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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, Docket No. 02N-0278, 68 Fed. Reg. 58,974 (Oct. 10, 2003)

The Food and Drug Administration (FDA) has 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 The rule is designed to enhance the FDA's ability to inspect imported food upon arrival in the United States.

On behalf of the Center for Science in the Public Interest (CSPI), we are writing to comment on the prior notice requirements 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. The Prior Notice Requirements Set Forth in the Interim Final Rule Are Too Short To Allow FDA to Fulfill its Inspection Obligations Under the Bioterrorism Act

Section 307 of the Bioterrorism Act gives the FDA authority to require food importers to give prior notice for food products offered for import into the United States. The purpose of the

¹ 68 Fed. Reg. 58,974 (Oct. 10, 2003).
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prior notice provision is to ensure that the FDA has sufficient information concerning an imported food – including the manufacturer and shipper, country of origin, food product category, and anticipated port of arrival – in advance of its arrival in the United States to determine whether it may pose a threat and warrant inspection before entering this country.

Under the Bioterrorism Act, the regulations implementing this provision shall require that the advance notice prior to the importation of the food article “shall 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.”²

In the proposed rule, the FDA determined that prior notice should be submitted to the FDA no later than noon of the calendar day before arrival of the article at the port of entry. To provide additional flexibility, the proposed rule also would have allowed importers to make one amendment up to 2 hours prior to arrival to update product identity information that was not known at the time of submission.³ According to the FDA, this time period was based on the agency’s assessment of the minimum amount of time it needed to “meet its statutory mandate of receiving, reviewing, and responding to prior notice.”⁴

In the interim final rule, the FDA greatly reduced the time frames for prior notice and imposed a rolling notice requirement, depending on the method of transport by which the imported food arrives in this country. Imports arriving by land via truck are only required to provide 2 hours advance notice, imports arriving by air or land via rail must provide 4 hours

² Section 307(a), amending Section 801 of the Federal Food, Drug and Cosmetic Act.

³ 68 Fed. Reg. 5428 (Feb. 3, 2003).

⁴ 68 Fed. Reg. at 58,994.

advance notice, while those coming by water must provide 8 hours notice prior to arrival.⁵ The notice also must be provided no earlier than 5 calendar days prior to arrival, except in the case of food traveling by international mail.

According to the FDA, the shortened advance notice periods are intended to address commenters' concerns about a lack of flexibility in the system. At the same time, however, the agency admits that the chosen time frames provide it "with very little leeway in the time it has to 'receive, review and respond' to the prior notice submissions."⁶ Unlike USDA's Food Safety and Inspection Service -- which verifies that other countries' regulatory systems for meat, poultry and egg products are equivalent to those of the U.S., performs on-site audits, and conducts point-of entry inspections -- to assure that incoming foods are safe and wholesome, the FDA relies solely on point-of-entry inspection. Nonetheless, the agency does not provide inspection staff at all ports of entry every day and around the clock. Given this lack of resources, the minimal prior notice requirements contained in the interim final rule completely undermine the Agency's ability to assure that food inspectors are present at those ports where the highest risk foods are entering.

By giving importers additional flexibility, the FDA has reduced its own flexibility and ability to meet its inspection obligations under the Bioterrorism Act, in particular the agency's ability to target and inspect suspect shipments of imported food. Indeed, the time periods for advance notice specified in the interim final rule appear too short given that:

- between October 2002 and September 2003, there were approximately 5.1 million food

⁵ 21 C.F.R. §1.279(a).

⁶ 68 Fed. Reg. at 59,013.

entries into the United States.⁷ Of these, approximately 2.8 million or 55% were by land;

- FDA expects to receive about 25,000 notifications about incoming shipments each day;⁸
- there are 361 ports of entry into the United States;
- FDA has inspectors at only 90 of these 361 ports of entry;⁹
- an increasing number of imports are coming from emerging economies with emerging or weak enforcement and/or regulatory infrastructures; and
- approximately 20% of fresh produce and 60% of all seafood consumed in the United States are imported;¹⁰ and
- fresh produce and fish cause the highest proportion of foodborne illnesses and outbreaks in this country.

Accordingly, the FDA should lengthen the time periods for advance notice to assure that the Agency can meet its inspection obligations under the Act and fully and adequately protect American consumers.

2. Any Change in Anticipated Arrival Information Should Be Grounds for Cancelling the Prior Notice and Requiring that a New One Be Submitted.

Even more problematic than the shortened time periods for advance notice is the fact that the interim final rule does not require an importer to notify the FDA if there is a change in anticipated arrival information, including the anticipated port of arrival or the anticipated date the

⁷ Telephone Conversation of Caroline Smith DeWaal, CSPI, with Louis J. Carson, FDA, Deputy Director, Food Safety and Security Staff, Center for Food Safety and Applied Research (Oct. 20, 2003) [hereinafter Smith DeWaal-Carson Telephone Conversation].

⁸ U.S. Department of Health and Human Services, News Release, *HHS Issues New Rules to Enhance Security of the U.S. Food Supply* (Oct. 9, 2003).

⁹ Smith DeWaal-Carson Telephone Conversation.

¹⁰ FDA, FDA News, *FDA and CBP Announce Their Transitional Compliance Policy on Food Imports Under the Bioterrorism Act* (Dec. 11, 2003).

food will arrive.¹¹ As a result of this exception, FDA will go from having little notice to *no* notice concerning where and when suspect food shipments may arrive in this country.

The Bioterrorism statute mandates that the regulation promulgated by the FDA implementing this provision must require prior notice of, among other things, the anticipated port of entry for the imported food article. An article of food imported without submission of notice in accordance with the requirements “shall be refused admission into the United States.”¹² The FDA’s decision to allow importers to change the anticipated port of arrival without *any* notice to the FDA of this change is wholly inconsistent with the language and intent of section 307. Anyone seeking to introduce contaminated food products into the United States could simply divert its shipment at the last minute to a port where the FDA’s food inspection resources are known to be non-existent. Even if the FDA targeted a shipment as suspect based on the prior notice filed, the agency would have no information concerning where and when that shipment may actually arrive so that it could assure that personnel are present to inspect the shipment. This exception to the prior notice requirement defeats the entire purpose of the prior notice provisions, which is to facilitate product tracking and ensure that consumers in the United States do not eat food that is contaminated, intentionally or otherwise.

The FDA should delete this exception to the interim final rule. Any change in anticipated arrival information – particularly the port of arrival and time of arrival - should be grounds for cancelling the prior notice and for requiring that a new one be submitted. Moreover, at a minimum, the FDA should assure that high risk imports arrive at ports staffed by FDA inspection

¹¹ 9 C.F.R. § 1.282(a)(1)(ii).

¹² Bioterrorism Act, section 307(a), amending FFDCA section 801(m)(1).

personnel. This could be accomplished by designating particular ports of entry for accepting high risk products or requiring importers of such products to provide longer notice to ensure adequate inspection coverage.

3. FDA's Justifications For Shortened Prior Notice Raise Questions

As justification for reducing the time periods for prior notice, the FDA explained that it has entered into a memorandum of agreement (MOA) with Customs and Border Protection (CBP) to use CBP personnel to perform examinations on behalf of the FDA at ports where the FDA may not currently have staff or to augment FDA staff.¹³ CBP also has agreed to modify its Automated Broker Interface of the Automated Commercial System (ABI/ACS) by the December 12, 2003 deadline so that FDA can receive, transmit and communicate prior notice information electronically between the two agencies for most entries of imported food.¹⁴ According to the FDA, it is working with CBP to develop a plan for developing a uniform integrated system and that such plan will be published by March 12, 2004.

Although a plan for developing an integrated system is to be developed by March 2004, there is no indication when such a plan will actually be implemented. Actual implementation could take months, even years. During the interim, however, the FDA's ability to target and inspect suspect imports will be severely hampered by the short notice the agency will receive before imported food arrives at America's shores.

In addition, while there should and must be cooperation between the FDA and the CBP personnel, the MOA raises certain questions. According to the FDA, since the CBP staff

¹³ 68 Fed. Reg. at 58,995. *See also* FDA, FDA News, *FDA and CPB Bolster Safeguards on Imported Food* (Dec. 3, 2003).

¹⁴ 68 Fed. Reg. at 58,995.

generally will be available where the FDA is not, "this means that FDA no longer needs lead-time to travel significant distances to conduct inspections."¹⁵ Under the MOA, the FDA has agreed to commission all CBP officers "deemed necessary" by the Commissioners of the CBP and the FDA to conduct examinations and investigations under the prior notice requirements.¹⁶

Assuming that CBP personnel will exercise these increased responsibilities while also performing their usual inspection functions, there are questions concerning: 1) how many CBP officers the FDA will commission and what criteria it will use to determine when those officers are "deemed necessary;" 2) how any dispute between the two agencies on whether CBP personnel are "necessary" will be resolved; 3) how the FDA will determine at which ports CBP as opposed to FDA inspection personnel should be employed; 4) how CBP personnel will adjust their priorities, particularly since they also have responsibilities to stop illegal drugs from entering the country, apprehend individuals from crossing U.S. borders illegally, and collect import duties; 5) whether CBP personnel will be under increased pressure to release suspect food shipments into the country because food inspectors are not present; and 6) whether CBP personnel will be checking paperwork and computer notifications or doing actual food inspections.

We believe that these questions must be addressed before FDA can rely on CBP staff to execute FDA food inspection functions.

¹⁵ 68 Fed. Reg. at 58,995.

¹⁶ Memorandum of Agreement Between Customs and Border Protection and the Food and Drug Administration (12/3/2003), at ¶ 4.A.1.

4. Assuring That the FDA Has Adequate Prior Notice Is Particularly Important Because of the Vulnerability of the Products Over Which It Has Jurisdiction

In its 2002 report, *Terrorist Threats to Food*, the World Health Organization recognized that 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 points for detection or removal of contamination.”¹⁷

The per capita consumption of fresh produce in the United States has increased in recent years partly as a result of increased importation that makes certain products available throughout the year. Contamination of fresh produce -- intentional or unintentional -- has been a source of concern for several reasons: 1) growers have less control over conditions in the field (compared to an enclosed production facility), 2) fruits and vegetables are grown in non-sterile environments, 3) harvesting, washing, cutting, slicing, packaging, and transporting may provide opportunities for contamination, and 4) fresh produce is likely to be consumed raw.¹⁸ In addition, “[p]roduce from a single grower, packinghouse, or shipper, whether located outside or within the United States, may be routinely distributed throughout the country, thus facilitating widespread dissemination of potential pathogens.”¹⁹

Unintentionally contaminated imported produce has been associated with numerous illness outbreaks in the United States. Recently, green onions imported from Mexico have

¹⁷ 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 [hereinafter WHO, *Terrorist Threats to Food*].

¹⁸ 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>>.

¹⁹ Larry R. Beuchat and Jee-Hoon Ryu, *Produce Handling and Processing Practices*, 3 EMERGING INFECTIOUS DISEASES, Oct.-Dec. 1997.

caused the largest Hepatitis A outbreak experienced in this country, resulting in several deaths.

Other outbreaks associated with imported food products have included:²⁰

- In 1996 and 1997, thousands of consumers contracted cyclosporiasis in the United States and Canada from raspberries imported from Guatemala contaminated with the parasite *Cyclospora*.²¹
- In 1989, 295 illnesses were linked to *Salmonella*-contaminated cantaloupes from Mexico.²²
- In 2000-2002, there were 155 cases, 28 hospitalizations and 2 deaths related to consumption of *Salmonella poona*-contaminated cantaloupes imported from Mexico.²³
- In 1989, 162 illnesses and 18 hospitalizations in the United States caused by staphylococcal food poisoning were linked to consumption of mushrooms that had been canned in China.²⁴
- In 1995, a *Salmonella* outbreak linked to alfalfa sprouts resulted in at least 242 illness in at least 17 states and Finland. The seeds were traced through 9 growers to one U.S.

²⁰ Data gathered by CSPI also show that a high percentage of foodborne illness outbreaks in this country are linked to fresh produce. Between 1990-2002, fruits, vegetables and produce dishes were responsible for 293 outbreaks, resulting in 18,084 cases. See CSPI, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net* (updated and Revised Sept. 2002), at p. 17. Newer unpublished CSPI outbreak data show that between 1990 and 2002, there were 362 outbreaks resulting in 21,386 cases.

²¹ Barbara L. Herwaldt, *et al.*, *An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries*, 336 NEW ENGLAND JOURNAL OF MEDICINE, May 29, 1997, at 1548-1556; Barbara L. Herwaldt, *et al.*, *The Return of Cyclospora in 1997: Another Outbreak of Cyclosporiasis in North America Associated with Imported Raspberries*, 130 ANNALS OF INTERNAL MEDICINE, Feb. 2, 1999, at 210-220. Strawberries contaminated with Hepatitis A that were grown in Mexico, frozen in the United States, and distributed through the school lunch program were also the source of a large illness outbreak in 1997. See Yvan J.F. Hutin, *et al.*, *A Multistate, Foodborne Outbreak of Hepatitis A*, 340 NEW ENGLAND JOURNAL OF MEDICINE, Feb. 25, 1999, at 595-602.

²² Nancy H. Bean, *et al.*, *Surveillance for Foodborne-Disease Outbreaks – United States, 1988-1992*, 45 (SS-5) MORBIDITY AND MORTALITY WEEKLY REPORT, Oct. 25, 1996, at 1-55.

²³ CDC, *Multistate Outbreaks of Salmonella Serotype Poona Infections Associated with Eating Cantaloupe from Mexico – United States and Canada, 2000-2002*, 51 MORBIDITY AND MORTALITY WEEKLY REPORT, Nov. 22, 2002.

²⁴ W.C. Levine, *et al.*, *Staphylococcal food poisoning caused by imported canned mushrooms*, 173 JOURNAL OF INFECTIOUS DISEASE, 1996, at 1263-67. See also CDC, *Epidemiologic Notes and Reports Multiple Outbreaks of Staphylococcal Food Poisoning Caused by Canned Mushrooms*, 38 MORBIDITY AND MORTALITY WEEKLY REPORT, June 23, 1989, at 417-418.

supplier that bought the seeds shipped from the Netherlands.²⁵

Likewise, imported seafood accounts for a large proportion of the seafood consumed in the United States – in 2002, almost 60% of the seafood consumed in the United States was imported.²⁶ Seafood has been a significant source of illness outbreaks in the United States, with 539 documented outbreaks resulting in 6,781 cases between 1990 and 2002.²⁷

Given that imported produce and seafood are widely distributed within the United States and that these foods may pose a high risk – as demonstrated by recent illness outbreaks, the FDA must be assured that importers provide sufficient time for the FDA to inspect these products destined for American consumers.

Conclusion

A whole range of foods, including ingredients and/or packaged food, seafood, and fresh produce, could be potential targets for food terrorists. The FDA has not justified how it can review the history of a product and its importer, identify suspect products, and provide for inspection of such products when it only has 2 to 8 hours notice of their arrival at the U.S. border.

In the prior notice provision of the Bioterrorism Act of 2002, Congress intended to give FDA sufficient time to inspect suspect imported foods. Adequate prior notice provides FDA with an early warning of food products that may pose a serious health threat to animals or

²⁵ Barbara E. Mahon, et al., “An International Outbreak of *Salmonella* Infection Caused by Alfalfa Sprouts Grown from Contaminated Seeds,” *Journal of Infectious Diseases*, Vol. 175 (1977), at p. 879. The seeds that came to the United States were reportedly a mixture of seed lots from Italy, Hungary or Pakistan.

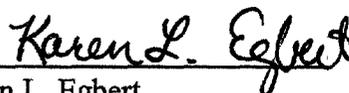
²⁶ U.S. Department of Commerce, National Oceanic and Atmospheric Administration, *Fisheries of the United States 2001*, at p. 90; NMFS, Fisheries Statistics and Economics Division, *Statistical Highlights, Fisheries of the United States*, 2002, at p. 1 (noting that imports (8.8 billion pounds) were up 10%).

²⁷ *Outbreak Alert!*, at p. 17.

humans, allowing the agency to mobilize its resources quickly to detain suspect foods arriving at American ports. FDA should not weaken this important tool provided by Congress by allowing importers to provide only minimal advance notice of food imports.

Therefore, we urge the FDA to: 1) reconsider the advance notice time periods in the interim final rule to assure that the agency obtains information sooner about food imports so that suspect food imports can be adequately inspected; 2) require that a new prior notice must be submitted when there is any change in anticipated arrival information, particularly the port and time of arrival; and 3) assign FDA inspection personnel at all arrival ports, particularly those where high risk shipments may arrive. With the simplicity of electronic submission through the new FDA Web interface, there is no reason why the FDA cannot require longer notice periods so that it can better marshal its limited inspection resources.

Respectfully submitted,



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