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Guidance for Industry: Sanitary Transportation of Food

Contains Nonbinding Recommendations

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Office of Food Safety

Division of Plant and Dairy Food Safety, HFS-317

Center for Food Safety and Applied Nutrition

Food and Drug Administration

5100 Paint Branch Parkway

College Park, MD 20740

(Tel) [REDACTED] (Updated phone: 240-402-2022)

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Food and Drug Administration

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(Tel) 240-276-9200

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Contains Nonbinding Recommendations

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Guidance for Industry¹ Sanitary Transportation of Food

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This guidance is intended for persons engaged in food transport, including persons who transport food (and store it during transport) as well as manufacturers or other persons who arrange for the transportation of food. The term "food" means articles used for food or drink for man or other animals, and components of any such article. (21 U.C.S. 231(f)).

We are issuing this guidance to provide all sectors of the food industry with broadly applicable recommendations for controls to prevent food safety problems during transport while we are implementing the Sanitary Food Transportation Act of 2005 (2005 SFTA; Pub. L. No. 109-59, 119 Stat. 1911). When those regulations are finalized, FDA will reassess the need for this guidance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. Background

In 2005, Congress passed the 2005 SFTA, which in part created section 416 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350e). Section 416 of the act requires FDA to promulgate regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport to ensure that food is not transported under conditions that may render the food adulterated. As part of our implementation of the 2005 SFTA, FDA issued an Advance Notice of Proposed Rulemaking in 2010 (the 2010 ANPRM) (Federal Register of April 30, 2010; [75 FR 22713](#)) to obtain data and information from the public about certain food transportation issues. As discussed in the 2010 ANPRM, over the past few decades there have been several incidents in which food was contaminated during transport, or which demonstrated the potential for food to become contaminated during transportation.

Over the years, FDA has addressed the transportation of food in several regulations and guidance documents (see Appendix). However, each of these regulations and guidance documents is limited in scope - e.g., to a particular circumstance (such as decontamination of food transport vehicles that have been flooded or otherwise impacted by hurricanes, before being placed back in service to transport or store food (Ref. 1)) or to a particular segment of the food supply (such as fresh produce (Refs. 2 and 3)). This guidance differs from the prior regulations and guidance in that it provides all sectors of the food industry with broadly applicable recommendations.

In the 2010 ANPRM, we described a 2009 report developed by Eastern Research Group, Inc. (ERG), under contract to us, regarding the findings of a study designed to characterize current baseline practices in the sectors involved in food transportation and to identify current areas where food is at risk for adulteration (Ref. 4; the ERG report). The ERG report describes the results of a comprehensive literature review pertaining to food handling practices in the food transportation industry. The ERG report also presents the findings from an expert opinion elicitation study, which ERG conducted to identify the main problems that pose microbiological, chemical, and/or physical safety hazards to food during transportation and storage, and to determine the preventive controls needed to address each of the problems identified. The

findings of the expert panel, as presented in the ERG report, are broadly consistent with agency policies, and we have incorporated many of their findings into our recommendations.

III. Discussion

In our effort to assist the food transport industry in preventing food safety problems during transport while we are implementing the 2005 SFTA, we want them to be aware of the following problem areas where food may be at risk for physical, chemical, or biological contamination during food transport:

- Improper refrigeration or temperature control of food products (temperature abuse).
- Improper management of transportation units (or storage facilities used during transport) to preclude cross-contamination, including improper sanitation, backhauling hazardous materials, not maintaining tanker wash records, improper disposal of wastewater, and aluminum phosphide fumigation methods in railcar transit;
- Improper packing of transportation units (or storage facilities used during transport), including incorrect use of packing materials and poor pallet quality;
- Improper loading practices, conditions, or equipment, including improper sanitation of loading equipment, not using dedicated units where appropriate, inappropriate loading patterns, and transporting mixed loads that increase the risk for cross-contamination;
- Improper unloading practices, conditions, or equipment, including improper sanitation of equipment and leaving raw materials on loading docks after hours;
- Poor pest control in transportation units (or storage facilities used during transport);
- Lack of driver/employee training and/or supervisor/manager/owner knowledge of food safety and/or security;
- Poor transportation unit design and construction;
- Inadequate preventive maintenance for transportation units (or storage facilities used during transport), resulting in roof leaks, gaps in doors, and dripping condensation or ice accumulations;
- Poor employee hygiene;
- Inadequate policies for the safe and/or secure transport (or storage during transport) of foods, e.g., lack of or improper use of security seals;
- Improper handling and tracking of rejected loads and salvaged, reworked, and returned products or products destined for disposal; and
- Improper holding practices for food products awaiting shipment or inspection, including unattended product, delayed holding of product, shipping of product while in quarantine, and poor rotation and throughput.

To address some of the problems enumerated above, we recommend that persons engaged in food transport concentrate their efforts at this time on the following, broadly applicable preventive controls:

- Appropriate temperature control during transport;
- Sanitation, including:

- Monitoring and ensuring the sanitation and condition of transportation vehicles as appropriate;
- Pest control; and
- Sanitation associated with loading/unloading procedures;
- Appropriate packaging/packing of food products and transportation units (e.g., good quality pallets, correct use of packing materials);
- Good communications between shipper, transporter and receiver; and
- Employee awareness and training.

IV. References

The following references are on display in Docket No. FDA-2010-N-0013 in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA. 2006. [A Notice from FDA to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products on Decontamination of Transport Vehicles.](#)
2. FDA. 1998. [Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.](#)
3. FDA. 2008. [Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables.](#)
4. Eastern Research Group, Inc. 2009. Characteristics Of Current Food Transportation And Holding Practices For Food Commodities. GSA MOBIS SIN 874-1. Contract No. GS-10F-0125P. Order No. HHSF223200730236G. ERG Task No. 0193.16.001.001.
5. FDA. 1998. [FDA Guidance for Industry 68. Small Entities Compliance Guide For Protein Blenders, Feed Manufacturers, And Distributors.](#)
6. The White House. Office of the Press Secretary. 1997. [President Clinton Announces Initiative To Ensure The Safety Of Imported And Domestic Fruits And Vegetables.](#) Accessed and printed on November 30, 2009.
7. FDA. 2003. [Guidance for Industry: Juice HACCP; Small Entity Compliance Guide.](#)
8. FDA. 2003. [Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices.](#)
9. FDA. 2007. [Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors: Food Security Preventive Measures Guidance.](#)
10. FDA. 2007. [Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance.](#)
11. FDA. 2004. [Guidance for Industry 122. Manufacture And Labeling Of Raw Meat Foods For Companion And Captive Non-companion Carnivores And Omnivores.](#)
12. FDA. 2004. [What You Need to Know About Establishment and Maintenance of Records.](#)
13. Grade A Pasteurized Milk Ordinance. [Appendix B - Milk Sampling, Hauling and Transportation.](#)

Appendix: FDA Regulations and Guidances Addressing the Transportation of Food

Year & Reference	Title	Type	Description	Circumstances
1976 (21 CFR 225.65; 41 FR 52618; November 30, 1976)	Current Good Manufacturing Practice for Medicated Feeds; Equipment Cleanout Procedures	Regulation	Requires adequate cleanout procedures for all equipment used in the manufacture or distribution of medicated feeds that are essential to avoiding unsafe contamination of feeds with drugs	Implemented requirements in section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B))
1986; (21 CFR 110.93 51 FR 22458; June 19, 1986)	Current Good Manufacturing Practice In Manufacturing, Packing, Or Holding Human Food; Warehousing and distribution	Regulation	Requires that storage and transportation of finished food be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container	Issued as part of a broad revision to our CGMP regulations for food
1997 (21 CFR 589.2000(c)-(e); 62 FR 30936; June 5, 1997), updated in 2008 (21 CFR 589.2000(c) - (e); 73 FR 22719; April 25, 2008) [Related Small Entity	Listing of Specific Substances Prohibited From Use in Animal Food or Feed; Requirements for renderers; Requirements for protein blenders, feed manufacturers, and distributors; and Requirements for persons that intend to separate mammalian and nonmammalian	Regulation	Requires distributors of mammalian and nonmammalian materials for animal food to provide for measures to avoid commingling or cross-contamination of the materials	To provide animal feed protections by prohibiting the feeding of mammalian protein to ruminant animals

Compliance Guide (SECG) published in 1998 (Ref. 5)]	materials			
1998; (Ref. 2)	Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*	Guidance	Includes recommendations regarding microbial food safety hazards and good agricultural and management practices common to the growing, packing, and transporting of most fresh fruits and vegetables	Issued as part of the 1997 Presidential “Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables” (Ref. 6)
2001; (21 CFR 120.24(c)); 66 FR 6138 at 6172, January 19, 2001) [Related SECG published in 2003 (Ref. 7)]	Hazard Analysis And Critical Control Point (HACCP) Systems; Process Controls	Regulation	Requires that juice processors complete a 5-log pathogen reduction treatment and final product packaging within a single processing facility operating under CGMPs ** (“single facility requirement”)	Added to the final rule to address comments expressing concern about the potential for recontamination or regrowth of surviving pathogens if individual treatments designed to achieve a 5-log reduction are separated by time or space
2003; (Ref. 8)	Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices	Guidance	Provides industry with recommendations for appropriate control measures to use in the bulk transport of covered juice products to ensure that the products do not become contaminated or re-contaminated with	Issued in response to a citizen petition requesting an exemption from the requirement in 21 CFR 120.24(c) when certain products manufactured in one facility are sent to another facility for final packaging

			microbial pathogens during bulk transport, and stated FDA's intent to consider the exercise of enforcement discretion with respect to the single facility requirement in 21 CFR 120.24(c) provided that certain conditions are met.	
2003 (updated 2007); (Ref. 9)	Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors: Food Security Preventive Measures Guidance	Guidance	Identifies the kinds of preventive measures operators of bulk milk transportation operations may take to minimize the risk that fluid milk under their control will be subject to tampering or other malicious, criminal, or terrorist actions	Issued in light of the potential for tampering or other malicious, criminal, or terrorist actions
2003 (updated 2007) (Ref. 10)	Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance	Guidance	Identifies the kinds of preventive measures operators of human or animal food establishments (including firms that distribute or transport food or food ingredients) may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions	Issued in light of the potential for tampering or other malicious, criminal, or terrorist actions
2004 (Ref. 11)	Guidance for Industry #122:	Guidance	Provides guidance on transport of	Issued to address health risks when

	Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores		foods that contain raw meat, or other raw animal tissues, for consumption by dogs, cats, other companion or pet animals, and captive noncompanion animal carnivores and omnivores	raw meat foods are used, particularly by pet owners
2004 (21 CFR 1.352, 1.360 - 1.363; 69 FR 71561; December 9, 2004) [Related SECG published in 2004 (Ref. 12)]	Establishment, Maintenance, and Availability of Records: What information must transporters establish and maintain?; What are the record retention requirements?; What are the record availability requirements?; What records are excluded from this subpart?; What are the consequences of failing to establish or maintain records or make them available to FDA?	Regulation	Requires persons who transport food for humans and animals to establish and maintain records identifying the immediate previous source of all food received, and the immediate subsequent recipient of all food released, as well as certain other information related to the transported food; Sets forth the record retention and record availability requirements for transporters	Implementation of section 306 of the 2002 Bioterrorism Act, which directs the HHS Secretary to issue regulations requiring persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for humans and animals to establish and maintain records identifying the immediate previous source of all food received, and the immediate subsequent recipient of all food released
2005 (revised 2006) (Ref. 1)	Notice from FDA to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products on Decontamination of Transport Vehicles	Guidance	Provides information and references that can be used for the decontamination of food transport vehicles that have been flooded or otherwise impacted by hurricanes, before being placed back in service to transport or store	Developed following Hurricanes Katrina and Rita in August and September 2005

			food	
2007 (Ref. 13)	Grade A Pasteurized Milk Ordinance, Appendix B, Milk Sampling, Hauling and Transportation	Model standard for voluntary adoption by State and local authorities	Sets forth training requirements, evaluation criteria, and standards to be met by bulk milk haulers and milk transporters	To facilitate the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce
2008 (Ref. 3)	Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables	Guidance	Recommends practices for transporting fresh-cut produce under conditions that will protect the food against physical, chemical, and microbiological contamination	Part of recommendations to enhance the safety of fresh-cut produce by minimizing microbial food safety hazards
2008 (21 CFR 589.2001(c); 73 FR 22719; April 25, 2008)	Cattle Materials Prohibited in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy	Regulation	Requires the use of dedicated equipment for handling and transporting cattle materials prohibited in animal feed	To provide an additional layer of animal feed protections by removing that material at highest risk for transmitting BSE through animal feed
2009 (21 CFR 118.1(b) and 118.4(e)); 74 FR 33029; July 9, 2009)	Production, Storage, And Transportation Of Shell Eggs	Regulation	Establishes requirements for refrigeration of shell eggs during storage and transportation	Part of a rule requiring measures to prevent <u>Salmonella</u> from contaminating eggs on the farm and from further growth during storage and transportation

¹This guidance has been prepared by the Division of Plant and Dairy Food Safety in the Center for Food Safety and Applied Nutrition and the Office of Surveillance and Compliance in the Center for Veterinary Medicine at the U.S. Food and Drug Administration.