

Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone: (817) 321-7716.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2010-0406/Airspace Docket No. 10-ASW-8." The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (*see ADDRESSES* section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Central Service Center, 2601 Meacham Blvd., Fort Worth, TX 76137.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking (202) 267-9677, to request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

This action proposes to amend Title 14, Code of Federal Regulations (14 CFR), Part 71 by establishing Class D

airspace at San Marcos Municipal Airport, San Marcos, TX. An air traffic control tower established at the airport has made controlled airspace necessary for the safety and management of IFR operations.

Class D airspace areas are published in Paragraph 5000 of FAA Order 7400.9T, signed August 27, 2009 and effective September 15, 2009, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish controlled airspace at San Marcos Municipal Airport, San Marcos, TX.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, and effective September 15, 2009, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AGL TX D San Marcos Municipal Airport, TX [New]

San Marcos Municipal Airport, TX
(Lat. 29°53'34" N., long. 97°51'47" W.)

That airspace extending upward from the surface to and including 3,100 feet MSL within a 4.2-mile radius of San Marcos Municipal Airport, and within 1 mile each side of the 313° bearing from the airport extending from the 4.2-mile radius to 4.6 miles northwest of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

Issued in Fort Worth, TX on April 19, 2010.

Anthony D. Roetzel,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2010-10039 Filed 4-29-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2010-N-0013]

RIN 0910-AG52

Implementation of Sanitary Food Transportation Act of 2005

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking (ANPRM) to request data and information on the food transportation industry and its practices. FDA also is

requesting data and information on the contamination of transported foods and any associated outbreaks. FDA is taking this action as part of its implementation of the Sanitary Food Transportation Act of 2005 (2005 SFTA), which requires the Secretary of Health and Human Services (HHS) to issue 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. This action is also part of a larger agency effort to focus on prevention of food safety problems throughout the food chain. The regulations would address the risks to human or animal health associated with the transportation of food.

DATES: Submit electronic or written comments by August 30, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2010-N-0013, by any of the following methods: *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the provisions with respect to human food: Michael Kashtock, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD

20740-3835, 301-436-2022.
Regarding the provisions with respect to food for animals: Shannon Jordre, Center for Veterinary Medicine (HFV-235), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9229.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this ANPRM as part of its implementation of the 2005 SFTA, which requires the Secretary of HHS to issue 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. Food is defined by section 201(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(f)) as "articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article." FDA notes that "food" includes live animals intended for food use and food such as meat and poultry during transport outside of official U.S. Department of Agriculture (USDA) establishments.^{1 2} This ANPRM is also part of a larger agency effort to focus on prevention of food safety problems throughout the food chain; preventing harm to consumers is the primary principle described in the Key Findings of the President's Food Safety Working Group (Ref. 3). The regulations would address the risks to human or animal health associated with the transportation of food.

A. Risk for Foodborne Illness Associated With Transportation of Food

Over the past few decades, there have been persistent concerns about the potential that food might become contaminated during transportation; however, only a limited number of such events have been documented. In this section, we discuss the events we are aware of, in chronologic order. The first two events described in the following paragraphs involved contamination of

¹ With regard to the latter, FDA notes that, to prevent duplication of effort, its compliance policy is to inform the USDA's Food Safety and Inspection Service (FSIS) when an apparent violation is encountered involving a meat or poultry product that has left a USDA inspected establishment (Ref. 1). FDA will not normally initiate action involving such products unless USDA does not wish to do so. As FDA moves forward to implement the SFTA, FDA intends to consult with FSIS to harmonize new regulations with current regulations as practicable.

² USDA's Food Safety and Inspection Service (FSIS) has issued guidelines entitled "FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry, and Egg Products" (Ref. 2).

food for animals; the remainder concerned food for humans.

In 1974, an incident involving contamination of a component of food for animals in a rail car occurred. This case, which FDA investigated after receiving reports of several sickened dogs, involved corn gluten used in dog food. The corn gluten was determined to have been transported in a rail car that had been previously used to transport lead monoxide. Samples taken of the dog food in which the corn gluten was used revealed that it was contaminated with lead monoxide at levels ranging up to 28,000 parts per million. A Class I recall was issued for the dog food and other food for animals manufactured at the same plant within the same time period. Additionally, FDA successfully prosecuted the carrier involved in this incident. See *United States v. Penn Central Transportation Co.* (S.D. Ill 1978) (Refs. 4 and 5).

In 1989, soybean hulls used as a component in animal feed were contaminated by barium carbonate, a chemical used in rat poison and paint, when they were transported in a rail car that had previously been used to transport the chemical (Refs. 6 and 7). The soybean hulls were incorporated into bulk dairy cow feeds distributed to farms in Louisiana and Texas. The contamination resulted in the deaths of dairy cows in herds from both Louisiana and Texas, and high levels of barium carbonate were detected in milk from two of the affected herds by the State of Louisiana. The manufacturer of the animal feed voluntarily recalled implicated feeds.

During the late 1980s, there were a number of press reports that some trucks that hauled garbage from the New York/New Jersey area to Midwestern landfills were used subsequently to carry meat, poultry, and produce (Ref. 8). An investigation by the U.S. General Accounting Office (GAO, now called the Government Accountability Office) found only limited, anecdotal information about food being transported in trucks that previously carried garbage, the types of trucks doing so, and the foodstuffs carried (Ref. 8). However, in its report (the 1990 GAO report), GAO concluded that long-distance transport of garbage was clearly on the increase. GAO also concluded that long-distance transport of garbage primarily originated in certain northeastern communities that generate more garbage than they can dispose of locally. In these communities, the quantity of consumer goods, including food, arriving by truck exceeded the quantity of goods leaving, and garbage had become a paying trucking

commodity on what might otherwise be an empty return trip (Ref. 8). GAO concluded that the extent to which the same trucks might subsequently carry food could not be determined at the time of the report because federal regulations did not require that type of recordkeeping.

In 1994, a large multi-state outbreak of salmonellosis was associated with an ice cream mix that became contaminated during transport in tanker trucks that had previously hauled raw liquid eggs (Ref. 9). Public health officials who analyzed data and information associated with 150 confirmed cases of salmonellosis in the State of Minnesota concluded that the outbreak may have affected more than 29,000 persons in Minnesota and more than 224,000 persons nationwide (Ref. 9).

In July 1999, an outbreak of *Salmonella* Muenchen occurred in 15 States and 2 Canadian provinces with more than 300 cases reported (66 FR 6138 at 6172, January 19, 2001). The product was fresh orange juice, a portion of which was imported. Several serotypes of *Salmonella* were isolated from tanker truckloads of juice tested at the United States/Mexican border. In such circumstances, there is a potential that *Salmonella* from one contaminated shipment could contaminate future shipments.

In 2007, the Motor Carrier Division of the Michigan State Police reported 22 cases of illegal and unsafe food transport on Michigan highways during 2006 (Ref. 10). The report listed findings such as:

- Raw poultry hanging from the roof inside the cargo area of a truck, with juices dripping onto open boxes of produce below, and with juices from the raw poultry dripping out onto the pavement from under the rear cargo box doors. The food was being transported in an unrefrigerated truck with an internal temperature greater than 70° F;
- Truck(s) with no refrigeration unit;
- Truck(s) with the refrigeration unit turned off or not working; and
- Truck(s) with a working refrigeration unit that was not set at the correct temperature.

As with the 1999 transport of contaminated orange juice in tanker truckloads, recent outbreaks of foodborne disease demonstrate the possibility of contaminated foods being widely transported, which could lead to cross-contamination between shipments. For example, in 2009, peanut butter and peanut paste were confirmed as the source of a large multi-state outbreak caused by *Salmonella* Typhimurium (74 FR 10598, March 11,

2009). These peanut-derived products were manufactured by two facilities owned by a single firm and distributed through various channels (Refs. 11 and 12). The firm recalled a large number of its products, including products distributed in 1,700-pound tanker containers, because the products had the potential to be contaminated with *Salmonella* (Ref. 13).

B. Sanitary Food Transportation Act of 1990 and Associated Actions by the U.S. Department of Transportation

After receiving the 1990 GAO report, Congress enacted the Sanitary Food Transportation Act of 1990 (1990 SFTA) (49 U.S.C. 5701 *et seq.* (2000), amended by Public Law 109–59 (2005)). The 1990 SFTA directed the U.S. Department of Transportation (DOT) to prescribe regulations regarding the transportation of food and food additives (including food and food additives intended for consumption by animals) in motor vehicles and rail vehicles that are used to transport nonfood products that would make the food or food additives unsafe to humans or animals.³ In essence, the 1990 SFTA directed DOT to establish regulations to prevent food or food additives transported in tank trucks, rail tank cars, or cargo tanks (tank vehicles) from being contaminated by nonfood products that are simultaneously or previously transported in those tank vehicles. Section 5704(b) of the 1990 SFTA specifically directed DOT to publish a list of acceptable nonfood products that DOT (in consultation with the Secretaries of the USDA, U.S. Department of Health and Human Services (HHS), and the Administrator of the Environmental Protection Agency) determined would not make food or food additives unsafe to humans or animals because of transportation of the nonfood products in a tank vehicle used to transport food or food additives.

On May 21, 1993, DOT's Research and Special Programs Administration (RSPA) issued a notice of proposed rulemaking (the 1993 NPRM) (58 FR 29698) that would restrict a cargo tank, tank car, or portable tank to carrying either food products or nonfood products. Under the 1993 NPRM, a cargo tank, tank car, or portable tank that carried food products would have been prohibited from carrying nonfood products. In the 1993 NPRM, RSPA

³ The 1990 SFTA also directed DOT to prescribe regulations regarding the transportation of cosmetics, devices, or drugs in motor vehicles and rail vehicles that are used to transport nonfood products that would make the cosmetics, devices, or drugs unsafe to humans. We do not discuss those provisions in this document.

stated that it had not identified any nonfood products that were acceptable to be carried in a tank vehicle that carries food products and, therefore, was not issuing a list of acceptable nonfood products within the meaning of section 5704(b) of the 1990 SFTA. For motor and rail vehicles other than tank vehicles, RSPA also proposed to forbid the transportation of food products in the same vehicle as poisons, infectious substances, hazardous wastes, or solid wastes (i.e., "unacceptable nonfood products"). However, such vehicles would be allowed to carry unacceptable nonfood products before or after they carried food products, provided the vehicles were free of any contaminating residues.

Subsequent to the publication of the 1993 NPRM, in a report issued on March 27, 1998, DOT's Office of the Inspector General (DOT/OIG) found that (1) DOT did not have the expertise to implement the 1990 SFTA, (2) performing food inspections could be incompatible with significant aspects of DOT's safety inspection operations, and (3) FDA had the requisite expertise, capability, and a directly related primary mission for regulating food safety (Ref. 14). DOT/OIG concluded that HHS/FDA should have primary responsibility for food transportation safety (Ref. 14).

Comments to the 1993 NPRM generally opposed its proposed provisions and recommended that DOT defer to FDA and USDA on food safety issues (69 FR 76423, December 21, 2004). In light of both these comments and the 1998 report of DOT/OIG, RSPA issued a supplemental notice of proposed rulemaking (69 FR 76423, December 21, 2004) (the 2004 SNPRM). Under the 2004 SNPRM, RSPA's regulations would reference requirements and recommendations, established by USDA or FDA, applying to persons who transport (or offer for transportation) food or food products by motor vehicle or rail car.

RSPA did not issue a final rule based on the 2004 SNPRM. Following the enactment of the 2005 SFTA (see discussion in section I.D of this document), which amended the 1990 SFTA and directed HHS (and, by delegation, FDA) to issue regulations prescribing sanitary transportation practices to ensure the safe transportation of food, DOT's Pipeline and Hazardous Materials Safety Administration (formerly RSPA) withdrew both the 1993 NPRM and the 2004 SNPRM (70 FR 76228, December 23, 2005).

C. The 1996 Joint ANPRM

In 1996, FDA and FSIS jointly issued an advance notice of proposed rulemaking (61 FR 59372, November 22, 1996) (the 1996 joint ANPRM). FDA and FSIS issued the 1996 joint ANPRM in part to address FDA's safety concerns regarding the transportation of food raised by a 1994 outbreak of salmonellosis involving ice cream mix that became contaminated during transport in tanker trucks that had previously hauled raw liquid eggs (Ref. 9). In the 1996 joint ANPRM, FDA and FSIS requested comments and information about approaches FDA and FSIS might take, under existing legal authorities, to foster food safety improvements that may be needed in the transportation and storage of potentially hazardous foods.⁴

FDA took no subsequent action on the 1996 joint ANPRM. Data and information received in response to the 1996 joint ANPRM are now more than 10 years old.

D. The 2005 SFTA

In 2005, Congress passed the 2005 SFTA, Public Law 109–59, 119 Stat. 1911, which:

- Requires the Secretary of HHS to issue 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; and
- Requires the Secretary of DOT, in consultation with the Secretaries of HHS and USDA, to establish procedures for transportation safety inspections for the purpose of identifying suspected incidents of contamination or adulteration of a food.⁵

1. Our Responsibilities Under Section 416 of the Act

The statutory authority in section 416 of the act extends to broader aspects of the sanitary transportation of food than the statutory authority in the 1990

⁴ As discussed in the 1996 joint ANPRM (61 FR 59372), potentially hazardous foods, including meat, poultry, eggs and egg products, fish, seafood, and dairy products, are those that are capable of supporting the rapid multiplication of microorganisms that cause foodborne illness. Currently, we generally use the term "Time/Temperature Control for Safety (TCS) Food" rather than "potentially hazardous food" and define a TCS food as a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation (Ref. 14). Examples of TCS foods include the foods identified as potentially hazardous foods in the 1996 joint ANPRM, and plant foods such as raw seed sprouts and cut melons (Ref. 14).

⁵ The procedures DOT would establish are outside the scope of this document. We intend to assist DOT as appropriate in developing DOT's procedures for these inspections.

SFTA, which was primarily directed toward preventing the contamination of food products by previously hauled nonfood products. The authority in section 416 of the act places a statutory obligation upon HHS (and, by delegation, to FDA) to issue regulations establishing requirements for the food transportation industry to use sanitary transportation practices to ensure that food is not transported under conditions that may render food adulterated. We describe key provisions of section 416 of the act in the following bulleted paragraphs.

- Section 416(b) (21 U.S.C. 350e(b)) requires us to establish regulations requiring shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation⁶ of food to use sanitary transportation practices prescribed by us to ensure that food is not transported under conditions that may render the food adulterated.
- Section 416(c) (21 U.S.C. 350e(c)) addresses the content of the regulations to be established under section 416(b).
 - Section 416(c)(1) (21 U.S.C. 350e(c)(1)) requires these regulations to prescribe such practices as we determine to be appropriate relating to: (A) sanitation; (B) packaging, isolation, and other protective measures; (C) limitations on the use of vehicles; (D) information to be disclosed (to a carrier by a person arranging for the transportation of food, and to a manufacturer or other person that arranges for the transportation of food by a carrier; or furnishes a tank vehicle or bulk vehicle⁷ for the transportation of food); and (E) recordkeeping.
 - Section 416(c)(2) (21 U.S.C. 350e(c)(2)) requires these regulations to include: (A) a list of nonfood products that we determine may, if shipped in a bulk vehicle, render adulterated food that is subsequently transported in the same vehicle; and (B) a list of nonfood products that we determine may, if shipped in a motor vehicle or rail vehicle (other than a tank vehicle or bulk vehicle), render adulterated food that is simultaneously or subsequently transported in the same vehicle.

⁶ "Transportation" is defined by section 416(a) of the act (21 U.S.C. 350e(a)) as "any movement in commerce by a motor vehicle or rail vehicle."

⁷ "Bulk vehicle" is defined by section 416(a) of the act as "a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, and any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle."

• Section 416(d) (21 U.S.C. 350e(d)) provides that we may waive any requirement under section 416, with respect to any class of persons, vehicles, food, or nonfood products, if we determine that the waiver (A) will not result in the transportation of food under conditions that would be unsafe for human or animal health; and (B) will not be contrary to the public interest. We must publish in the **Federal Register** any waiver and the reasons for the waiver.

• Section 416(e) (21 U.S.C. 350e(e)) provides that State or local requirements concerning transportation of food are preempted if: (A) complying with both the State or local requirement and section 416, or a regulation prescribed under section 416, is not possible; or (B) the State or local requirement as applied or enforced is an obstacle to accomplishing and carrying out section 416 or a regulation prescribed under section 416.

2. Amendments to Sections 301, 402, and 703 of the Act

The 2005 SFTA also amended the act to add or revise provisions as follows:

- Sections 402(i) and 301(hh) (21 U.S.C. 342(i) and 331(hh)): Section 402(i) provides that a food shall be deemed adulterated if it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations issued under section 416 of the act. Under section 301(hh), the failure (or the causing thereof) by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by us under section 416 is a prohibited act subject to the sanctions and penalties provided in Chapter III of the act.

- Sections 703(b) and 301(e) (21 U.S.C. 373(b) and 331(e)): Section 703(b) requires any person subject to section 416 to permit a designated officer or employee who requests required records (i.e., records required to be kept in accordance with section 416(c)(1)(E)) to have access to all such records at reasonable times and to copy all such records. Under section 301(e), the refusal to permit access to or copying of any record as required by section 416, or the failure to establish or maintain any record required under section 416, or the refusal to permit access to or verification or copying of any such required record is a prohibited act subject to the sanctions and penalties provided in Chapter III of the act.

E. Our Current Regulations and Guidance Documents Addressing Transportation of Food

We have addressed the transportation of food in several regulations (in Title 21 of the Code of Federal Regulations (21 CFR)) and guidance documents that are limited in scope. We describe the most relevant regulations and guidance documents in table 1 of this document.

The regulations DOT proposed in the 2004 SNPRM would have included a recommendation that each person who offers for transportation or transports food or food products by motor vehicle or rail car use guidance documents and materials issued by FDA and USDA, and specifically identified three of FDA's guidance documents that were then in effect: FDA Guidance on Bulk Transport

of Juice Concentrates and Certain Shelf Stable Juices; FDA Guidance on Food Security Preventive Measures for Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations, and Fluid Milk Processors; and FDA Guidance on Food Security Preventive Measures for Food Producers, Processors, and Transporters (i.e., the guidances in Refs. 16, 17, and 18).

TABLE 1.—FDA REGULATIONS AND GUIDANCES ADDRESSING THE TRANSPORTATION OF FOOD

Year & Reference*	Title	Type	Description	Circumstances
1976 (§ 225.65; 41 FR 52612 at 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; (§ 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 current good manufacturing practice (CGMP) regulations for food
1997 (§§ 589.2000(c) through (e); 62 FR 30936, June 5, 1997), updated in 2008 (§§ 589.2000(c) through (e); 73 FR 22720, April 25, 2008) [Related Small Entity Compliance Guide (SECG) published in 1998 (Ref. 19)]	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 non-mammalian materials	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
1998; (Ref. 20)	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. 21)
2001; (§ 120.24(c)); 66 FR 6138 at 6172, January 19, 2001) [Related SECG published in 2003 (Ref. 22)]	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

TABLE 1.—FDA REGULATIONS AND GUIDANCES ADDRESSING THE TRANSPORTATION OF FOOD—Continued

Year & Reference*	Title	Type	Description	Circumstances
2003; (Ref. 16)	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 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 § 120.24(c) provided that certain conditions are met.	Issued in response to a citizen petition requesting an exemption from the requirement in § 120.24(c) when certain products manufactured in one facility are sent to another facility for final packaging
2003 (updated 2007); (Ref. 17)	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. 18)	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. 19)	Guidance for Industry #122: Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores	Guidance	Provides guidance on transport of 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	Issued to address health risks when raw meat foods are used, particularly by pet owners
2004 (§ 1.352 and §§ 1.360 through 1.363; 69 FR 71562, December 9, 2004) [Related SECG published in 2004 (Ref. 24)]	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. 25)	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 food	Developed following Hurricanes Katrina and Rita in August and September 2005

TABLE 1.—FDA REGULATIONS AND GUIDANCES ADDRESSING THE TRANSPORTATION OF FOOD—Continued

Year & Reference*	Title	Type	Description	Circumstances
2007 (Ref. 26)	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. 27)	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 (§ 589.2001(c); 73 FR 22720; 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 33030, July 9, 2009)	Production, Storage, And Transportation Of Shell Eggs	Regulation	Establishes requirements for refrigeration of shell eggs during transportation	Part of a rule requiring measures to prevent <i>Salmonella Enteritidis</i> in shell eggs during production, storage, and transportation

* All section numbers cited in Table 1 refer to sections in 21 CFR.

** We have requested comments and scientific data to enable us to improve this guidance (73 FR 51306, September 2, 2008).

*** If a treated juice is transported to another facility for final packaging or blending and packaging operations, the entire 5-log reduction must be repeated (66 FR 6138 at 6172, January 19, 2001).

F. Current Industry Practices and Areas Where Food Is At Greatest Risk For Contamination

1. Interstate Food Transportation Assessment Project

In 2007, the Michigan Department of Agriculture released information obtained from its Interstate Food Transportation Assessment Project, conducted with the States of Michigan, Illinois, Indiana, and Ohio (Ref. 28). The purpose of the project was to determine the current state of food safety and food defense in the context of in-transit food in interstate commerce. The project identified several areas of concern in food transport that increase the likelihood of food contamination, such as improper refrigeration, transport of raw meat and poultry simultaneously or sequentially in trucks also used to carry fruit and vegetables, food products lacking label or source information, improper packaging, infestation with insects, insanitary storage (e.g., roof leaks and moldy walls, animal blood and food on bed floors), lack of security seals or locks, low driver awareness of safe food temperatures, and inadequate food safety training of drivers (Refs. 28 and 29). Most of the specific instances where food transportation problems were found involved smaller box trucks and transporters of ethnic food; there were “little or no areas of concern” identified with larger (semi-tractor

trailer) trucks inspected during the survey (Ref. 28).

2. Report by Eastern Research Group, Inc.

The data and information we received in response to the 1996 joint ANPRM are now dated. To obtain more current data and information, we recently contracted with Eastern Research Group, Inc. (ERG) to undertake 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. 29). In 2009, ERG issued a report (the ERG report) with its findings (Ref. 29). 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 ERG report largely discusses its findings from the perspective of food intended for consumption by humans (e.g., raw seafood, meat, poultry, produce, eggs, and refrigerated foods that are ready-to-

eat) but also reports some findings related to animal feed.

In its report, ERG provides an overview of the domestic food supply chain (Ref. 29). A manufacturing facility may be served by a tier of suppliers. These manufacturing facilities then serve distribution facilities, which eventually serve retailer outlets, including restaurant retail facilities that serve the end consumer. Some food manufacturers use third-party logistics providers to outsource transportation procurement, while others organize the transport of their goods internally. (A third-party logistics provider is a firm that provides outsourced or “third party” logistics services to companies for part or sometimes all of their supply chain management function.) In this complex system, risk associated with an undetected problem increases the further one moves back in the supply chain, because a problem that is introduced further back in the supply chain system can spread out to many distributors and retailers who serve consumers.

Through its literature review, ERG identified:

- Existing food transportation guidelines prepared by Federal agencies, foreign countries, international organizations, and trade associations;
- Three types of potential contamination that could arise during

transportation and storage (i.e., physical, chemical, and biological contamination) and risk factors during transportation and holding; and

- Best practices for food transportation and holding (i.e., temperature control, increased security and tracking, proper loading/unloading practices, monitoring and ensuring the sanitation and condition of transportation vehicles, good communication, employee awareness and training, and pest control programs).

Through its literature review and expert opinion elicitation study, ERG identified the following 15 problem areas where food may be at risk for physical, chemical, or biological contamination during transport and storage:

- Improper refrigeration or temperature control of food products (temperature abuse). This may be intentional (abuse or violation of practices by drivers, i.e., turning off refrigeration units) or unintentional (due, for example, to improper holding practices or shortages of appropriate shipping containers or vessels).
- Improper management of transportation units or storage facilities 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, 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;
- Lack of security for transportation units or storage facilities, including lack of or improper use of security seals and lack of security checks or records of transporters;
- Poor pest control in transportation units or storage facilities;
- 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, 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 of foods;
- Improper handling and tracking of rejected loads and salvaged, reworked, and returned products or products destined for disposal;
- 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; and

- Lack of traceability for food products during transportation and storage.

Through its literature review and expert opinion elicitation study, ERG identified the following seven preventive controls with the broadest applicability across all food sectors and modes of transport:

- Employee awareness and training;
- Management review of records;
- Good communication between shipper, transporter, and receiver;
- Appropriate loading procedures for transportation units;
- Appropriate unloading procedures for transportation units;
- Appropriate documentation accompanying each load (e.g., tanker wash record, seal numbers, temperature readings, time in-transit, and time on docks); and
- Appropriate packaging/packing of food products and transportation units (e.g., good quality pallets, correct use of packing materials).

II. Issues and Requests for Data and Information

As already noted, the data and information received in response to the 1996 joint ANPRM are dated and are of limited usefulness. The more recent data and information in the ERG report enhances our understanding of current baseline practices in the food transportation industry, problem areas that pose microbiological, chemical, and/or physical safety hazards to food during transportation and storage, and preventive controls that have the potential to address the problem areas.

The purpose of this document is to obtain data and information that would be more current and of greater relevance than the data and information we received in response to the 1996 joint ANPRM and to augment the more current information in the ERG report. Specifically, we request public

comments containing data and information on the issues and questions listed in sections II.A through II.G of this document.

A. Issue 1: Firms Subject to the 2005 SFTA

We are seeking data and information about firms that are subject to the 2005 SFTA and the food for humans or animals that such firms transport. Firms subject to the 2005 SFTA include shippers, carriers by motor vehicle or rail vehicle, receivers, and any other person engaged in the transportation of food. These data and information will enhance our understanding of the characteristics of the firms that are providing food transportation services.

Question 1a. What types of vehicles or methods are used to transport food by motor vehicle or rail vehicle (e.g., bulk tank trucks, cargo tanks, and freight containers)?

Question 1b. How much food, and what percentage of food, is carried by each type of vehicle on an annual basis?

Question 1c. What are the amounts and percentages of foods that are transported completely enclosed by packaging, not completely enclosed by packaging (e.g., grain, some fresh produce items), or in bulk tanks (e.g., juices, oils)?

Question 1d. What proportion of vehicles is exclusively dedicated to transporting foods? What proportion of vehicles transport both food and nonfood products?

B. Issues 2 through 6: Current Practices Used By Firms Subject to the 2005 SFTA

We are seeking data or information on the specific sanitary transportation practices that must be prescribed under regulations we establish under section 416(c)(1) of the act.

1. Issue 2: Sanitation Practices

Question 2a. What industry standards exist for the cleaning of food transportation vehicles?

Question 2b. How are appropriate protocols established for cleaning vehicles (including bulk vehicles and nonbulk vehicles)?

Question 2c. How is the adequacy of cleaning vehicles (including bulk vehicles and nonbulk vehicles) assessed?

2. Issue 3: Packaging, Isolation, and Other Protective Measures

Question 3a. What procedures and practices are in place to prevent contamination of foods not completely enclosed by packaging during transport?

Question 3b. How are the physical integrity and physical security of a food

transport vehicle ensured during its run?

Question 3c. What operations associated with food transport (e.g., intermodal transfer and pumping food from transport tanks into receiving vessels at the destination) pose the greatest potential for contaminating food?

Question 3d. What procedures and practices are in place to ensure temperature control for TCS foods?

3. Issue 4: Limitations on the Use of Vehicles

Question 4a. What types of food products are typically transported simultaneously? What types of food products are typically transported sequentially?

Question 4b. Are there any industry standards or State or local restrictions on the simultaneous or sequential transport of different categories of food?

4. Issue 5: Information Sharing Among Parties Involved in the Transportation of Food

Through the 2005 SFTA, Congress provided express authority to specify the types of information that must be disclosed to carriers by persons arranging to transport food and to manufacturers or other persons that arrange for the transport of food or furnish a vehicle for the transportation of food. In our exercise of this authority, it is critical that we understand what sort of information exchange is feasible, practical, and/or desirable.

Question 5a. What types of information are currently disclosed to carriers by persons arranging to transport food? In what form is this information disclosed? What additional information would be useful or necessary to achieve the goals of the 2005 SFTA?

Question 5b. What types of information are currently disclosed to manufacturers or other persons that arrange for the transport of food by a carrier? In what form is this information disclosed? What additional information would be useful or necessary to achieve the goals of the 2005 SFTA?

Question 5c. What types of information are currently disclosed to manufacturers or other persons that furnish a tank vehicle or bulk vehicle for the transportation of food? In what form is this information disclosed? What additional information would be useful or necessary to achieve the goals of the 2005 SFTA?

5. Issue 6. Records Currently Kept By Firms Subject to the 2005 SFTA

Question 6a. What types of records are currently kept by persons arranging to transport food? What additional records would be useful or necessary to achieve the goals of the 2005 SFTA? How long should persons arranging to transport food keep applicable records?

Question 6b. What types of information are currently kept by shippers and by carriers by motor vehicle or rail vehicle? What additional records would be useful or necessary to achieve the goals of the 2005 SFTA? How long should shippers and carriers by motor vehicle or rail vehicle keep applicable records?

Question 6c. What types of records are currently kept by receivers of food? What additional records would be useful or necessary to achieve the goals of the 2005 SFTA? How long should persons who receive food keep applicable records?

C. Issue 7. Simultaneous or Subsequent Shipment of Nonfood Products in Vehicles Used to Transport Food

Question 7a. Are food products transported simultaneously or sequentially with nonfood products? If the answer to this question is yes, what nonfood products are commonly transported in vehicles that also transport food?

Question 7b. What nonfood products may, if shipped in a bulk vehicle, pose a risk of contamination to food that is subsequently transported in the same vehicle?

Question 7c. What nonfood products may, if shipped in a motor vehicle or rail vehicle (other than a tank vehicle or bulk vehicle), pose a risk of contamination to food that is simultaneously or subsequently transported in the same vehicle?

Question 7d. Are there any industry standards or State or local restrictions on the simultaneous or sequential transport of food and nonfood products?

D. Issue 8. Acceptable Reasons for Waiver of Requirements

Question 8. What reasons might exist for a waiver of any or all foreseeable requirements under section 416 with respect to any class of persons, vehicles, food, or nonfood products? For any such reason for waiver, identify and provide data and information that would support a possible determination that the waiver (A) will not result in the transportation of food under conditions that would be unsafe for human or animal health; and (B) will not be contrary to the public interest.

E. Issue 9. Federal Preemption of State and Local Food Transportation Requirements

Section 416(e) of the act, as amended by the 2005 SFTA, states that a requirement of a State or political subdivision of a State that concerns the transportation of food is preempted if it conflicts with or presents an obstacle to implementing the requirements of this section or a regulation prescribed under this section. FDA is seeking comments on existing requirements of a State or political subdivision of a State regarding the sanitary transportation of food. FDA intends to solicit further comments regarding this provision in the proposed rule.

Question 9. What States or political subdivisions of a State have requirements for the sanitary transportation of food and what are these requirements?

F. Issue 10. Risk for Foodborne Illness Associated With Transportation of Food

We have limited data and information about outbreaks of foodborne illness associated with transportation of food; see sections I.A and I.F of this document for a description of the data and information currently available to us. There are, however, a number of known areas where food is at risk for adulteration and reported instances of unsafe food transport (Refs. 10, 28, and 29). We are seeking data and information to enable us to focus our regulatory efforts in areas that present the greatest risk to public health.

Question 10a. What data or information are available on investigations that have shown a suspected or documented link between an outbreak of foodborne illness and the transport process?

Question 10b. What data or information are available in instances where food was suspected or documented of being contaminated during transport, even if the food was not implicated in an outbreak of foodborne illness?

Question 10c. What data or information are available from State or local authorities regarding compliance with or enforcement of State or local food transportation requirements?

Question 10d. What are the problem areas where food may be at greatest risk for physical, chemical, or biological contamination during transport?

G. Issue 11. Benefits and Costs

We are seeking data and information to enable us to estimate the benefits and costs of regulations implementing the 2005 SFTA and to estimate of the effects of regulatory options on small entities.

Question 11a. What is the size of carrier firms (e.g., based on annual revenue or on number of vehicles)?

Question 11b. What is the number of small entities that could be affected by regulations implementing the 2005 SFTA?

Question 11c. What steps could be taken to lessen the burden on small entities while still protecting the public health?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

We have placed the following references on display in the Division of Dockets Management (see **ADDRESSES**). You may see them between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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HHSF223200730236G, ERG Task No.
0193.16.001.001.

Dated: April 26, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-10078 Filed 4-29-10; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 780, 784, 816, and 817

RIN 1029-AC63

Stream Protection Rule; Environmental Impact Statement

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; notice of intent to prepare an environmental impact statement.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), intend to prepare an environmental impact statement (EIS) under section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA) to analyze the effects of potential rule revisions under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act) to improve protection of streams from the adverse impacts of surface coal mining operations. We are requesting comments for the purpose of determining the scope of the EIS.

DATES: To ensure consideration, we must receive your electronic or written comments on June 1, 2010.

ADDRESSES: You may submit comments by any of the following methods, although we request that you use electronic mail if possible:

- *Electronic mail:* Send your comments to sra-eis@osmre.gov.
- *Mail, hand-delivery, or courier:*

Send your comments to Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 252-SIB, 1951 Constitution Avenue, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: John Craynon, Chief, Division of Regulatory Support, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave., NW., MS 202-SIB, Washington, DC 20240; Telephone 202-208-2866.

SUPPLEMENTARY INFORMATION:

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- I. Why are we planning to revise our rules?
- II. What is the proposed federal action?

III. How do I submit comments?

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I. Why are we planning to revise our rules?

On December 12, 2008 (73 FR 75814-75885), we published a final rule modifying the circumstances under which mining activities may be conducted in or near perennial or intermittent streams. That rule, which this document refers to as the 2008 rule, took effect January 12, 2009. A total of nine organizations challenged the validity of the rule in two complaints filed on December 22, 2008, and January 16, 2009 (amended complaint filed February 17, 2009): *Coal River Mountain Watch, et al. v. Salazar*, No. 08-2212 (D.D.C.) (“*Coal River*”) and *National Parks Conservation Ass’n v. Salazar*, No. 09-115 (D.D.C.) (“*NPCA*”). Under the terms of a settlement agreement signed by the parties on March 19, 2010, we agreed to use best efforts to sign a proposed rule by February 28, 2011, and a final rule by June 29, 2012. We also agreed to consult with the Fish and Wildlife Service pursuant to the Endangered Species Act, as appropriate, prior to signing the final action. On April 2, 2010, the court granted the parties’ motion to hold the judicial proceedings in abeyance.

However, we had already embarked on that course following the change of Administrations on January 20, 2009. On June 11, 2009, the Secretary of the Department of the Interior, the Administrator of the U.S. Environmental Protection Agency (EPA), and the Acting Assistant Secretary of the Army (Civil Works) entered into a memorandum of understanding¹ (MOU) implementing an interagency action plan designed to significantly reduce the harmful environmental consequences of surface coal mining operations in six Appalachian states, while ensuring that future mining remains consistent with Federal law. Among other things, the MOU committed us to consider revisions to key provisions of our rules, including the 2008 rule and approximate original contour requirements, to better protect the environment and public health from the impacts of Appalachian surface coal mining.

Consequently, on November 30, 2009, we published an advance notice of proposed rulemaking (ANPRM) soliciting comments on ten potential rulemaking alternatives. See 74 FR

62664-62668. In addition, consistent with the MOU, we invited the public to identify other rules that we should revise. We also announced our intent to prepare a supplement to the EIS developed in connection with the 2008 rule.

We received approximately 32,750 comments during the 30-day comment period that closed December 30, 2009. After evaluating those and other comments, we determined that development of a comprehensive stream protection rule (one that is much broader in scope than the 2008 rule) would be the most appropriate and effective method of achieving the goals set forth in the MOU and the ANPRM. We believe that this holistic approach will better protect streams and related environmental values. The broader scope of the stream protection rule means that we will need to prepare a new environmental impact statement rather than the supplement to the 2008 EIS that we originally intended to prepare.

II. What is the proposed federal action?

The proposed Federal action consists of revisions to various provisions of our rules to improve protection of streams from the impacts of surface coal mining operations nationwide. We do not believe that it would be fair, appropriate, or scientifically valid to apply the new protections only in central Appalachia, as some commenters on the ANPRM advocated. Streams are ecologically significant regardless of the region in which they are located. Principal elements of the proposed action include—

- Adding more extensive and more specific permit application requirements concerning baseline data on hydrology, geology, and aquatic biology; the determination of the probable hydrologic consequences of mining; and the hydrologic reclamation plan; as well as more specific requirements for the cumulative hydrologic impact assessment.

- Defining the term “material damage to the hydrologic balance outside the permit area.” This term is critically important because, under section 510(b)(3) of SMCRA, the regulatory authority may not approve a permit application unless the proposed operation has been designed to prevent material damage to the hydrologic balance outside the permit area. This term includes streams downstream of the mining operation.

- Revising the regulations governing mining activities in or near streams, including mining through streams.

¹The MOU can be viewed online at <http://www.osmre.gov/resources/ref/mou/ASCM061109.pdf>.