

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
<http://www.regulations.gov/>

Re: Sanitary Transportation of Human and Animal Food. Docket No. FDA-2013-N-0013; RIN 0910-AG98

The United Fresh Produce Association appreciates the opportunity to comment on the proposed regulation *Sanitary Transportation of Human and Animal Food* ("Sanitary Transportation rule").

United Fresh represents more than 1,200 companies at the forefront of the fresh and fresh-cut produce industry, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. United Fresh works to increase consumption of fresh produce for public health, shape legislative and regulatory policies that serve the public and provide for a sound business climate for its members, provide scientific and technical leadership in food safety, quality assurance, nutrition and health, and develop educational programs and business opportunities to assist member companies in growing successful businesses.

General Comments

1. Exclusion for Intra-company Transport and Temperature Control for Raw Agricultural Commodities (RACs) that are Fresh Produce

In the preamble, FDA notes that they "have tentatively concluded that the sanitary transportation practices that would be required by this proposed rule are not necessary to prevent RACs from becoming adulterated during transportation by farms, and are proposing to exclude such foods from the scope of these requirements." We agree with this position, and also agree with FDA's redefinition 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".

Many farm operations will transport fresh produce RACs between sites; e.g., from a field to a cooling operation and on to a packinghouse. Such transport is generally over relatively short distances and is considered intra-company (i.e., ownership of the RACs does not change), even if such transport is by independent carriers contracted by a farm. In such cases, we submit that the risk of adulteration during intra-company transport is intuitively not different than the risk under the proposed exclusion described above, and so such transportation should remain the responsibility of voluntary procedures and practices internal to the company without the mandatory recordkeeping required by this rule.

We are unaware of any science that demonstrates that any RACs that are fresh fruits or vegetables require temperature control for safety during transport. Fresh produce RACs that are transported under temperature control are done so for quality purposes exclusively and at temperatures that are commodity-specific. Indeed, temperature control for some RACs are not at refrigeration temperatures; e.g., tomatoes and avocados do not do well as refrigerated commodities and, if shipped under temperature control, would intentionally be at temperatures above 40°F. Such shipments would not be considered temperature abused.

Some inoculated laboratory studies have demonstrated an ability for pathogens like *Salmonella* to grow on some low-acid fresh produce commodities under temperature abuse conditions, but

none have demonstrated such growth under actual transport conditions. Further, no foodborne illness investigations linked to fresh produce have identified lack of temperature control during transport as a likely contributor. Consequently, any temperature requirements during such transport should remain voluntary and not subject to the costs of the recordkeeping requirements that this rule would impose, even if the product(s) are typically shipped under controlled temperature conditions and particularly if so stated in a facility's food safety plan.

Additional Specific Comments

Notwithstanding our comments above, we provide the following for FDA's consideration:

- A. § 1.900(b) "The requirements of this subpart do not apply to shippers, receivers, or carriers when they are engaged in transportation operations of...(2) Food that is imported for future export and that is neither consumed nor distributed in the United States." We agree with this exemption and suggest that any export shipment that is neither consumed nor distributed in the United States should likewise be exempted.
- B. § 1.904 "*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." We agree with this definition in its strictest terms and only so far as it includes microorganisms reasonably likely to cause the specific food to become adulterated under the conditions of the shipment, including the intended duration of the shipment. FDA should make clear that microorganisms that have only the potential to cause spoilage without food safety risk should not be included in this definition.
- C. § 1.904 "*Non-covered business* means a shipper, receiver, or carrier engaged in transportation operations that has less than \$500,000 in total annual sales." We believe that, by this definition, a large majority of the independent carriers that are used by the fresh produce industry would be non-covered businesses. In a case where the shipper or carrier is a non-covered business, we submit that it would be pointless for the others (i.e., shipper, carrier or receiver) to be covered by this rule. For example, if the carrier is a non-covered business, the requirement in § 1.908(d) would be unassigned, leading to confusion of who or whether the supplier or receiver is required to perform the unassigned tasks. Therefore, we respectfully suggest that carriers not be exempted on the basis of size.
- D. § 1.906(d) "Each freezer and mechanically refrigerated cold storage compartment in vehicles or transportation equipment ... must be equipped with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to show the temperature accurately within the compartment." For fresh and fresh-cut produce shipments, it is common for the shipper to include a temperature recording device in the shipment. The rule should allow for shippers' procedures to include temperature measuring/recording devices instead of requiring carriers to have such devices installed. In other situations, produce companies may ship product in small cooler boxes with icepacks, relying on such for temperature control, not the carrier; the rule should allow the shipper to employ such options.
- E. § 1.908(a)(2) "Responsibility ...must be assigned to competent supervisory personnel." The rule is silent on qualifications for such personnel, and we agree that it should remain silent.
- F. § 1.908(b)(2) "the shipper must visually inspect the vehicle...for cleanliness. The shipper must determine that the vehicle...is in appropriate sanitary condition for the transport of the food".
 - a. This conflicts with the definition of shipper in § 1.904: "Shipper means a person who initiates a shipment of food...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." If the "shipper" is the receiver (e.g., free-on-board/FOB shipments) and is not on-site, they cannot be held responsible for visually inspecting the carrier. Neither can the shipper be responsible for an individual who "physically transfers it onto a vehicle arranged for by the shipper" if the individual is not an employee of the shipper.

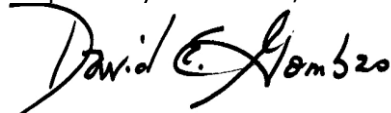
- b. As farms are not covered, shippers are expected to be covered by the proposed Preventive Controls rule, and these "cleanliness" requirements appear redundant with the requirements in part 117; i.e., "§ 117.93 Warehousing and distribution. Storage and transportation of food must be under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and the container."
 - c. In less-than-truckload (LTL) shipments, the shipper of a partial load will likely be present only for their shipment, and not for subsequent loads, therefore cannot be held responsible to "visually inspect the vehicle ... for cleanliness" or "that the vehicle ... is in appropriate sanitary condition" for subsequent loads. The rule must also take into account cross-docking situations, where employees of neither the shipper nor receiver will be present during loading into the subsequent vehicle, and the subsequent vehicle may not be from the same carrier as the first.
- G. § 1.908(b)(3) "A shipper of food that can support the rapid growth of undesirable microorganisms ... must specify in writing to the carrier...the temperature conditions necessary during the transportation operation..." FDA should make clear that such temperature requirements may be in existing documents (e.g., contracts or bills of lading) and do not need to be in separate, dedicated documents.
- H. § 1.908(b)(4) "Before loading food, a shipper of food...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..." FDA should make clear that pre-cooling procedures should take into account the potential for condensate formation during loading, and pre-cooling may not always be appropriate. Verification of pre-cooling should be required only when included in the shipper's instructions to the carrier.
- I. § 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." Most "handling" of food during shipments is by fork lift or other equipment. This requirement should only apply if the vehicle operator is reasonably expected to touch (i.e., come in physical contact with) the food.
- J. § 1.908(d)(1) "A carrier must supply a vehicle and transportation equipment..." In some cases, the equipment will be provided by the shipper or receiver; the carrier will only be the transporter (e.g., a tractor driver who picks up a trailer at the shipper). Further, the carrier cannot be held responsible if it is a non-covered business, which we believe further supports our position that all carriers of food under this rule should be covered businesses.
- K. § 1.908(d)(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..." The proposed rule is silent on the how violations of prescribed temperature conditions will affect the acceptability of the shipped product that requires temperature control for safety. We agree that such is beyond the scope of this rule and suggest that FDA make clear that acceptability of the shipped product should be left to a risk assessment performed by the receiver and/or shipper. Even when the carrier experiences multiple short term violations of a temperature maximum, the temperature of the product may not be impacted. For example, a refrigerated trailer that heats to 45°F for 10 minutes would have no impact on the product temperature in palletized cartons of leafy greens that are shipped at

temperatures not to exceed 40°F, let alone in a high density bin of cooled iceberg lettuce with the same temperature restriction.

- L. § 1.912 record retention. The only records proposed to require retention are the shipper's instructions to the carrier, the carrier's cleaning procedures and agreements with the shipper regarding cleaning and temperature control, and the carrier's training records. The rule is silent on retention of shipment records related to truck inspections, precooling, and temperature monitoring, and we suggest that FDA make clear that retention of such records is outside the scope of the rule. Actual shipment records should be retained according to the voluntary procedures of the companies involved, which may include a short time after the records are made, or even non-retention.
- M. § 1.912(d) "...carriers must make all records required by this subpart available to a duly authorized individual promptly upon oral or written request." Small carrier operations (e.g., owner/operator) may not carry required records (e.g., training records or records from previous loads) with them, and so "promptly" may be difficult. Similar comments apply to § 1.912(d) "The written procedures required by § 1.908(d)(6) must remain onsite as long as the procedures are in use in transportation operations." For owner/operators, "onsite" may be the owner's home or vehicle. FDA should provide lenience and guidance for such situations.
- N. § 1.912(e) "...electronic records, which must be kept in accordance with part 11 of this chapter." Part 11 requires specialized, and typically expensive, software, which may be beyond affordability for small shippers and carriers. FDA should provide lenience and guidance for such situations.
- O. § 1.916 "FDA will consider whether to waive a requirement of this subpart...on the petition submitted under § 10.30 of this chapter by any person who is subject to the requirements of this subpart..." We agree with and support the opportunity for persons to submit a petition for a waiver, but urge FDA to not make such a petition too onerous or burdensome for individuals, e.g., small shippers or owner/operator carriers. FDA should provide lenience and guidance for such situations.
- P. § 1.916(c) "Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing." We suggest that such a response should be expedited and include a timeframe for decision (e.g., 180 days) and steps to be taken if the deadline is missed.

The members of United Fresh hope that FDA finds value in these considered comments, and we stand ready to clarify or assist FDA in these recommended interpretations and changes to the proposed rule.

Respectfully submitted,



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