CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

July 7, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Comments on Proposed Administrative Detention Regulations, 68 Fed. Reg. 25,241 (May 9, 2003), Docket No. 2002N-0275

The Food and Drug Administration (FDA) has published a notice of proposed rulemaking to implement section 303 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). Section 303 amends section 304 of the Federal Food, Drug, and Cosmetics Act (FFDCA) to give FDA officers the authority to detain food where they have credible evidence or information indicating that the food article presents a threat of serious adverse health consequences or death to humans or animals.[1]

On behalf of the Center for Science in the Public Interest (CSPI), we are writing to comment on the proposed administrative detention provisions necessary to protect the U.S. food supply from intentional contamination and adulteration. CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

[1] 21 U.S.C. § 334 *et seq.*

02N-0275 EM C34

1. FDA's Interpretation That It Has Authority to Administratively Detain Intrastate Food Products is Reasonable.

Section 303 of the Bioterrorism Act adds a new section 304(h) to the FFDCA, giving FDA authority to order the detention of any article of food that is found during inspection, examination, or investigation under the Act where the agency has credible evidence indicating that the food article presents a threat of serious adverse human health effects. Section 304(g) of the FFDCA already grants FDA authority to detain medical devices "if during an inspection conducted under section 704 of a facility or a vehicle, a device which [FDA] has reason to believe is adulterated or misbranded is found in such facility or vehicle. . . ."[2] Section 704 of the FFDCA authorizes FDA to enter any factory, warehouse, or establishment in which "food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce . . . ."[3]

In the preamble to the proposed rule, FDA notes that although section 304(g), authorizing detention of medical devices, includes an interstate commerce component (by referring to section 704), the language of new section 304(h) does not impose a similar limitation.[4] Based on the differences between the language of section 303 of the Bioterrorism Act and section 304(g) of the FFDCA, FDA has tentatively concluded that any food may be subject to administrative detention under section 304 of the Bioterrorism Act, whether or not the food was in interstate

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[2] 21 U.S.C. § 334(g).

[3] 21 U.S.C. § 374(a)(1)(A).

[4] 68 Fed. Reg. 25,241, 25,243 (May 9, 2003). FDA also notes that the language of section 301(bb) also does not include an interstate commerce component.

commerce at the time.[5] However, FDA has requested comment on whether its conclusion that it has authority to administratively detain food in intrastate commerce is correct and if so, whether FDA should use that authority.[6] We believe that FDA's interpretation is a reasonable one under the statute.

The Bioterrorism Act is silent on the question of whether FDA can detain intrastate food under the administrative detention provision. Through this silence, Congress gave FDA interpretative authority.[7] The FDA's construction is consistent with the plain language of section 303. That provision broadly authorizes the detention of "any" article of food and does not specify that such food must be in interstate commerce at the time it is detained. If Congress had intended to require FDA to demonstrate an interstate commerce connection at the time of a detention, it could have included such a requirement as it has in other provisions of the FFDCA, including section 304(g). "'[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'"[8]

FDA's interpretation of section 303 also is supported by the fact that other provisions of the Bioterrorism Act do not mention an interstate commerce connection. For instance, section

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[5] 68 Fed. Reg. at 25,244.

[6] The question is not whether FDA has "correctly" interpreted the Bioterrorism Act but whether the agency's interpretation is a reasonable one consistent with the language and legislative history of the statute, as well as the law's purpose and goals. *See* United States v. Mead Corporation, 533 U.S. 218 (2001).

[7] Chevron U.S.A., Inc. v. NRDC, 467 U.S. 837, 843-44 (1984) (When Congress has "explicitly left a gap for an agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation."); Department of Treasury v. FLRA, 494 U.S. 922, 933 (1990) (where "an agency is charged with administering a statute, part of the authority it receives is the power to give reasonable content to the statute's textual ambiguities").

[8] Bates v. United States, 552 U.S. 23, 29-30 (1997) (quoting Russello v. United States, 464 U.S. 16, 23 (1983).

306 of the Bioterrorism Act authorizes records inspection whenever the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death. It does not require that the food be in interstate commerce for FDA to obtain records concerning that food, but focuses on the threat posed by the food if it were to enter commerce and sicken people. Likewise, the registration provision of the Bioterrorism Act (section 305) requires that *any* facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States -- whether or not that food is in interstate commerce – must register with FDA. Thus, there is no evidence that Congress intended to preclude FDA from pursuing an administrative detention against intrastate food. Indeed, if FDA lacked the ability to detain intrastate food products for which it had credible evidence that they could cause serious adverse human health consequences, the agency would be failing in its public health protection mission.

Although Congress may not have required FDA to demonstrate, as a matter of proof, that a food is manufactured, processed, packed or held for introduction into interstate commerce or is in interstate commerce for the agency to exercise its administrative detention authority, this does not mean, however, that an interstate commerce connection is absent.[9] The Bioterrorism Act, like the FFDCA, plainly falls within Congress' power to keep interstate commerce channels free from deleterious, adulterated and misbranded articles of food – in this case intentionally contaminated food – where the public health and safety might be harmed.[10] The Act also seeks to

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[9] An agency should not interpret a statute in a way that may cast doubt on the constitutionality of the statute. *See* Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers, 531 U.S. 159 (2001).

[10] The Supreme Court has defined the scope of Congress' power to regulate under the Commerce Clause to include: (1) the use of the channels of interstate commerce, *see* United States v. Darby, 312 U.S. 100, 114 (1941); (2) the instrumentalities of interstate commerce, or persons or things in interstate commerce, *see* Shreveport Rate

regulate activities that can substantially affect interstate commerce since as FDA has noted, intentionally contaminated foods can broadly impact the public health. Indeed, intrastate food that is intentionally contaminated could have a substantial impact on interstate commerce in several ways.[11]

For instance, the contaminated food could be consumed by out-of-state visitors or tourists who are only visiting a state temporarily. Because people freely cross state borders, they could consume tainted food manufactured, processed or sold only within a state, but become sick and seek medical care in another state, thus causing a substantial impact on an out-of-state health care system.[12]

In addition, a company may produce and sell its food or food products only within state, but the foods may, in turn, be processed into other products which are then sold in other states. Thus, the original ingredients, although produced and sold intrastate, could end up in products

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Cases, 234 U.S. 342 (1914); and 3) activities having a substantial relation to interstate commerce or that "substantially affect" interstate commerce, *see* NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 37 (1937); Maryland v. Wirtz, 392 U.S. 183, 196 n.27. The Supreme Court has upheld congressional acts regulating intrastate economic activity where it has concluded that the activity substantially affects interstate commerce. Thus, laws regulating restaurants using substantial interstate supplies, *see* Katzenbach v. McClung, 379 U.S. 294 (1964), and inns and hotels catering to interstate guests, *see* Heart of Atlanta Motel, Inc. v. United States, 379 U.S. 241 (1964), have been upheld as legitimate exercises of Congress's power under the Commerce Clause of the Constitution.

[11] The Supreme Court has stated that "[i]t is the effect upon interstate commerce or upon the exercise of the power to regulate it, not the source of the injury which is the criterion of Congressional power." United States v. Wrightwood Dairy Co., 315 U.S. 110, 119 (1942). Courts have construed the interstate commerce requirement broadly. For instance, in one case, allegedly contaminated mushrooms that had been imported from Taiwan were considered to be "introduced into interstate commerce" for purpose of an FDA seizure and condemnation action, even though they were never released from Customs Service upon arrival in the United States because they were shipped for the purpose of sale into the United States. United States v. Food, 2998 Cases, 64 F.3d 984 (5th Cir. 1995). In another case, the court found that the FFDCA applied to foods processed within a state because the individual components had been shipped interstate. United States v. 40 Cases, More or Less of Six One Gallon Cans Article Labeled in Part (Can) Pinocchio Brand 75% Corn, Peanut Oil and Soya Bean Oil Blended with 25% Pure Olive Oil, 289 F.2d 343 2nd Cir. 1961).

[12] CSPI's comment on the proposed rules implementing the recordkeeping requirements of the Bioterrorism Act (68 Fed. Reg. at 25,191), provided many of the same reasons as support for FDA's conclusion that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to the recordkeeping requirements whether or not they directly engage in interstate activities involving food.

sold interstate. Or vice-versa, food components may be shipped in interstate commerce to one state, but all the processing and manufacturing takes place solely within that state.

Finally, a finding that a single intrastate food product is intentionally contaminated could have widespread, nationwide, even international, implications. The recent discovery of a single cow in Alberta, Canada which tested positive for Bovine Spongiform Encephalopathy (BSE) demonstrates the substantial impact that a food emergency could have on a single industry. Although the cow did not enter the human food chain, cattle prices across all of Canada, as well as the retail sales of beef products, were severely impacted. An intentional food contamination event relating to an intrastate food product could cause even more dramatic consequences, with restrictions being imposed on the distribution and sale of all similar products, or consumers across the country deciding not to buy the product, thus impacting the whole economy.

Bioterrorism presents a national threat that must be addressed on a national basis. The statute is intended to provide FDA with the necessary authorities to prevent intentionally contaminated products – whereever they are located and whether or not they have yet entered interstate commerce – from entering the market place and removing them if they are released. Only in this way can the public's health be protected against an intentional contamination event.

2. FDA has adopted the appropriate criteria for a detention order

To administratively detain a food item, FDA must have "credible evidence or information" that the article of food poses a threat of serious adverse health consequences or death to humans or animals. Congress did not identify what specific evidence FDA must have in order to detain a food product. As a result, Congress has again given FDA latitude to determine what information is sufficient to constitute "credible evidence."

In the preamble to the proposed rule, FDA also did not define what constitutes credible

evidence. Rather, it has concluded that what constitutes credible evidence or information that a food poses a serious threat is a determination that should be made on a case-by-case basis, considering a number of factors including, but not limited to reliability, reasonableness, and the totality of the facts and circumstances.[13]

We agree that this is an appropriate interpretation of the requirement, and that FDA should make such decisions on a case-by- case basis. Given that a bioterrorism event may arise in an unanticipated scenario, FDA should not bind its discretion by identifying the types of evidence that it ultimately may need to rely upon to support a detention order.

CONCLUSION

The administrative detention provisions of the Bioterrorism Act are an important component of FDA's ability to effectively prevent an intentional attack on the food supply. Contaminated foods that are only in intrastate commerce can substantially impact interstate commerce in many ways, particularly by burdening the health care systems of many states. Therefore, FDA should not hesitate to exercise the detention authority against intrastate food products wherever and whenever necessary.

Respectfully submitted,

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[13] 68 Fed. Reg. at 25,246.

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