

Brook Jamison
called
at 4:00 PM

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Thursday, August 09, 2007

Congresswoman Gillibrand's Hudson District Office
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Please forward this with the attached to Brook Jamison who I was told is working on this issue.

On 4/30/07 I spoke to Brook and dropped off information to your office on 5/1/07 to be forward to her, which she received. I have been trying to contact Brook at (202) 225-5614 and evidently she is too busy to take my call or this issue is not as important to her as it is to Congresswoman Gillibrand.

February 17, 2007 I spoke to Congresswoman Gillibrand who told me this issue was very important to her and she would have her staff work on it right away.

The attached shows that the Bush administration has dropped the ball since 9/11/01 when it comes to the safety of our food supply and the transportation of it. These Laws are still not being enforced.

Especially since , "Tommy Thompson, in announcing Friday (From the Dec. 4, 2004, editions of the Milwaukee Journal Sentinel) that he will leave the Department of Health and Human Services, warned that America's food supply is vulnerable to terrorism."

The former Wisconsin governor, addressing reporters, raised eyebrows when he remarked: "I, for the life of me, cannot understand why the terrorists have not attacked our food supply, because it is so easy to do. And we're importing a lot of food from the Middle East, and it would be easy to tamper with that."

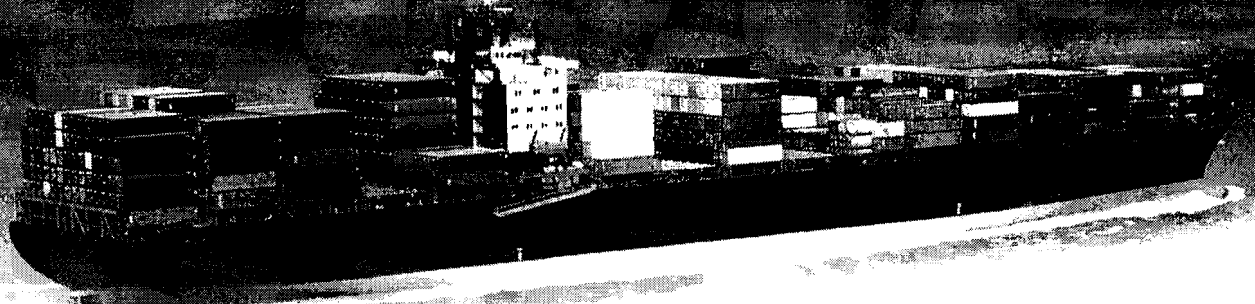
If Congresswoman Gillibrand has changed her position on this very important issue please let me know.

Respectfully


Charles Lake

received 8/9/07
Megan Henry

Safeguarding the Food Supply—FDA Given Sanitary Food Transport Authority



by Diane B. McColl and Noelle C. Sitthikul

On August 10, 2005, President Bush signed into law the Sanitary Food Transportation Act of 2005 (2005 SFTA).¹ The 2005 SFTA amends the Federal Food, Drug, and Cosmetic Act (FDCA) to reallocate responsibilities for the transportation of food products among the U.S. Department of Health and Human Services (HHS), the U.S. Department of Transportation (DOT), and the U.S. Department of Agriculture (USDA). The new law requires the Secretary of HHS to promulgate regulations establishing sanitary food transportation practice. Such regulations will apply to shippers, motor vehicle and rail carriers, receivers, and any other persons engaged in the transportation of food. Failure to comply with these regulatory requirements would render the food adulterated and constitute a “prohibited act” under the FDCA.² The 2005 SFTA went into effect on October 1, 2005.

Background

Fifteen years ago, Congress enacted the Sanitary Food Transportation Act of 1990 (1990 SFTA), which instructed DOT to establish regulations to promote the safe transportation of food products.³ Congress was concerned by the practice of transporting wastes and potentially harmful nonfood products in the same vehicles that carry food, food additives, drugs, devices, and cosmetics.⁴ The 1990 SFTA specifically called for DOT to issue regulations prohibiting the transportation of food and food additives in motor or rail vehicles that are used to transport refuse or nonfood products.⁵ The Secretary of Transportation was required to publish a list of acceptable nonfood products that may be transported in tank vehicles that are suitable for food products. DOT determined there were no such nonfood products and, consequently, did not propose an “acceptable nonfood product list.”⁶

Rather than issuing its own regulations on the safe transportation of food and food products, DOT instead referenced requirements by USDA and the Food and Drug Administration (FDA), such as “FDA guidance documents on food security applicable to dairy farms and milk processors, food producers and processors, and bulk transporters of juice; and USDA safety and security guidelines for the transportation and distribution of meat, poultry, and egg products.”⁷ DOT concluded that the “expertise for ensuring the safety of our nation’s food supply, including transportation, lies with USDA and FDA.”⁸

Scope of the 2005 SFTA

The 2005 SFTA shifted authority for the regulation of sanitary food transportation practice from DOT to FDA. It amended FDCA § 402 so as to render unsanitary transport adulteration, and added a new FDCA § 416 concerning “sanitary transportation



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practices.”⁹ Section 416(b) requires FDA to develop and implement regulations governing the safe transportation of food and food products. The new FDA regulations will apply to any “shipper, carrier by motor vehicle or rail vehicle, receiver or any other person engaged in the transportation of food.”¹⁰ “Transportation” is defined in the 2005 SFTA as “any movement in commerce by motor vehicle or rail vehicle.”¹¹ Thus, interstate and intrastate rail carriers and truckers, as well as shippers and receivers must comply with the forthcoming FDA regulations. Section 416(a)(1) of the FDCA defines a “bulk vehicle” to include 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.”¹² The agency’s sanitary food transportation regulations must address sanitation; packaging, isolation, and protective measures; limits on vehicle use; and information disclosure between carriers and manufacturers or other persons who arrange transportation of food or furnishes a tank vehicle or bulk vehicle for food transportation.¹³ In addition, section 416(c)(1)(E) mandates that FDA’s forthcoming sanitary food transportation regulations prescribe appropriate recordkeeping.¹⁴

The 2005 SFTA requires FDA to include in its regulations a list of “non-food products” that, if shipped in a bulk vehicle, may render adulterated any food subsequently transported in the same vehicle.¹⁵ FDA also must develop a list of “nonfood products” that, if shipped in a motor vehicle or rail vehicle (other than a tank vehicle or bulk vehicle), may render adulterated any food simultaneously or subsequently transported in the

same vehicle.¹⁶ The 2005 SFTA fails to define “motor vehicle,” leaving open to agency interpretation the question of which type of moving vehicles will be subject to the sanitary food transportation requirements. A broad interpretation of the statutory language would allow FDA to impose regulatory requirements on a wide range of vehicles, from traditional trucks to farm equipment. In the past, FDA has voiced concerns about potential food safety issues associated with all types of prior cargos in food transport vehicles, not just nonfood products.¹⁷

The 2005 SFTA allows FDA to waive any of the sanitation transportation requirements with respect to any class of persons, vehicles, food, or nonfood products provided any such waiver will not endanger human or animal health and will not be contrary to public policy.¹⁸ State and local governments are preempted from establishing regulations that conflict with the new federal sanitary transportation requirements.¹⁹ The 2005 SFTA directs DOT, USDA, and the Environmental Protection Agency to assist FDA in carrying out the provisions, as applicable.²⁰

Records and Inspections

Several aspects of the 2005 SFTA address FDA’s authority to assess and inspect transportation carriers. Currently, section 703(a) of the FDCA permits FDA, at reasonable times, to access and copy

all records showing movement in interstate commerce of any food ... or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof.²¹

The 2005 SFTA adds section 703(b) to the FDCA to similarly authorize

FDA inspection and copying of the section 416 food transportation records that must be maintained by shippers, rail and motor vehicle carriers, and other persons engaged in food transportation.²² Specifically, section 703(b) states that:

A shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 shall, on request of an officer or employee designated by the Secretary, permit the officer or employee, at reasonable times, to have access to and copy all records that the Secretary requires to be kept under section 416(c)(1)(E).²³

This provision broadens FDA’s existing access by allowing the agency to inspect food transportation records maintained solely for the purpose of compliance with the sanitary food transportation practices regulations.²⁴ Nevertheless, the protection afforded under section 703(a) of the FDCA against the use of evidence obtained via written request in a criminal prosecution arguably remains intact provided the food transportation records show “movement in interstate commerce.”²⁵

The 2005 SFTA also directs DOT, in conjunction with FDA and USDA, to establish procedures for transportation safety inspections for the purpose of identifying suspected incidents of contamination or adulteration of food, including violations of the sanitary food transportation regulations.²⁶ Further, it requires the Secretary of Transportation to train DOT and state inspectors who perform motor vehicle and railroad related safety inspections to identify practices and conditions that could pose a threat to food safety.²⁷ The Secretary must promptly

notify FDA or USDA, as applicable, of any instances of potential food contamination or adulteration identified during such transportation safety inspections.²⁸

Conclusion

The 2005 SFTA raises several issues for the food industry with respect to the transportation of food and food products. Broadly interpreted, the forthcoming FDA regulations on sanitary food transportation practice may apply to all moving vehicles, including even certain farm equipment. Failure to comply with the new regulations is deemed a prohibited act under the FDCA, which may subject

offenders to criminal prosecution and the affected shipment to seizure. Δ

¹ Sanitary Food Transportation Act (SFTA) of 2005, Pub. L. No. 109-59, 119 Stat. 1911.

² 21 U.S.C. § 331(hh) (FDCA § 301(hh)).

³ 49 U.S.C. § 5701 et seq.

⁴ 58 Fed. Reg. 29,698 (May 21, 1993).

⁵ 49 U.S.C. § 5703(a).

⁶ 58 Fed. Reg. 29,698, 29,700 (May 21, 1993).

⁷ 69 Fed. Reg. 76,423, 76,425 (Dec. 21, 2004).

⁸ *Id.*

⁹ 2005 SFTA, Pub. L. No. 109-59, § 7202, 119 Stat. 1911, 1911.

¹⁰ 21 U.S.C. § 350e(b).

¹¹ *Id.* § 350e(a)(2).

¹² *Id.* § 350e(a)(1).

¹³ *Id.* § 350e(c).

¹⁴ *Id.* § 350e(c)(1)(E).

¹⁵ *Id.* § 350e(c)(2)(A).

¹⁶ *Id.* § 350e(c)(2)(B).

¹⁷ 61 Fed. Reg. 59,372, 59,378 (Nov. 22, 1996).

¹⁸ 21 U.S.C. § 350e(d)(1).

¹⁹ *Id.* § 350e(e)(1).

²⁰ *Id.* § 350e(f).

²¹ *Id.* § 373(a).

²² *Id.* § 373(b).

²³ *Id.*

²⁴ The Bioterrorism Preparedness and Response Act of 2002 (BTA) generally requires transporters to maintain records of the immediate previous sources and immediate subsequent recipients of food. 21 C.F.R. §§ 1.326(a), 1.337, 1.345, 1.352. A "transporter" is a person having "possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air." *Id.* § 1.328. In a recent guidance document, FDA acknowledged that the agency can access these records only when the BTA statutory criteria are met (i.e., "when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals"). FDA, Guidance for Records Access Authority Provided in Title III, Subtitle A, of the [BTA] (Nov. 2005). The 2005 SFTA should have no effect, therefore, on FDA's existing authority to access transporter records under the BTA.

²⁵ 21 U.S.C. § 371(a).

²⁶ 49 U.S.C. § 5701(a)(1).

²⁷ *Id.* § 5701(a)(2)(A).

²⁸ *Id.* § 5701(b).