)) 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 transportation operations under conditions that are not in compliance with this subpart.

(b) The failure by a shipper, carrier by motor vehicle or rail vehicle, or receiver engaged in transportation operations to comply with the requirements of this subpart is a prohibited act under section 301(hh) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(hh)).
**PMA Comment:** Temperature Deviations and Food Adulteration

The implications of proposed §1.902(b) are that if a simple temperature deviation of a shipment occurs and violates proposed sections §1.908 (a)(3)(iii) and (b)(3), the food in that shipment is “adulterated,” rendering it unsuitable for any purpose. PMA suggests that FDA consider amending the final rule to accommodate minor deviations from the temperature specified by the shipper as human pathogen growth is an integrated function of both time and temperature. Minor breaks in the cold chain do not definitively mean that a food is unsafe for human or animal consumption. Additionally, since only the ambient air temperature around the product is typically being monitored it does not necessarily mean that food product temperatures have exceeded temperatures specified by the shipper. It should also be anticipated that minor ambient temperature fluctuations in excess of those specified by the shipper will occur in transit due to activities such as routine de-frosting of refrigeration unit coils and the opening and closing of carrier unit truck doors to take on or drop-off portions of the cargo on less than full loads (LTL), which are routinely employed in commerce.

**§ 1.904 What definitions apply to this subpart?**

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) are applicable to such terms when used in this part. The following definitions also apply:

- **Adequate means** that which is needed to accomplish the intended purpose in keeping with good public health practice.

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

- **Bulk vehicle** means 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.

**PMA Comment: Raw Agricultural Commodities (RACs) and Bulk Transport.**

PMA believes that the definition of “bulk vehicle” is overly broad in scope and should not include the transport of fruit and vegetable RACs. Currently potatoes, carrots, onions, cucumbers (for pickling) watermelon, hard squash and tomatoes (for processing) may be transported in bulk from growing fields to food facilities or from grower/shippers to wholesalers. As many of these items go on for further thermal processing with a kill step or are cooked by consumer before being consumed, the bulk vehicle requirements for such RACs is onerous and adds little to protect public health. Hence, the definition of bulk transport should exclude RACs that will receive further thermal processing with a kill step or are rarely consumed raw.
Carrier means a person who owns, leases, or is otherwise ultimately responsible for the use of a motor vehicle or rail vehicle to transport food. The carrier is responsible for all functions assigned to a carrier in this subpart even if they are performed by other persons, such as a driver that is employed or contracted by a trucking firm. A carrier may also be a receiver or a shipper if the person also performs the functions of those respective persons as defined in this subpart.

Cross-contact means the unintentional incorporation of a food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act into food, except animal food.

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term “farm” includes 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.

PMA Comment: PMA strongly supports FDA’s departure from the definition of “Farm” definition found in 21 CFR §1.227 (b)(3) as the new proposed definition in this rule is more closely aligned with the practical meaning of farming operations. It also clearly demonstrates that the FDA can were needed have different definitions for entities such as “farms” in various FSMA rules, allowing the Agency to take a customized approach to each rule. However, PMA still believes that the FDA definition of “farm” is inadequate and should be amended as suggested below.

- Redefining “farm” to include pack and hold activities performed on select RACs not grown on the farm, provides more uniform and effective regulation of all farm pack and hold activities covered by this regulation.
- “One general physical location” is an irrelevant descriptor that cannot be clearly defined without being arbitrary or capricious. Hence, it should be removed from the definition of farm.

As per PMA’s previously comments provided for the proposed rule regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food (Docket No. 2011-N-0920/RIN 0910-AG36), PMA is not supportive of FDA’s current definition of “farm” and requests FDA consider amending the definition.

PMA recommends that the definition of “farm” be amended as follows:

PMA proposed definition of farm: “Farm” means an individual tract or tracts of land where crops are grown, harvested, packed and held, animals are raised (including
seafood), or both and have a similar farm/ranch manager, operator or landowner(s) and are operated under a common on-farm food safety management scheme. The term “farm” includes:

(i) Facilities that perform harvesting activities on RACs and do not transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act [FFDCA], into a processed food as defined in section 201(gg) of the FFDCA.

(ii) Facilities that receive RACs from other “farms”, that perform harvesting activities on RACs and do not transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act [FFDCA], into a processed food as defined in section 201(gg) of the FFDCA.

(iii) Facilities that manufacture/ process food, provided that all food used in such activities is consumed on that farm or another farm under same ownership.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. Food includes animal food and food also subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

Food not completely enclosed by a container means any food that is placed into a container in such a manner that it is partially open to the surrounding environment. Examples of such containers include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. This term does not include food transported in a bulk vehicle as defined in this subpart.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Non-covered business means a shipper, receiver, or carrier engaged in transportation operations that has less than $500,000 in total annual sales.

Pest means any objectionable animals or insects including birds, rodents, flies, and larvae.

Receiver means any person who receives food after transportation, whether or not that person represents the final point of receipt for the food. A receiver may also be a carrier or a shipper if the person also performs those functions as defined in this subpart. A receiver does not include an individual consumer or a person who receives or holds
food on behalf of an individual consumer and who is not also a party to the transaction and who is not in the business of distributing food. 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.

**Shipper** means a person who initiates a shipment of food by motor vehicle 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 may also be a carrier or a receiver if the shipper also performs those functions as defined in this subpart.

**PMA Comment:** The currently proposed definition of “shipper” is unclear as to whether or not certain entities in the supply chain meet the definition of “shipper” and would hence be covered by this regulation. PMA suggests the FDA consider development of guidance that specifically addresses the coverage and applicability of this rule to the numerous entities that may be involved in food transportation (e.g., property transaction brokers, third party logistics entities, truck brokers, freight forwarders, etc.).

**Small business** means a business subject to § 1.900(a) employing fewer than 500 persons except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to § 1.900(a) having less than $25,500,000 in annual receipts.

**Time/temperature control for safety (TCS)** Food means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

**PMA Comment:** PMA supports FDA’s tentative conclusion in the preamble discussion of this rule that: “FDA would not consider bananas and other foods that are similar in this regard and typically transported under temperature control solely for marketability purposes to be food that can support the rapid growth of undesirable microorganisms in the absence of temperature control and these foods therefore would not be subject to proposed § 1.908(a)(3)(iii).”

- However, PMA requests clarification regarding what is meant by “a food that requires time/temperature for safety to limit pathogenic microorganisms growth or toxin formation”? How does the FDA propose to define growth and what is the quantitative measure of “growth”? If growth is defined as a one log increase in human pathogens, many microbial assays have a standard deviation of ± 1 log and this may prove
difficult to accurately measure. The scientific community has engaged in lengthy technical discussions, including at the Conference for Food Protection, regarding time/temperature control for safety and what constitutes “growth”. It is suggested that the definition of “growth” in this proposed criteria should be more explicitly defined.

- It is also unclear as to how FDA expects food manufacturers such as fresh-cut produce processors to determine whether or not “a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation” or in the case where there is insufficient data in the scientific literature to make such a determination.

- The concept of time/temperature control for safety seems overly protective and a redundant preventive control, as foods should not contain human pathogens when placed into commerce by manufacturers. Time and temperature should most certainly be considered during transport to maintain food quality but it is of questionable relevancy regarding food safety for many produce items.

- Product temperature versus ambient transportation air temperature. The use of the concept of time/temperature control for safety requires an integrated approach whereby both variables; time and temperature are accounted for and integrated. Additionally, the ambient temperature of a refrigerated vehicle compartment is almost always not the temperature of the food product since food products do not warm or cool instantaneously because the product is insulated by primary and secondary packaging. There is concern that ambient transportation temperatures slightly above those specified by the shipper for a short period of time, as recorded by an ambient air temperature recorder, may cause entire loads of fresh-cut produce to be declared adulterated. Therefore, it is suggested that FDA consider using a time/temperature integrated approach of the food product itself, and not simply the monitoring of ambient air temperature within a transportation cargo area. However, it must also be noted that the temperature of food products as they warm and cool are NOT homogenous in their temperature profile. Therefore it will be important for FDA to clearly define using the best available science when and where increased temperature of a food product constitutes an increased public health risk and where the temperature of products should be monitored. Additionally, requiring monitoring of food products may also introduce risk, if practitioners breach primary or secondary packing with temperature probes to assess and monitor temperatures in-transit as well as the
potential for small temperature monitoring devices being introduced into food products and becoming of physical hazard. Careful consideration and guidance needs to be developed taking currently employed industry best practices into consideration regarding how product temperatures should be monitored in-transit to assure the safety of foods. Additionally, micro-environments created inside the cargo compartments must be taken into account as these micro-environments introduce variability in temperature inside the cargo space of the refrigerated transport vehicle and are due to many factors, such as but not limited to: outside ambient conditions, leak rates, thermal efficiency, age and condition of the refrigerated transport vehicle, insufficient cargo unitization, packaging and stowage of cargo, short cycling of condition air, product’s field heat and heat of respiration, and the condition, age and/or maturity of cargo. Use of validated integrated time / temperature models for specific foods may be worthy of further consideration to assist the responsible party with determining when a food product has been temperature abused and may pose a public health risk, as simply monitoring product or ambient air conditions alone may lead to incorrect conclusions regarding the safety of a particular food product.

**Transportation** means any movement of food in commerce by motor vehicle or rail vehicle.

**Transportation equipment** means equipment used in food transportation operations, other than vehicles, e.g., bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

**Transportation operations** means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation solely of shelf stable food that is completely enclosed by a container, compressed food gases or live food animals. In addition, transportation operations do not include any transportation activities for raw agricultural commodities that are performed by a farm.
PMA Comment: PMA has concerns regarding FDA’s proposed definition of “transport operations” specifically that, “transportation operations do not include any transportation activities for raw agricultural commodities that are performed by a farm.”

- Many fresh produce items are harvested and transported to postharvest cooling operations, packinghouses and processing plants by contract carriers that are not “farms”. Additionally, packinghouse operations may perform intercompany transfers of produce to facilitate shipping of mixed loads of various fresh produce raw agricultural commodities. These are very low risk activities since no manipulation or handling of the raw agricultural commodity occurs during this transport from fields to where postharvest handling occurs or among intercompany packinghouse facilities. The proposed FDA definition of “transportation operations” is not risk-based or science-based since it is predicated on who is performing the activity not the risk of the activity itself.
- It is suggested that all transportation activities for raw agricultural commodities before they are sold and placed into commerce, irrespective of who performs this activity, would not be considered transportation operations for the purposes of this rule.

PMA Comment: “Short-Hauls” and “Intra-Company” Transfers

- The FDA proposed rule provisions do not make exempt transport operations that are conducted within a single company, such as when the shipper and carrier are part of the same corporate-parent ownership. It is recommended that FDA consider developing provisions that exempt intra-company shipments with consideration being given to permit the use of, for example, an internal company SOP to document rule compliance, rather than requiring additional documentation.
- The FDA proposed rule would regulate all food transportation in a similar manner regardless of the distance the food travels. However, shorter distance shipments do not need the same level of regulatory oversight as other transportation. PMA suggests that FDA consider development of a definition in the final rule for “short haul” transportation operations and apply risk-based modified requirements.

Vehicle means 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.

Vehicles and Transportation Equipment

§ 1.906 What requirements apply to vehicles and transportation equipment?

(a) Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately
cleanable for their intended use to prevent the food they transport from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations.

(b) Vehicles and transportation equipment must be maintained in such a sanitary condition as to prevent the food they transport from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations.

(c) Vehicles and transportation equipment that are used in transportation operations for food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation must be designed, maintained, and equipped, to maintain the food under temperature conditions that will prevent the rapid growth of undesirable microorganisms.

(d) Each freezer and mechanically refrigerated cold storage compartment in vehicles or transportation equipment used in transportation operations for food that can support the rapid growth of microorganisms in the absence of temperature control during transportation, must be equipped with an indicating thermometer, temperature measuring device, or temperature recording device installed to show the temperature accurately within the compartment.

(e) Vehicles and transportation equipment must be stored in a manner as to prevent the vehicles or transportation equipment from harboring pests or becoming contaminated in any other manner that could result in food for which they will be used becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations.

PMA Comment: PMA requests clarification from FDA regarding proposed provision §1.906(b), in that fresh fruits and vegetables are perishable food products and hence are decomposing and senescing toward being unfit for human consumption by their very nature after harvest. This will be problematic for the fresh produce transportation and we believe that FDA is mixing the concepts of food safety and food quality. Specifically, a produce raw agricultural commodity being unfit due to decomposition is a quality issue but not necessarily a food safety issue. Produce raw agricultural commodities routinely experience decomposition during transport due to the perishable nature of fresh produce. Temperature control is used in the perishable produce industry to retard decomposition due to naturally occurring senescence processes and decay caused by plant pathogens. It is recommended the word “decomposed” be redacted and the provisions set forth only address food safety associated with the transport of foods and animal feed.
Transportation Operations

§ 1.908 What requirements apply to transportation operations?

(a) General requirements.

(1) Unless stated otherwise in this section, the requirements of this section apply to all shippers, carriers, and receivers engaged in transportation operations.

(2) Responsibility for ensuring that transportation operations are carried out in compliance with all requirements in this subpart must be assigned to competent supervisory personnel.

(3) All transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations, including:

   (i) Taking effective measures such as segregation or isolation to protect food from contamination by raw foods and non-food items in the same load.

   (ii) Taking effective measures such as segregation, isolation, or other protective measures such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations.

   (iii) For food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, ensuring that the food is transported in a manner, including the temperature conditions, such that the transportation operation meets the requirements of paragraph (a)(3) of this section.

(b) 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, including any specific design requirements and cleaning procedures to ensure that the vehicle is in appropriate sanitary condition for the transportation of the 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. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a).

(2) Before loading food not completely enclosed by a container onto a vehicle provided by a carrier or into transportation equipment provided by a carrier, the shipper must visually inspect the vehicle or the transportation equipment provided by the carrier for cleanliness. The shipper must determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, e.g., it is free of visible evidence of pest infestation and...
of debris, previous cargo, or dirt that could cause the food to become adulterated.

(3) A shipper of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, whether a TCS food or a non-TCS food, must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, the temperature conditions necessary during the transportation operation, including the pre-cooling phase, to ensure that the operation will maintain the temperature conditions and meet the requirements of paragraph (a)(3) of this section. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a).

(4) Before loading food, a shipper of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, must verify that each freezer and mechanically refrigerated cold storage compartment or container has been pre-cooled in accordance with information submitted by the shipper as required by paragraph (b)(3) of this section.

(5) The shipper assumes the requirements applicable to the carrier in §1.908(d)(2)(i) with respect to providing a demonstration to the receiver if the shipper and carrier have agreed in writing under § 1.908(d)(2)(ii) that the shipper is responsible for ensuring that the food was held under acceptable temperature conditions during transportation operations. When the shipper and carrier have established such an agreement, the shipper also assumes the corresponding records requirements of §§ 1.908(d)(6)(ii) and 1.912(b).

PMA Comment: As per FDA proposed § 1.908 (a)(3)(iii) and (b)(3) regarding how the carrier or shipper would demonstrate that it maintained requisite temperature conditions, FDA should align requirements with current industry practices that are adequate to ensure safe food transport. Specifically, FDA should be explicit and unambiguous in the final rule that continuous temperature monitoring is not expected by the Agency for compliance with these provisions. Current industry practice often does not involve the use of continuous time/temperature recording devices for most temperature controlled food shipments—regardless of whether they are TCS. Temperatures are simply taken at discreet time intervals by the recording device. Typically, truck trailer and container microprocessor controllers record temperatures approximately every 15 to 60 minutes.

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

(2) Shippers and receivers of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation must carry out loading and unloading operations under conditions that will prevent the food from supporting such microbial growth.

(d) Requirements applicable to carriers engaged in transportation operations.

(1) A carrier must supply a vehicle and transportation equipment that meets any requirements specified by the shipper in accordance with paragraph (b)(1) of this section and is otherwise appropriate to 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.

(2) A carrier:

(i) Must, once the transportation operation is complete, demonstrate to the shipper and if requested, to the receiver, that it has maintained temperature conditions during the transportation operation consistent with those specified by the shipper in accordance with § 1.908(b)(3). Such demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper such as the carrier presenting printouts of a time/temperature recording device or a log of temperature measurements taken at various times during the shipment.

(ii) Is not subject to the requirement of paragraph (d)(2)(i) of this section if the carrier and shipper agree in writing, before transportation operations, that the shipper is responsible for monitoring the temperature conditions during the transportation operation or otherwise ensuring that the food was held under acceptable temperature conditions during the transportation operation. The carrier must provide the written agreement to the receiver, if requested. The written agreement is subject to the records requirements of §1.912(b).

(3) Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control, a carrier must precool each mechanically refrigerated freezer and cold storage compartment as specified by the shipper in accordance with paragraph (b)(3) of this section.

(4) A carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the three previous cargoes transported in the vehicle. 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 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).

(5) A carrier that offers a bulk vehicle for food transportation must provide information to the shipper that describes the most recent cleaning of the bulk vehicle, except that a shipper and carrier may agree in writing that the carrier need not provide any such information, if the carrier follows procedures that would ensure that the bulk vehicle offered will be adequate for the intended transportation operation, e.g., if the carrier has contractually agreed to use a specified cleaning procedure at specified intervals or if the shipper cleans the vehicle at his own facility. The written agreement is subject to the records requirements of § 1.912(b).

(6) A carrier must develop and implement written procedures subject to the records requirements of § 1.912(b) that:

(i) Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and the transportation equipment in appropriate sanitary condition as required by § 1.906(b);

(ii) Describe how it will comply with the provisions for temperature control in paragraph (2) of this section, and;

(iii) Describe how it will comply with the provisions for the use of bulk vehicles in paragraphs (d)(4) and (d)(5) of this section.

PMA Comment: Raw Agricultural Commodities (RACs) and Bulk Transport. If the definition of “bulk transport is not amended as proposed, RAC shippers and carriers for some produce items will be subjected to proposed §1.908 (d)(4) and (d)(5) which will be burdensome and onerous and provide little to no enhanced public health benefits. PMA asserts that the definition of bulk transport is overly broad in scope and should not include the transport of fruit and vegetable RACs. Currently potatoes, carrots, onions, cucumbers (for pickling) watermelon, hard squash and tomatoes (for processing) may be transported in bulk from growing fields to food facilities or from grower/shippers to wholesalers. As many of these items go on for further thermal processing with a kill step or are cooked by consumer before being consumed, the bulk vehicle requirements for such RACs is onerous and adds little to protect public health. Hence, it is suggested that the definition of bulk transport be amended to exclude RACs that will receive further thermal processing with a kill step or are rarely consumed raw.
Training

§ 1.910 What training requirements apply to carriers engaged in transportation operations?
(a) Carriers must provide training to personnel engaged in transportation operations that provides an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems and the responsibilities of the carrier under this part. The training must be provided upon hiring and as needed thereafter.
(b) Carriers must establish and maintain records documenting the training described in paragraph (a) of this section. Such records must include the date of the training, the type of training, and the person(s) trained. These records are subject to the records requirements of § 1.912(c).

PMA Comments: PMA requests clarification from FDA if the Agency will be developing harmonized training materials that will be updated on a regular basis for this required transportation operations training or will it be left up to individual transportation operations to develop such materials. PMA would be supportive of development and delivery of harmonized training materials perhaps to be made available from the Produce Safety Alliance, Preventive Controls Alliance and the Sprout Safety Alliance, as FSMA Sanitary Transportation rule compliance training is a natural and logical extension of the Alliance training efforts.

Records

§ 1.912 What record retention and other records requirements apply to shippers and carriers engaged in transportation operations?
(a) Shippers must retain records that demonstrate that they provide information to carriers as required by § 1.908(b)(1) and (3) as a regular part of their transportation operations for a period of 12 months beyond when the shipper is subject to any requirement to provide such information.
(b) Carriers must retain any written agreements required by § 1.908(d)(2)(ii) of this subpart and records of the written procedures required by § 1.908(d)(6) for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.
(c) Carriers must retain training records required by § 1.910(b) for a period of 12 months beyond when the person identified in any such records continues to perform the duties for which the training was provided.
(d) Shippers and carriers must make all records required by this subpart available to a duly authorized individual promptly upon oral or written request.
(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.

(f) Except for the written procedures required by § 1.908(d)(6), offsite storage of records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The written procedures required by § 1.908(d)(6) must remain onsite as long as the procedures are in use in transportation operations. Electronic records are considered to be onsite if they are accessible from an onsite location.

(g) All records required by this subpart are subject to the disclosure requirements under part 20 of this chapter.

**PMA Comment:** The agency’s stated approach to recordkeeping that focuses on ensuring that appropriate contracts and procedures are in place has been conveyed repeatedly to stakeholders at FDA public meetings regarding this proposed rule. However, this approach to compliance verification was not included in the preamble to Sanitary Transportation of Human and Animal Food Proposed Rule. PMA would like to suggest that FDA consider more fully expounding on the Agency’s implementation, compliance and enforcement strategy in the Sanitary Transportation of Human and Animal Food Proposed Rule final rule preamble and specifically include discussion of an emphasis on ensuring that appropriate contracts and procedures are in place to determine compliance. This would explicitly state the Agency’s current intent and reduce the uncertainty of deviations from this policy in the future.

**Waivers**

§ 1.914 Under what circumstances will FDA waive a requirement of this subpart?
FDA will waive any requirement of this subpart with respect to any class of persons, vehicles, food, or nonfood products, when FDA determines that:
(a) The waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health; and
(b) The waiver will not be contrary to the public interest.

§ 1.916 When will FDA consider whether to waive a requirement of this subpart?
FDA will consider whether to waive a requirement of this subpart on FDA’s own initiative or on the petition submitted under § 10.30 of this chapter by any person who is subject to the requirements of this subpart with respect to any class of persons, vehicles, food, or nonfood products.

§ 1.918 What must be included in the Statement of Grounds in a petition requesting a waiver?
In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a waiver must:

(a) Describe with particularity the waiver requested, including the persons, vehicles, food, or nonfood product(s) to which the waiver would apply and the requirement(s) of this subpart to which the waiver would apply; and

(b) Present information demonstrating that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and will not be contrary to the public interest.

§ 1.920 What information submitted in a petition requesting a waiver or submitted in comments on such a petition are publicly available?
We will presume that information submitted in a petition requesting a waiver and comments submitted on such a petition does not contain information exempt from public disclosure under part 20 of this chapter and would be made public as part of the docket associated with this request.

§ 1.922 Who will respond to a petition requesting a waiver?
The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN) or the Center for Veterinary Medicine (CVM), or the Director, Office of Compliance, CFSAN, or the Director, Office of Surveillance and Compliance, CVM, will respond to a petition requesting a waiver.

§ 1.924 What process applies to a petition requesting a waiver?
(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a waiver.
(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the Federal Register, requesting information and views on a filed petition, including information and views from persons who could be affected by the waiver if the petition were to be granted.
(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing.
   (1) If we grant the petition, either in whole or in part, we will publish a notice in the Federal Register setting forth any waiver and the reasons for such waiver.
   (2) If we deny the petition (including partial denials), our written response to the petitioner will explain the reason(s) for the denial.
(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting waivers, including the status of each petition (for example, pending, granted, or denied).

§ 1.926 Under what circumstances may FDA deny a petition requesting a waiver?
We may deny a petition requesting a waiver if the petition does not provide the information required under § 1.918 (including the requirements of § 10.30 of
this chapter), or if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health, or that the waiver could be contrary to the public interest.

§ 1.928 What process will FDA follow when waiving a requirement of this subpart on FDA’s own initiative?
If FDA, on its own initiative, determines that a waiver is appropriate, FDA will publish a notice in the Federal Register setting forth the waiver and the reasons for such waiver.

§ 1.930 When will a waiver granted by FDA become effective?
Any waiver granted by FDA will become effective on the date that notice of the waiver is published in the Federal Register.

§ 1.932 Under what circumstances may FDA modify or revoke a waiver?
FDA may modify or revoke a waiver if FDA determines that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health or that the waiver could be contrary to the public interest.

§ 1.934 What procedures apply if FDA determines that a waiver should be modified or revoked?

(a) We will provide the following notifications:
   (1) We will notify the entity that initially requested the waiver, in writing at the address identified in its petition, if we determine that a waiver granted in response to its petition should be modified or revoked.
   (2) We will publish a notice of our determination that a waiver should be modified or revoked in the Federal Register. This notice will establish a public docket so that interested parties may submit written submissions on our determination.

(b) We will consider timely written submissions submitted to the public docket from interested parties.

(c) We will publish a notice of our decision in the Federal Register. The effective date of the decision will be the date of publication of the notice.

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