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IN THE
PUBLIC INTEREST

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May 10, 2004

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

To Whom It May Concern:

The Center for Science in the Public Interest (CSPI) respectfully submits the attached comments to Docket Number 02N-0278, 69 Federal Register 19,763, issued on April 14, 2004. CSPI greatly appreciates the opportunity to comment on this proposed rule.

Sincerely,



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2002N-0278

C299

May 10, 2004

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

Re: Comments on Interim Final Rule to Implement Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Comment Period, Docket No. 02N-0278, 69 Fed. Reg. 19,763 (April 14, 2004).

In December 2003, the Food and Drug Administration (FDA) published an interim final rule implementing section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), which requires prior notification to the FDA of food that is imported or offered for import into the United States.¹ Subsequently, FDA has reopened the comment period, raising numerous issues concerning the rule's implementation, including whether the time frames for advance notice should be shortened.

On behalf of the Center for Science in the Public Interest (CSPI), we are writing to submit our responses to the reopened comment period. 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 68 Fed. Reg. 58,974 (Oct. 10, 2003).

I. Foods Subject to FDA's Prior Notice Requirements Arriving Via Truck Should Not Be Eligible for Shortened Notice Requirements under the C-TPAT and FAST programs.

Under the Interim Final Rule, FDA must receive prior notice of imported food no less than 8 hours prior to arrival by ship, 4 hours by air or rail, and 2 hours by land via road. FDA has announced its intention to review these time periods and to provide flexible alternatives for submission of prior notice for foods covered by programs of other agencies, including the Bureau of Customs and Border Protection (CBP).

Under the CBP's "Required Advance Electronic Presentation of Cargo Information" rule, advance notice is required for all cargo arriving into the United States via truck, rail, air and sea.² Cargo arriving via ocean vessel must provide 24 hours notice and rail cargo two hours notice. Cargo arriving via flights from nearby foreign areas must provide "wheels up" notice, while 4 hours notice is required for air cargo arriving from other foreign areas. Truck cargo must provide advance notice no later than one hour prior to arrival. However, participants in CBP's Free and Secure Trade/Customs-Trade Partnership Against Terrorism (FAST/C-TPAT) program are only required to provide 30 minutes advance notice for cargo arriving via truck.³ FDA now is considering the feasibility of including the FAST time frame in FDA's prior notice final rule.

For the reasons set forth below, FDA should not shorten the prior notice required for food arriving into the United States via truck.

² 68 Fed. Reg. 68,140 (Dec. 5, 2003).

³ These are bilateral programs with Mexico and Canada aimed at increasing the integrity of supply chain security while expediting clearance of transborder shipments for participants.

A. The Food Supply Remains A Potential Target for Terrorist Attack

In its 2003 Risk Assessment for Food Terrorism, FDA noted that the Centers for Disease Control and Prevention (CDC) identified several foodborne pathogens as critical agents for possible terrorist attacks. Two high priority biological agents are *Bacillus anthracis* (anthrax) and *Clostridium botulinum* (botulism), which are both deadly.⁴ Heavy metals, pesticides, dioxins, furans and polychlorinated byphenyls (PCBs) also have been identified as potential agents for a terrorist attack on the food supply. The range of possible agents for food terrorism is broad and the types of food that could be contaminated are equally broad. The FDA, in its risk assessment, therefore concluded that “there is a high likelihood, over the course of a year, that a significant number of people will be affected by an act of food terrorism or by an incident of unintentional food contamination that results in serious foodborne illness.”⁵

Between 1980 and 2001, fresh fruit imports into the United States increased by 155 percent and fresh vegetable imports by 265 percent. In 2001, 28.9 percent of fresh fruit and 11.6 percent of fresh vegetables consumed in the United States were imported.⁶ Costa Rica is the largest supplier of fresh fruits and Mexico is the largest supplier of fresh vegetables.⁷ At the same time, fresh fruits and vegetables are particularly vulnerable to a potential terrorist attack since they are “consumed directly, with minimal processing [and] there are few critical control

⁴ FDA, Center for Food Safety and Applied Nutrition, *Risk Assessment for Food Terrorism and Other Food Safety Concerns* (Oct. 13, 2003), found at <http://www.cfsan.fda.gov/~dms/rabtact.html>.

⁵ FDA, Center for Food Safety and Applied Nutrition, *Risk Assessment for Food Terrorism and Other Food Safety Concerns*, at p. 6.

⁶ Roxanne Clemens, *The Expanding U.S. Market for Fresh Produce*, Iowa Ag Review, vol. 1, No. 1 (Winter 2004) [hereafter Clemens, *The Expanding U.S. Market for Fresh Produce*], available at <http://www.card.iastate.edu/iowa/ag/review/>.

⁷ Clemens, *The Expanding U.S. Market for Fresh Produce*, Table 1.

points for detection or removal of contamination.”⁸ Contamination, intentional or otherwise, is a source of concern since: 1) growers have less control over field conditions compared to enclosed production facilities; 2) harvesting, washing, cutting, slicing, packaging, and transporting provide opportunities for contamination; and 3) fresh produce is likely to be consumed raw.⁹

Given that these and other foods are widely distributed in the United States, and that they may pose a high risk, FDA should not further reduce the required prior notice for food imports arriving by truck. The notice deadline must be sufficient to allow the FDA adequate time to identify suspect shipments and inspect them to ensure that intentionally contaminated products do not reach American consumers. Adequate inspection is particularly crucial for imported seafood since FDA does not have seafood equivalence or compliance agreements (except for molluscan shellfish) with any foreign country.¹⁰ Evidence of an intentional contamination episode might come to light after a truck has left a production facility. One hour would not be adequate to stop the truck.

B. Further Shortening of the Required Prior Notice Is Inconsistent with the Bioterrorism Act

Under section 801(m)(2)(a) of the Food, Drug and Cosmetic Act, implementing regulations shall require that the advance notice prior to the importation of the food article “shall

⁸ World Health Organization, Food Safety Department, FOOD SAFETY ISSUES: Terrorist Threats to Food, Guidance for Establishing and Strengthening Prevention and Response Systems (2002), at p. 13.

⁹ FDA, Center for Food Safety and Applied Nutrition, Office of Plant and Dairy Foods and Beverages, *Survey of Imported Fresh Produce, FY 1999 Field Assignment* (Jan. 30, 2001), at p. 2, available at <<http://vm.cfsan.fda.gov/~dms/prodsur6.html>>.

¹⁰ Indeed, the General Accounting Office has identified several deficiencies in FDA’s efforts to assure the safety of imported seafood, finding that FDA’s port of entry examinations for seafood “have been unable to keep pace with the growing volume of seafood product imported into the United States.” GAO, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*, Report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate (Jan. 2001), at pp. 31-32.

be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days.”¹¹ Between October 2002 and September 2003, there were approximately 5.1 million food entries into the United States.¹² Although there are approximately 360 ports of entry in the United States, the FDA has inspectors at only 90 of these ports of entry.¹³ Testifying before the House Appropriations Committee Subcommittee on Agriculture, Acting FDA Commissioner Lester Crawford admitted that the agency is overwhelmed by imports, acknowledging that “[i]t’s difficult for us, and we are missing the mark, but we pledge to do better.”¹⁴ In the interim final rule, the agency also admitted that the chosen prior notice time frames provide it “with very little leeway in the time it has to ‘receive, review and respond’ to the prior notice submissions.”¹⁵

Despite the agency’s recognition that it already has “very little leeway” in fulfilling its statutory responsibilities and is “missing the mark” on food import inspections, FDA now is assessing whether to shorten the prior notice for imports arriving via truck even further. The two justifications for this action – the FDA-CBP memorandum of understanding (MOU) allowing CBP personnel to perform examinations at ports where the FDA may not currently have staff or to augment FDA staff action and to achieve integration with the CBP’s time periods for advance

¹¹ Section 307(a) of the Bioterrorism Act, amending Section 801 of the Federal Food, Drug and Cosmetic Act.

¹² Telephone conversation of Caroline Smith DeWaal, CSPI, with Louis Carson, FDA, Deputy Director, Food Safety and Security Staff, Center for Food Safety and Applied Research (Oct. 20, 2003).

¹³ FDA, FDA News, *FDA and CBP Announce Their Transitional Compliance Policy on Food Imports Under Bioterrorism Act* (Dec. 11, 2003).

¹⁴ See Ira Dreyfuss, Associated Press, “Food Inspections” (Mar. 12, 2004), found at <http://131.104.232.8.fsnet.2994.302994.fsnet_march_12.htm>.

¹⁵ 68 Fed. Reg. at 59,013.

cargo notice – raise critical questions concerning food import inspections.¹⁶

Under the MOU, the FDA has agreed to commission all CBP officers “deemed necessary” by the Commissioner of CBP and the FDA to conduct examinations and investigations. However, a number of key issues remain, including:

- what criteria the Agency will use to determine when those CBP officers are “deemed necessary;”
- what percentage of CBP personnel will be doing food inspection as opposed to paper or computer work;
- whether every port of entry will be covered by an FDA inspector or FDA-trained inspector; and
- how CBP personnel will adjust their current inspection priorities of stopping illegal drugs and other potentially deadly contraband from entering the country, while also performing food inspections.

It is also unclear how, with only 30-minute notice, FDA can adequately determine that a particular shipment may be suspect and deploy its inspection resources to the port of entry.

C. Compliance Data Demonstrate That FDA Is Still Receiving Incomplete Prior Notice

Under the Interim Final Rule, prior notice can be provided either through FDA’s Prior Notice System Interface (PNSI) or through CBP’s Automated Commercial System (ACS).

According to recent compliance data, roughly 88 percent of the total prior notice submissions are made through the ACS.

At the same time, over 40 percent of the ACS submissions had incomplete carrier

¹⁶ See FDA, FDA News, FDA and CBP Bolster Safeguards on Imported Food (Dec. 3, 2003).

information and over 20 percent lacked incomplete submitter, arrival and manufacturer registration information.¹⁷ Significantly, over 70 percent of the ACS entries for road-delivered goods had incomplete owner information, 60 percent had incomplete manufacturer registration information, and over 20 percent had incomplete bill of lading and arrival information.

Accordingly, FDA is receiving incomplete prior notice on the majority of imported foods arriving at United States ports of entry. FDA should be focusing even more effort on educating those subject to the prior notice rule of the rule's requirements – not giving them even more flexibility concerning the timing for providing advance notice.

For these reasons, FDA's prior notice final rule should assure that the agency has sufficient time – at least two hours notice – of food imports arriving via land/road.

II. Alternatively, C-TPAT Should Be Modified To Address Food Regulated by the FDA

As set forth above, it is inconsistent with FDA's statutory mandate to further reduce the time periods for prior notice of food imports arriving via land/road. If, however, FDA acts to shorten the notice required for food imports arriving via truck based on participation in Custom and Border Protection's FAST/C-TPAT program, then certain changes should be made in that program vis-a-vis food imports.

A. The C-TPAT Verification Processes Should be Changed

Manufacturers, carriers and drivers who are certified under the C-TPAT program may become eligible for shorter advance notice of imports and expedited clearance at U.S. ports-of-entry under the FAST program. To obtain certification they must, among other things, submit a supply chain security profile, establish a security system for manufacturing, production, cargo

¹⁷ FDA, Center for Food Safety and Applied Nutrition, *Compliance Summary Information: Prior Notice* (Apr. 2, 2004).

storage and handling facilities, and ensure that high security mechanical seals are affixed on all loaded containers or trailers destined for the U.S.¹⁸ If FDA determines to adopt shorter prior notice requirements based on C-TPAT participation, then certain changes in C-TPAT should be made.

First, although CBP states that it will verify the application, it appears that CBP verification is a paper review. At a minimum, the C-TPAT verification procedure must be strengthened for manufacturers of “food” as it is defined in the Prior Notice rule. Among other things, FDA should verify that other countries’ regulatory systems for food production and safety are equivalent to those of the United States. In addition, the agency should perform on-site audits and inspection of production facilities before a food manufacturer or carrier can be certified.

Second, the CBP Foreign Manufacturer agreement only states “please submit any change to CBP in the event of significant changes to company structure or internal process that could change or alter the commitment that you have made to CBP under C-TPAT.”¹⁹ Notice concerning any changes in manufacturing processes or supplies, as well as those that may affect physical and personnel security, should be mandatory for food manufacturers. Moreover, the requirement that manufacturers “periodically” review the security commitment of their service providers to detect weakness or potential weaknesses in security should be altered to require: 1) that the review is conducted on an annual basis, and 2) a certification that the review has been conducted. Only with strengthened verification procedures should FDA consider reducing the prior notice time periods.

¹⁸ See C-TPAT, Foreign Manufacturer Agreement to Voluntarily Participate in Customs-Trade Partnership Against Terrorism.

¹⁹ C-TPAT Agreement, ¶ 8.

B. FDA Should Not Adopt Flexible Notice Requirements for High-Risk Truck Imports

Even with strengthened security and verification procedures for C-TPAT participants who import food, FDA should not allow shortened prior notice or expedited entry for manufacturers, carriers, and drivers of high-risk foods. High-risk foods include those that are subject to minimal or no further processing and which may be consumed raw, such as fresh produce. As set forth above, these are also the foods that cause the largest percentage of foodborne illnesses, are more likely to be subject to intentional contamination, and accordingly, may require extra scrutiny at the U.S. border.

III. FDA Should Require 24-Hour Prior Notice for Imports Arriving by Ocean Vessel

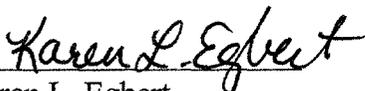
One of the rationales advanced by FDA for adopting shorter prior notice requirements for food imports arriving via truck is to increase integration and coordination with the CBP's advance notice time frames. Significantly, in reopening the comment period, FDA only discusses coordinating with CBP's advance notice requirements for shipments arriving by land via truck, while ignoring the longer time frames adopted by CBP for imports arriving via ocean vessel.

Under the CBP rules, ocean shipments must provide 24 hour notice. Under FDA's prior notice interim final rule, food imports arriving by ocean only require 8 hours advance notice. If FDA's goal is to increase integration with the CBP's time frames, then the FDA should *lengthen* the advance notice requirements for food arriving by ocean. It is inconsistent for the agency to offer integration with the CBP's notice requirements as the justification for shortening the notice required for food imports arriving via truck while ignoring that justification when it comes to food imports arriving via ocean.

Conclusion

Any action by the FDA to further shorten the time period for prior notice of food imports arriving via truck would be inconsistent with the provisions of the Bioterrorism Act, particularly given FDA's admissions that it lacks sufficient resources to adequately inspect food imports. Allowing only 30 minutes notice of food arriving via truck would further stretch the agency's limited resources. If, however, FDA determines to adopt prior notice time periods based on CBP requirements, then, at a minimum, the C-TPAT requirements for verification must be strengthened and high-risk foods exempted from both shorter notice and expedite treatment at border crossings. In addition, if FDA is to advance integration with CBP requirements as justification for altering FDA prior notice requirements, then the agency must lengthen the prior notice required for food imports arriving via ocean vessel.

Respectfully submitted,


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