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April 2, 2003

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

**Re: Comments on Proposed Regulations to Implement Section 307
(Prior Notice of Imported Food) of the Bioterrorism Act, Docket No.
02N-0278**

The Food and Drug Administration (FDA) has published proposed regulations implementing section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), which requires prior notification to FDA of food that is imported or offered for import into the United States. The rule is designed to enhance 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 proposed 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*.

In assessing the terrorist threat to food safety, the World Health Organization (WHO) in a recent report on terrorist threats to food has stated that

“food is . . . the most vulnerable to intentional contamination by debilitating or lethal agents. The diversity of sources of foods, including the global market, makes prevention difficult, if not impossible. At the same time, many developing countries lack basic food safety infrastructures and are vulnerable to deliberate acts of

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sabotage.”¹

Fresh fruits and vegetables are particularly vulnerable to a potential terrorist attack since, as the WHO has recognized, they are “consumed directly, with minimal processing [and] there are few critical control points for detection or removal of contamination.”² Therefore, implementation of stringent prior notice requirements with respect to imported fresh produce is particularly important so that FDA can better set its inspection priorities and allocate its resources to respond swiftly in the event of a terrorist threat.

Because the prior notice requirements are a key provision in addressing the threat of intentional contamination of the food supply, the FDA should, among other things:

- maintain strict time limits on pre-entry notification;
- assure that the notification deadlines for amendments are adequate for the agency to deploy its inspection resources; and
- include countries of intermediate destination in the definition of “country from which the article of food was shipped.”

The earlier FDA has information concerning the precise food articles coming into this country, the better equipped it will be to determine which articles should be targeted for inspection and the better able the agency will be to protect American consumers.

1. *FDA Should Maintain Strict Time Limits on Pre-Entry Notification Consistent With Its Own Resource Needs*

Under section 1.286 of the proposed rule, prior notice of an imported food article would be required no later than noon of the calendar day before the day the article will arrive at the

¹ 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. 5 [hereinafter WHO, *Terrorist Threats to Food*].

² WHO, *Terrorist Threats to Food*, at p. 13.

border crossing or the port of entry. Prior notice may not be submitted more than 5 days before the anticipated date of arrival of the imported food.

We are aware that some industry members (e.g., those who service quick turnaround orders such as catch-of-the-day or same-day orders) have advocated more flexibility in the prior notice deadlines to account for commercial realities. However, the proposed deadlines are consistent both with the terms of the statute and the discretion afforded to FDA under the statute.

Although the Bioterrorism Act specifically sets the outer limit for prior notice to FDA – 5 days in advance of importation – it does not identify the minimum amount of time for prior notice. Rather, it states that the time period for prior notice shall be “no less than the minimum amount of time necessary for the [FDA] to receive, review and appropriately respond to such notification, but may not exceed five days.”³ As a result, the statute gives FDA considerable discretion to set the minimum amount of time prior to importation based on its own resource needs and ability to respond to the prior notice.⁴ The question, therefore, is not whether the Act has mandated the particular deadline set by FDA, but whether FDA’s choice of deadline is a reasonable exercise of the discretion given to it by Congress.

The proposal to require notice no later than noon on the calendar day before the food is due to arrive at a U.S. port of entry is a reasonable exercise of this discretion. As the agency has noted, it “must have enough time, on a daily basis, to process the information in the approximately 20,000 prior notices” it expects to receive.⁵ The prior notice information is crucial

³ Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [hereinafter Bioterrorism Act], section 307(a).

⁴ The statute specifically allows FDA to consider among other things the “various modes of transportation” in setting prior notification deadlines. Section 307(a).

⁵ 68 Fed. Reg. 5428, 5433 (Feb. 3, 2003).

to FDA's ability to assess which imported food shipments it should physically inspect and sample. FDA fully explained in the proposed rule that for it to inspect food imports that may be at risk of intentional adulteration, it must be able to effectively deploy its staff – staff that must be able to quickly travel to the 250 ports where over 4.7 million entry lines of food were entered in fiscal year 2001.⁶ At least with respect to imported seafood, the General Accounting Office previously has found that FDA's port of entry examinations "have been unable to keep pace with the growing volume of seafood product imported into the United States."⁷

The sooner that FDA has information sufficient to target its inspection resources at those food products posing the greatest risk, the greater the likelihood that tainted products can be discovered and stopped before they enter the United States. Accordingly, given FDA's articulation of its resource needs and the clear need for protection of the public, the prior notice deadlines represent a reasonable exercise of the Agency's discretion under the statute.⁸

2. *FDA Should Assure That Notification Deadlines For Amendments Are Adequate for the Agency To Deploy its Inspection Resources*

According to the FDA, the prior notice deadlines may have the most impact on those who import food by truck and rail over the land borders. Recognizing that exact product identity information may not be known at the time the product is ordered, FDA has proposed to allow

⁶ 68 Fed. Reg. at 5433.

⁷ General Accounting Office, *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 [hereinafter GAO, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*].

⁸ The fact that the statute has a "default" minimum time limit of 8 hours is not a limitation on FDA's discretion to increase the minimum notice required. Congress specifically provided that the minimum time period shall be "no less" than the minimum amount of time FDA determines is necessary to "receive, review and appropriately respond to" the prior notice. Bioterrorism Act, section 307(a). As a result, FDA was given broad flexibility to weigh competing considerations and exercise its judgment based on numerous factors.

submitters to amend their prior notices to provide more specific product identity information that does not exist by noon of the calendar day prior to arrival.⁹ Such information must be submitted no later than 2 hours prior to arrival time.¹⁰

In the preamble, FDA has stated its belief that the proposed amendment procedures will have most applicability to those who import fresh seafood and fresh produce from countries close to the United States, like Mexico and Canada.¹¹ While we recognize the need to adapt the rule to the practicalities of importing, we urge the agency to assure that the 2-hour notice of amendment is sufficient time to marshal inspection resources – particularly with respect to imported fresh seafood and produce.

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.¹² 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

⁹ Proposed rule, §§ 1.289, 1.290, 68 Fed. Reg. at 5438.

¹⁰ Proposed rule, § 1.291.

¹¹ 68 Fed. Reg. at 5438.

¹² 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>>.

dissemination of potential pathogens.”¹³

Unintentionally contaminated imported produce has been associated with numerous illness outbreaks in the United States:¹⁴

- in 1996, 1465 cases of cyclosporiasis in the United States and Canada were linked to raspberries imported from Guatemala contaminated with *Cyclospora*. In 1997, another outbreak caused 1012 cases.¹⁵
- an outbreak linked to cantaloupes from Mexico contaminated with *Salmonella* resulted in 295 illnesses in 1989.¹⁶
- a *Salmonella poona* outbreak in 2002 – the third consecutive year – was linked to cantaloupes imported from Mexico.¹⁷

¹³ Larry R. Beuchat and Jee-Hoon Ryu, *Produce Handling and Processing Practices*, 3 EMERGING INFECTIOUS DISEASES, Oct.-Dec. 1997.

¹⁴ Data gathered by CSPI also shows 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.

¹⁵ 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.

¹⁶ 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.

¹⁷ FDA, News Release, *Nationwide Recall of Susie Brand Imported Cantaloupe Due to Potential Health Risk*, <http://www.fda.gov/oc/po/firmrecalls/kunik05_02.html> Mexican cantaloupe recall raises questions (May 23, 2002), at <http://www.foodmarketexchange.com/datacenter/news/dc_ns_index_detail.php3?newsid+=7103>; See also 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.

- in 1989, staphylococcal food poisoning outbreaks in the United States were associated with consumption of mushrooms that had been canned in China.¹⁸

Likewise, imported seafood accounts for a significant portion of the seafood consumed in the United States. In 2001, almost 50% of the seafood consumed in the United States was imported.¹⁹ 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 2002.²⁰

A review of FDA's Operational and Administrative System for Import Support (OASIS) refusals for one month alone – January 2003 – also demonstrates that imported fresh fruits and vegetables and seafood pose a high risk for contamination – unintentional or otherwise. In January 2003, there were 298 entry refusals in the Fishery/Seafood Product category.²¹ Many of these refusals related to products that were described as “filthy,” “*Salmonella*,” or “poisonous.” In the fruit/fruit products categories, there were 208 refusals for January 2003, while there were 236 refusals in the vegetables/vegetable products categories.²² These refusals were for reasons described, among other things, as “filthy,” “pesticides,” and “*Listeria*.”

Given that imported produce and seafood are widely distributed within the United States

¹⁸ 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.

¹⁹ U.S. Department of Commerce, National Oceanic and Atmospheric Administration, *Fisheries of the United States 2001*, at p. 90.

²⁰ *Outbreak Alert!*, at p. 17.

²¹ FDA, *OASIS Refusals by Industry for January 2003*, <http://www.fda.gov/ora/oasis/1/ora_oasis_prod_1st.html>.

²² FDA, *OASIS Refusals by Industry for January 2003*, <http://www.fda.gov/ora/oasis/1/ora_oasis_prod_1st.html>.

and that these foods may pose a high risk, the amendment process should not be allowed to become a dangerous loophole in the law. The FDA must assure that the notification deadline for amendment is sufficient to allow the agency adequate time to inspect incoming products to assure that intentionally contaminated products do not reach American consumers.²³

3. FDA Lacks Authority to Waive Prior Notice Requirements Based on Duplicative Submissions

Noting that the prior notice requirements may result in persons submitting prior notice information to more than one federal agency, FDA seeks comments on whether there is any way, consistent with the Bioterrorism Act, to minimize duplication of information.²⁴ Although the Bioterrorism Act gives FDA discretion in terms of the timing for submission of prior notification, the Act strictly prescribes the requirements for prior notification. Nothing in section 307 or elsewhere in the Bioterrorism Act gives FDA authority to waive any prior notice requirements based on duplicative submissions to other agencies.

If FDA were to allow notice to other agencies in lieu of notice to FDA, there is no guarantee that FDA would receive the information in a timely manner to determine whether a particular shipment should be inspected. Moreover, the scope of information submitted to U.S. Customs may be different and have a different purpose than that required by the prior notice provisions. As FDA has observed in the context of the definition of “country of origin,” the “U.S. Customs term primarily serves tariff, quota, and other trade purposes; it does not provide information needed for the evaluations that Congress has directed FDA to make under the

²³ 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. The GAO, in a report issued in 2001, has identified other deficiencies in FDA’s efforts to assure the safety of imported seafood. See GAO, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*, at pp. 23-24.

²⁴ 68 Fed. Reg. at 5434.

Bioterrorism Act . . .²⁵

Moreover, the fact that FDA intends to establish an electronic prior notice system should significantly reduce the burden on submitters. FDA has indicated that it plans to develop its Prior Notice System to allow submitters to automatically repeat information already entered in the submission where appropriate. In addition, prior notices for shipments consisting of different kinds of food products may all be contained in one submission.²⁶

4. *Countries of intermediate destination should be included in definition of "country from which the article of food was shipped"*

The prior notice provisions of the Bioterrorism Act require that the notice include, among other things, information on the "country from which the article is shipped."²⁷ FDA has defined this term to be the "country in which the article of food was loaded onto the conveyance that brings it to the United States," but has requested comment on whether this term should include the countries of intermediate destination.²⁸ The definition should include countries of intermediate destination as part of the definition.

One of the articulated goals of the Bioterrorism Act in general and the prior notice provisions in particular is to facilitate product tracking. As the agency explained, the information required in the prior notice would "assist FDA and other authorities in determining the source and cause of problems and in communicating with affected firms."²⁹ Although the country of

²⁵ 68 Fed. Reg. at 5431.

²⁶ 68 Fed. Reg. at 5435.

²⁷ Bioterrorism Act, section 307(a).

²⁸ Proposed rule, § 1.277(c)(2), 68 Fed. Reg. at 5430.

²⁹ 68 Fed. Reg. at 5429.

origin must be identified as part of the notice, FDA-regulated foods may be shipped to several other countries for purposes of processing or packaging. Under the registration provisions of the Act, a foreign facility that conducts a significant activity with respect to food is required to register. Unless intermediate destinations are included as part of the notice requirement, a facility could ship food products to another country for further processing but FDA would lack information on the country in which that additional step was taken – even though the facility in the second country would be required to register.

Even if a food product is merely shipped through another country without further manufacturing or processing, the potential for tampering still exists. Without information on every intermediate country, FDA would lack the ability to trace food for potential contamination back through the distribution chain. Accordingly, the definition should be expanded to include intermediate countries.

Conclusion

As long as the American food supply remains vulnerable to terrorist attack, the agencies responsible for protecting the food supply must have the best tools available to identify and respond to any actual or perceived threat. The prior notice provision of the Act gives FDA broad authority to obtain crucial information concerning a food product before it arrives at the U.S. borders. In the absence of adequate notice, the agency simply would not have sufficient time to adequately marshal and deploy its inspection resources. Accordingly, we urge FDA to maintain the time limits for submission of prior notice and amendment as set forth in the proposed rule.

Respectfully submitted,

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April 2, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
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Dear Sir or Madam:

Enclosed please find the original and two copies of CSPI's comments on the Proposed Regulations to Implement Section 305 (Registration) of the Bioterrorism Act. Please file these comments under Docket No. 02N-0276.

In addition, enclosed please find the original and two copies of CSPI's comments on the Proposed Regulations to Implement Section 307 (Prior Notice of Imported Food) of the Bioterrorism Act. Please file these comments under Docket No. 02N-0278.

Please note that we have also submitted these comments electronically. Thank you very much.

Sincerely,



Karen Egbert
Senior Staff Attorney, Food Safety