

2316 '03 FEB 23 AD 52

December 17, 2003

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 Registration of Food  
Facilities Under the Public Health Security and Bioterrorism  
Preparedness and Response Act of 2002,  
Docket No. 02N-0276, 68 Fed. Reg. 58,894 (Oct. 10, 2003)**

Dear Docket Management:

The Food and Drug Administration (FDA) has published an interim final rule implementing section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), which requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with the FDA.<sup>1</sup> The rule is designed to give the FDA information about food facilities that can assist the agency in several ways, including determining the source and cause of an outbreak of foodborne illness, identifying facilities that might have received contaminated products so that they might be more quickly notified, and facilitating quicker product recalls.<sup>2</sup> In addition, information provided in the registration may assist FDA in screening food imports more carefully and better focus the agency's inspection resources.

---

<sup>1</sup> 68 Fed. Reg. 58,894 (Oct. 10, 2003).

<sup>2</sup> 68 Fed. Reg. at 58,895.

In general, the interim final rule creates a registration system that will help FDA to meet these goals. However, we believe that the rule could be strengthened in the ways set forth below.

***1. The time period for reporting changes in registration information should be shortened.***

The interim final rule requires both domestic and foreign facilities to provide certain mandatory information in their registration. Mandatory information includes, among other things, the name, address and phone number of the facility; an emergency contact phone number for a domestic facility and, for a foreign facility, an emergency contact phone number of its U.S. agent; all trade names the facility uses; and applicable food product categories, unless the facility checks either the “most/all human food product categories” box or produces none of the food product categories.<sup>3</sup> Although the proposed rule would have required registrants to provide updated information within 30 days of any change to previously submitted mandatory information, the interim final rule provides that such information must be updated within 60 calendar days of any change.<sup>4</sup>

FDA lengthened the time for providing changes in mandatory information based on industry comments that the 30-day period would be too burdensome. As its rationale, FDA has stated that the new time frame “strikes a balance between the commenters concern and FDA’s requirement under the Bioterrorism Act to keep [its] database current.”<sup>5</sup> FDA also noted that because facilities have the option of specifying the “most/all” food product categories in the food product section of the registration, it would help decrease the number of updates that facilities

---

<sup>3</sup> 21 C.F.R. § 1.232. Foreign facilities must include the name of an emergency contact phone number of its U.S. agent if there is no other emergency contact designated under section 1.233(c), which sets forth optional information.

<sup>4</sup> 21 C.F.R. §1.234(a)

<sup>5</sup> 68 Fed. Reg. at 58,92.

would have to provide to FDA as they process different types of food.

The 60-day notice of changes is unwarranted. First, there is an increased burden only if a facility must update its information frequently. FDA has estimated that large manufacturing/processing facilities would have to submit two updates per year with a 60-day update period, rather than 3 times per year with a 30-day update period. For other facilities, FDA estimates that 50% of facilities would have to update each year with a 30-day update and every 2 years with a 60-day requirement.<sup>6</sup> FDA has estimated that on average 55% of facilities would have to submit updates each year.

At the same time, however, FDA stated that it believes that its estimate of frequency of updates is overestimated since it is based on changes in both optional and mandatory information, and that optional information is not required to be updated.<sup>7</sup> In addition, FDA has estimated that, once a facility has registered, an updated response would only take one hour.<sup>8</sup> The burden is further minimized since facilities may provide updated info either electronically, CD-ROM, or by fax.

Third, FDA has retained the “most/all” product category information. As a result, the likelihood that facilities will have to frequently report changes in product processing/manufacturing information is minimized, thus reducing the burden of updating such information.

---

<sup>6</sup> 68 Fed. Reg. at 58,942.

<sup>7</sup> 68 Fed. Reg. at 58,942.

<sup>8</sup> 68 Fed. Reg. at 58,958, at table 19.

The ability of the FDA to respond quickly and notify potentially affected facilities in the event of an intentional terrorist attack, real or threatened, far exceeds the burden imposed on facilities to update their contact information more frequently. The FDA has explained that “with emergency contact information and product categories, FDA can quickly call or e-mail the emergency contact at both domestic and foreign facilities that may be targeted by a specific food threat. If FDA suspects a particular product is at risk, we can quickly identify which facilities to contact. This quick communication will allow facilities to respond quickly to a threat and possibly limit the effect of a deliberate strike on the food supply, as well as public health emergencies due to accidental contamination of food.”<sup>9</sup>

However, if there is a potential or actual bioterrorist threat, the FDA may lack essential emergency contact information if it has changed over the past two months. At a minimum, facilities should be required to update their emergency contact information earlier than 60 days following any change.

Quite simply, requiring a facility to provide updated emergency contact information on a shorter schedule does not impose any increased burden on facilities. Indeed, by extending the period during which the FDA may be relying on inaccurate information, the agency has agreed to shoulder the much larger burden of trying to respond to an intentional food attack with insufficient or out-of-date information.

---

<sup>9</sup> 68 Fed. Reg. at 58,952.

## **2. The FDA should clarify the “most/all” food product categories**

The interim final rule requires registrants to provide information on applicable food product categories, unless the registrant checks either “most/all” or none of the above.<sup>10</sup>

According to FDA, “[f]ood product categories are necessary for FDA to communicate directly with subgroups of facilities and to help verify prior notices from facilities that are subject to both registration and the prior notice requirements.”<sup>11</sup> FDA explained that this option would apply mostly to facilities that handle a large variety of foods, such as warehouses. However, to ensure that FDA’s ability to communicate with appropriate subgroups of facilities in the event of a terrorist threat is not compromised, FDA should clarify, either through guidance or an amended rule, the use of the “most/all” product category. Specifically, the agency should provide some parameters for checking this box rather than leaving it solely to discretion of facility owner operator. This should not be difficult since the FDA has stated that ‘most facilities are small and do not produce a large number of products.’<sup>12</sup>

## **3. The FDA Should Clarify That It Will Cancel Registrations That Contain False or Misleading Information**

In the interim final rule, the FDA identifies two circumstances under which it will cancel a registration: (1) where the agency independently verifies that a facility has gone out of business or is under new ownership, and a new registration has not been filed, and (2) if FDA establishes that the submitted registration is for a facility that does not exist.<sup>13</sup>

---

<sup>10</sup> 9 C.F.R. § 1.232(g).

<sup>11</sup> 68 Fed. Reg. at 58,941.

<sup>12</sup> 68 Fed. Reg. at 58,941

<sup>13</sup> 68 Fed. Reg. at 58,929; 9 C.F.R. § 1.241.

Although a failure to update mandatory information is a “prohibited act,” even repeated violations of this requirement do not appear to provide grounds for FDA to cancel a registration. In addition, under the interim final rule, FDA would not cancel a registration even if it had information that the registration had been falsified. FDA should amend the rule to clarify that it may also cancel a registration where the agency has information demonstrating that a registration has been falsified or where there have been repeated violations of the requirement to update required information.

### *Conclusion*

Registration of food facilities helps create an information trail that will enable FDA to respond quickly in the event of a threatened or actual bioterrorist attack on the U.S. food supply. The registration system could be considerably strengthened if FDA would amend the rule to provide that facilities must provide updated mandatory information within 30, rather than 60 days. In addition, FDA should further clarify the circumstances under which it will cancel a registration, as well as when facilities may check the “most/all” product category box in their registration.

Respectfully submitted,



Karen L. Egbert  
Senior Food Safety Attorney

Caroline Smith DeWaal  
Director, Food Safety Program

December 17, 2003

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

To Whom It May Concern:

Enclosed are comments submitted by the Center for Science in the Public Interest (CSPI) regarding dockets 02N-0278 and 02N-0276, the interim final rule to implement prior notice of imported food and registration of food facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. CSPI greatly appreciates the opportunity to submit these comments.

Sincerely,

Stephen Watkins  
Program on Food Safety  
Center for Science in the Public Interest