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MEMORANDUM

TO: The Produce Safety Project
DATE: December 19, 2008
RE: Legal Authority of the U.S. Food and Drug Administration over Produce Safety

This memorandum addresses the question of whether the U.S. Food and Drug Administration (FDA) can rely on existing statutory authority to adopt regulations related to the safety of fresh produce.

I. Legal Authority to Address Produce Safety

Our research indicates that FDA does not need additional legislative authority to implement such requirements. There is no explicit statutory language that either permits or forbids the regulation of on-farm activities by the FDA.¹ At the same time, the agency could

¹ Congressional Research Service, Vanessa K. Burrows, FDA Authority to Regulate On-Farm Activity (August 14, 2008).

rely on provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA or “the Act”) of 1938² and the Public Health Service Act (PHSA) of 1944³ in issuing produce-safety regulations.

A. Relevant Statutory Provisions

1. The Federal Food, Drug, and Cosmetic Act

The FFDCA is comprised of a set of laws passed by Congress in 1938. Section 903 of the Act⁴ establishes FDA as an agency within the Department of Health and Human Services (HHS), and it is charged with “ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled.”⁵ FDA has oversight of all domestic food products not under the authority of the U.S. Department of Agriculture (USDA);⁶ it is responsible for fresh produce and a wide range of other foods.⁷

The FFDCA prohibits the “adulteration” of food,⁸ and section 402⁹ enumerates the grounds for finding food to be “adulterated.” One provision finds adulteration if a food “has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”¹⁰ The

² 21 U.S.C. § 301 *et seq.*

³ 42 U.S.C. § 201 *et seq.*

⁴ 21 U.S.C. § 393.

⁵ 21 U.S.C. § 393(b)(2)(A).

⁶ Congressional Research Service, Geoffrey Becker & Donna Porter, *The Federal Food Safety System: A Primer* 4 (2008). The USDA has jurisdiction over most meat and poultry products as well as egg products. FDA has authority over game meats such as rabbits, buffalo, and elk.

⁷ These include dairy products, shell eggs, and seafood. The most recent Farm Bill, however, grants USDA jurisdiction over catfish. *See* Section 11016(b) of the 2008 Farm Bill, P.L. 110-246.

⁸ 21 U.S.C. § 331(b).

⁹ 21 U.S.C. § 342.

¹⁰ 21 U.S.C. § 342(a)(4). Another subsection of section 342 states that food is adulterated “if it bears or contains any poisonous or deleterious substances which may render it injurious to health.” 21 U.S.C. § 342 (a)(1). This particular subsection includes two different standards, depending on whether the substance at issue is “added” or not: a food containing an “added” substance is adulterated if the substance “may render it injurious to health, while if the substance at issue is “not added” (i.e. naturally occurring) the food is adulterated if the quantity of the substance in the food would “ordinarily render it injurious to health.” The Center for Science in the Public Interest has argued that FDA could consider fresh produce contaminated with pathogens like *Salmonella* and *E. coli* O157:H7 to be adulterated under either of these two standards. *See* CSPI, Citizen Petition to the FDA (Nov. 15, 2006) available at http://cspinet.org/new/pdf/fda_produce_petition.pdf.

FFDCA further grants FDA the “authority to promulgate regulations for the efficient enforcement of this Act.”¹¹

2. Public Health Service Act

The PHS Act was enacted in 1944 to consolidate the laws affecting the federal Public Health Service (PHS).¹² By delegation,¹³ section 361 of the PHS Act authorizes FDA to “make and enforce such regulations as in [its] judgment are necessary to prevent the introduction, transmission, and spread of communicable diseases” in interstate commerce and from foreign countries.¹⁴

B. FDA Interpretation of its Statutory Authority

The preambles to three FDA rules -- the two final rules addressing seafood¹⁵ and juice¹⁶ safety and the proposed shell egg rule¹⁷-- provide clear examples of how the agency interprets its statutory authority to support food-safety regulations. In these rules, FDA repeatedly asserts that the FFDCA and the PHS Act permit the agency to regulate safety as it deems necessary.

FDA believes that it has expansive regulatory authority relating to food safety. In discussing the juice rule, the agency notes that it is “well-settled that the [FFDCA] is to be interpreted broadly so as to achieve its goal of public health protection.”¹⁸ In the case of both seafood and juice, FDA has used its grants of authority to require that those industries adopt measures (known as Hazard Analysis and Critical Control Points (“HACCP”) programs) to prevent and control foodborne contamination. The agency cites sections 402(a) (4) and 701(a) of the FFDCA, and section 361 of the PHS Act as authority for these HACCP regulations.

¹¹ Section 701(a) of the Act, 21 U.S.C. §371(a).

¹² “Public Health Service Act,” 59 *Public Health Reports* 28 (July 14, 1944).

¹³ 5 C.F.R. § 5.10(a)(4). *See* 69 Fed. Reg. 56823, 56842 (Sept. 22, 2004).

¹⁴ 42 U.S.C. §264(a).

¹⁵ 60 Fed. Reg. 65095 (Dec. 18, 1995).

¹⁶ 66 Fed. Reg. 6137 (Jan. 19, 2001).

¹⁷ 69 Fed. Reg. 56823 (Sept. 22, 2004).

¹⁸ 66 Fed. Reg. at 6158.

In relying on section 402(a)(4) in adopting its seafood rule, the agency notes that the statute declares that food is adulterated “if it has been prepared, packed, or held under insanitary conditions whereby it *may* have become contaminated with filth, or whereby it *may* have been rendered injurious to health.”¹⁹ The agency asserts that, given this language, it does not have to establish that the conditions at issue *actually* cause the food to be injurious. As the agency explains, the “question is thus whether the conditions in a plant are such that is *reasonably possible* that the food may be rendered injurious to health.”²⁰ For seafood, FDA concluded that the answer was yes.²¹ The agency came to the same result for juice products.²²

In these rulemakings, the agency emphasized the fact that the food products in question have a history of contamination. For example, the preamble to the juice rule notes that “there is a long history of foodborne illness outbreaks associated with microbial contamination of a variety of juices,” and that “it has become well documented that some pathogens have adapted to this acidic environment, making juices susceptible to microbial contamination.”²³ In the preamble to its proposed egg rule, FDA notes that because contaminated shell eggs are the predominant identified food source of [*Salmonella Enteritidis*]-related cases of *salmonellosis* in the United States, it had the authority to mandate comprehensive on-farm preventative measures, which would decrease the occurrence of this contamination.²⁴

In implementing section 361 of the PHSA, the FDA has defined “communicable diseases” as “[i]llnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.”²⁵ FDA has relied on section 361 to enact a wide range of health-related regulations.²⁶

¹⁹ 60 Fed. Reg. at 65098 (*emphasis added*).

²⁰ *Id.* (*emphasis added*).

²¹ *Id.* at 65099.

²² 66 Fed. Reg. at 6158.

²³ *Id.* at 6160.

²⁴ 69 Fed. Reg. at 56843. Section 701(a) is cited by the FDA in conjunction with Section 402(a)(4) in all three of the rules discussed above. *See, e.g.*, 69 Fed. Reg. at 56843.

²⁵ 21 C.F.R. §1240.3(b).

²⁶ 69 Fed. Reg. at 56842-43. Regulations that address food safety include those aimed at controlling the interstate shipment of molluscan shellfish (21CFR 1240.60); requiring pasteurization of milk and milk products (21 CFR

In response to commenters who challenged FDA’s authority under the PHSa to enact the Juice HACCP regulations, the agency asserted that “the record in this rulemaking amply demonstrates that juice can function as a vehicle for transmitting food-borne illness caused by pathogens such as *Salmonella* and *E. coli* O157:H7.”²⁷ As such, “FDA has concluded that a system of HACCP controls is necessary to prevent the spread of communicable disease via consumption of contaminated juice, and that the [PHSA] provides the agency with the authority to establish such HACCP requirements for juice.”²⁸

C. Case Law Supporting FDA Interpretation of its Statutory Authority

Court decisions bolster FDA’s interpretation of the relevant provisions of the FFDCa and the PHSa.²⁹ In *U.S. v. Nova Scotia Food Products Corp.*,³⁰ a company challenged FDA’s regulations governing the time, temperature, and salinity for processing smoked fish,³¹ as well as provisions designed to minimize the outgrowth and toxin formation of *Clostridium botulinum* Type E.³² Fish processed under conditions not complying with these regulations were deemed by the FDA to be adulterated within the meaning of section 402(a)(4) of the FFDCa.³³ Nova Scotia Food Products Corp. challenged these regulations, in particular, FDA’s reading of the term “insanitary conditions,” as exceeding the authority granted to the agency by the Act.

The Second Circuit rejected the company’s restrictive reading of “insanitary conditions,” finding instead that FDA was operating within its authority when it established the processing parameters to control or eliminate harmful substances present in the food. The court recognized

1240.61); requiring a safe handling statement on cartons of shell eggs (21 CFR 101.17(h)) and adequate refrigeration (21 CFR 115.50); and requiring HACCP systems for juice (21 CFR Part 120).

²⁷ 66 Fed Reg. at 6159

²⁸ *Id.*

²⁹ The Supreme Court generally defers to an agency’s interpretation of the statutory provisions it implements. The Court has held that if statutory language is ambiguous, the agency’s interpretation should be upheld as long as they are based on a “permissible construction of the statute.” *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-44 (1984). However, in recent cases, the Court appears to have limited the deference in *Chevron*, holding that it applies only if the agency interpretation is the result of a formal process such as notice and comment proceedings. See *Christensen v. Harris County*, 529 U.S. 576 (2000); *United States v. Mead Corp.*, 533 U.S. 218 (2001).

³⁰ 568 F.2d 240 (2d Cir. 1977).

³¹ 568 F.2d at 243, 247-248.

³² 568 F.2d at 243.

³³ 21 CFR 128a.2 (1971); 35 FR 17401 (November 13, 1970).

a “larger general purpose on the part of Congress in protecting the public health,”³⁴ and held that, under section 402(a) (4) of the act, “insanitary conditions” may include “inadequate sanitary conditions of prevention.”³⁵

The FDA’s authority to issue broad regulations under the PHSA was upheld in *State of Louisiana v. Mathews*.³⁶ Plaintiffs in that case argued that the law only provided the agency with authority to ban individual lots of affected product (in this case turtles) and not take more widespread action. The court in that case held that “Congress has granted broad, flexible powers to federal health authorities who must use their judgment in attempting to protect the public health against the spread of communicable disease.”³⁷

In *Public Citizen v. Heckler*,³⁸ the court considered a request to compel HHS to act on a petition to ban all domestic sales of raw milk and raw milk products because of the risk of transmission of disease from such products. The court ordered FDA to respond to the petition, finding that HHS had the authority to ban raw milk and milk products under the PHSA: “Under both the [PHSA’s] authorization for regulations to control communicable diseases, and the [FFDCA’s] provisions for the control of adulterated foods, the Secretary has both the authority and the heavy responsibility to act to protect the nation’s health in situations such as this one.”³⁹

II. Conclusion

The FFDCA requires the FDA to protect the public against adulterated food, and the PHSA gives the agency the authority to prevent the spread of communicable diseases. FDA has relied on these two statutes to protect the public from unsafe food and other products, and this reliance has been upheld by the courts.

³⁴ 568 F.2d at 248. See also *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969), and *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

³⁵ 568 F.2d at 247.

³⁶ 427 F. Supp. 174 (E.D.La. 1977).

³⁷ *Id.* at 176.

³⁸ 602 F. Supp. 611 (D.D.C. 1985).

³⁹ 602 F. Supp. 611, 613. (*Internal citations omitted*).

Seafood and juice are highly susceptible to contamination by pathogens that cause communicable diseases, and the agency has determined that preventive measures such as the implementation of HACCP programs for these foods will be effective in reducing the prevalence of disease-causing microbes and adulterated food. FDA's adoption of the seafood and juice rules, as well as its proposal regarding shell eggs, are all grounded in well-established authority set out in the FFDCA and the PHSA.

The legal rationale underlying the seafood and juice HACCP rules can be applied to the adoption of regulations implementing on-farm measures for fresh produce safety, whether these measures follow a HACCP-type approach or some other system of preventive controls. Fresh produce -- like seafood and juice -- is highly susceptible to contamination with dangerous pathogens.⁴⁰ The proposed shell egg rule, while it has yet to be finalized, also supports FDA's adoption of on-farm preventive for produce.

⁴⁰ See Produce Safety Project, "Foodborne Pathogens Associated with Fresh Fruits and Vegetables," *available at* <http://www.producesafetyproject.org/get-the-facts?id=0004>.