

March 3, 2003

Office of Information and Regulatory Affairs  
Office of Management and Budget  
New Executive Office Bldg.  
725 17th Street NW, Room 10235  
Washington, DC 20503  
Docket No. [02N-0276]  
Attn: Stuart Shapiro, Desk Officer for FDA

Dear Mr. Shapiro:

Founded in 1919, the National Restaurant Association is the leading trade association for the restaurant industry. Representing more than 60,000 members and over 300,000 restaurant outlets in 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands, the National Restaurant Association has always supported government security enhancement of the nation's food supply. The restaurant industry has invested billions of dollars in the last two years to improve food security and food safety. Our efforts have clearly made a difference in protecting our nation's food supply.

We have a direct and vested interest in the proposed rules regarding the Registration of Food Facilities which were released in February 2003 and wish to submit formal written comments for the record concerning the information collection provisions of Docket No. 02N-0276, Federal Registrar, Volume 68, Number 22, February 03, 2003, pages 5414 -5416. We appreciate the opportunity to comment on the newly released FDA registration guidance and are encouraged that the Agency has requested input for the restaurant industry and others regarding their food security recommendations for the food industry from farm-to-table.

The restaurant industry has a long standing commitment to food safety and food security to protect our customers and our industry. The safety and security of the food supply, our customers and our employees is a top priority, and has been underscored by the September 11th attacks. We fully support the need and intent of the 2002 Bioterrorism Act, and we commend the Agency for attempting the very difficult task of developing registration guidelines for the multiple diverse food industry segments. However, at this critical time the full impact on business and international trade must be fully understood and considered. We are concerned that the proposed FDA registration rules lack real world international business input and may inadvertently negatively impact international trade. If even a small percentage of imported foods are delayed or removed from international trade, the cost implications for small and chain restaurants could be immediate and dramatic.

The FDA has requested specific comments to questions; we have provided detailed responses to the specific questions below.

## ***1. Background***

The Bioterrorism Act contains a provision requiring the Secretary to issue a regulation requiring that domestic and foreign facilities that manufacture/process, pack, or hold food intended for consumption in the United States register with FDA by December 12, 2003. The Bioterrorism Act defines foreign facilities as those that manufacture/process, pack, or hold food for export to the United States without further processing or packaging outside the United States before export. Information FDA proposes to require on the form includes the name and full address of the facility; emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available) and e-mail address; all trade names the facility uses; general food product categories under Sec. 170.3; and a certification statement that includes the name, title/position, and phone number (e-mail address and fax number if available) of the registrant.

Additionally, under the proposed rule, facilities would be encouraged to submit their preferred mailing address; type of activity conducted at the facility; food categories not included under Sec. 170.3, but which are helpful to FDA for responding to an incident; type of storage, if the facility is solely a warehouse/holding facility, and approximate dates of operation if the facility's business is seasonal. Under the proposed rule, facilities would also be required to submit timely updates when any information on their registration forms changes, including cancellation of the registration on a separate form.

The registration requirement applies to “facilities” as that term is defined in the statute and further explained by the legislative history. Specifically, “facility” includes any factory, warehouse, or establishment that manufactures, processes, packs or holds food, but does not include farms, restaurants, other retail food establishments, certain nonprofit food establishments, or fishing vessels. 21 U.S.C. 9 415(b).

When FDA receives the registration, FDA is required to notify the registrant that the registration was received and to assign a registration number to each facility. The Agency is further required to compile and maintain an up-to-date list of facilities that are registered under Section 415. The list and registration documents are not subject to disclosure under the Freedom of Information Act, nor are any information derived from the list or registration documents to the extent that such derivative information would disclose the identity or location of a specific registered person. See 21 U.S.C. 9 415(a)(4).

***2. Is the proposed collection of information necessary for the proper performance of FDA's function including whether the information would have practical utility?***

**The FDA should request only information necessary for oversight:**

The information FDA is requiring on the form is somewhat overly precise, and may go beyond what is mandated by the statute. While the name and full address of the facility; emergency contact information, and trade names are needed, much of the information beyond that will become inaccurate and will create unnecessary technical violations of the Act. Because of the international scope of the proposal, the amount of information required or requested, translation and the need for timely information updates, creates a real potential for the FDA registration database system to become clogged, resulting in adverse consequences for domestic commerce and international trade.

**The proposed means of registration should be expanded:**

The proposed registration process has clearly not fully considered the costs and difficulties electronic registration poses to small international suppliers in remote areas of the world. The statute did not prescribe a specific process by which FDA should implement the registration requirement for facilities; instead it left the process and development phase to the Agency's discretion. Although primarily a logistical issue for the FDA to solve, we recommend that any process must allow for maximum flexibility to reflect the varied and complex nature of the international food industry. It is expected that registrations will be submitted from almost every area of the globe. Specifically, FDA should permit registrations to be filed with the Agency in almost any form to include: electronic, telephone, fax, mail or via paper. We expect that many in the international food industry will prefer electronic filing, but that some, particularly those small businesses in remote areas may not yet have that capability to perform electronic filing.

**The electronic registration system should be absolutely secure:**

The reliability and security of the newly proposed electronic registration system will be critical to international trade and to the free flow of foods. A new vulnerable terrorist target must not be created by FDA inattention or inexperience in this area. The economic survival of many restaurants today depends upon the reliable and cost effective flow of food products from far flung international suppliers. We believe that the FDA has not fully considered the costs associated with disruption of their newly developed electronic registration system. To the extent that FDA establishes an electronic registration system, the Agency must consider the need for absolute redundancy and state of the art methods to protect the system's integrity. The system must be easy to use, in every world language, safe and must incorporate multiple safeguards to prevent the system from being used fraudulently or shut down. Without multiple and overlapping safeguards, and absolute redundancy persons intent on disrupting the international food supply might be able to enter fraudulent facility information for a targeted company or completely stop world food trade.

**The electronic registration system must be totally reliable and easy to use:**

It is expected that the FDA will develop an electronic registration system that will be able to incorporate suitable safeguards for the system and still be easy to use. In that eventuality registration numbers should be assigned to facilities promptly; an immediate confirmation number must be generated electronically, and a return letter with a registration number should be mailed as quickly as possible to those who choose to register through first class mail or other means. The FDA should permit multiple facilities that are owned by a common entity to register individually or centrally, through the entity of common ownership.

3. ***Is the FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used accurate?***

**The FDA estimate of burden appears to be low:**

The estimate of the burden of the proposed collection of information which FDA has documented seems to be consistently under what even our best industry estimate would be. The FDA appears to have underestimated the complexity of translation to all world languages, the registration process itself, the number of facilities that would be required to register, and the annual reporting burden on facilities and parent firms. For example, FDA makes the assumption that those individuals, who do not understand English and do not have internet access, can meet the specific requirements for registration in approximately 12 hours. We have undertaken the task as native English speakers, and internet access and find that the task as taken us over 20 hours of staff time to read, comprehend, gather the necessary data and complete the form. That is ten times the FDA estimated time and almost double the time for a non-English speaking, non-internet user. How can one assume that non-English speaking individuals can meet the registration requirements in the time estimated by FDA, without FDA being knowledgeable of these foreign facilities day to day operations? Many foreign facilities do not even have specific addresses, plant managers or advanced technology

to communicate and rely solely on the simplest of methods to do business. Again, how can these types of facilities been included in FDA's estimations of the total numbers and burden of time needed. Based upon our clearly unscientific analysis we would estimate that the burden on international registrants would be at least double and the time for domestic registrants should be increased by a factor of ten.

**Many more facilities will need to be registered than FDA estimates:**

We truly believe that the facilities needing to meet the registration requirement is at least double of the estimated number provided by FDA. For instance, FDA in particular has underestimated the number of international transportation/shipping facilities, which would be required to register since they ultimately hold some food in transit, some examples to consider are FedEx, UPS, every international airline and the United States Postal Service. These types of transit companies may not have the specific detailed or the required information requested by FDA to properly register the various unknown food products they routinely transport.

**4. *What ways can minimize the burden of the collection of information on respondents?***

**The FDA should consider exemptions and eliminations of small quantities of food:**

The burden of registration for respondents can be minimized by FDA collection only the information that is absolutely necessary, exempting small quantities of food shipped on common carriers, and facilitating registration by any means of effective communication. Additionally, we request that the FDA look to the specific exemptions granted by Congress. Congress was precise in providing an exemption from registration to restaurants. Unfortunately, although this proposed document discusses that restaurants are exempt from registration; the document continues to define when it is necessary for food facilities to register and provides an opportunity for the foreign facilities to designate a U.S. agent for registration. This language alone contradicts the exemption in many circumstances within the restaurant industry. The intention of Congress was to exempt restaurants, and then language must be incorporated to state that foreign facilities should not have the ability to designate as a U.S. agent for registration. This would minimize the burden of collection of information placed upon the restaurant industry.

**The FDA registration should be a one time only process:**

The registration process should be a one time only process. The legislative history regarding registration clearly expresses the intent of Congress that facilities perform a one-time (rather than an annual) registration and that such registration should serve to fulfill the statutory registration requirement. See 148 Cong. Rec. at H2726. Accordingly, FDA's regulations should only require that facilities subject to the registration requirement submit a single, one-time registration.

**The ability to use a set time of 6-12 months for compliance with “timely notification”:**

The statute was equally clear, that the registrant must notify FDA “in a timely manner of changes” to the information contained in the registration. It would be expected that such changes would include changes in the facility’s ownership or other significant changes in the products distributed, manufactured, handled or processed at the facility. Although no clear precedent exists for timely notification in the food context, FDA should look to existing drug regulations for guidance. Specifically, FDA drug listings must be updated every June or December if a new drug is manufactured or discontinued in the facility during the previous six months. See 21 C.F.R., Subpart C, e.g., 0 207.30. We believe that the established FDA rules for drugs should be used as a guide for food. A time component of twelve to six months for changes should be adequate in the food context, as well. Moreover, temporary changes in the general food categories held or processed at the facility should not require additional notification to FDA.

**The FDA should allow trade associations, commodity groups or parent companies the ability to register for facilities within their organizations:**

The FDA should allow companies the flexibility to submit registrations and updates for all the company facilities from a single corporate headquarters. Many small food suppliers may not have access to electronic registration systems on site. The FDA should consider allowing company headquarters, trade associations or commodity groups to register the facilities on our members’ behalf. Because each component member must identify their facilities for purposes of membership, third party inspections, financial audit or quality control many companies and trade associations already have well developed data bases throughout the United States and some foreign countries. Flexibility in the registration process is also needed because many larger companies have developed positions at their corporate headquarters that are responsible for the licensing and permitting required at the state and local levels. By providing the flexibility to manage the FDA registration process as appropriate for their company, costs of compliance, the burdens on business will be diminished and compliance should increase.

National Restaurant Association

Page 7

Docket No. [02N-0276]

In closing, the National restaurant Association strongly believes that sharing information and expertise with all food industry partners is crucial to the food industry's preparedness for potential food-contamination events. As such, The National Restaurant Association would like to thank you for this opportunity to submit these comments and thanks FDA for soliciting the opinion of the restaurant industry. Please feel free to call our Health and Safety Regulatory Affairs Department with any questions you may have regarding this issue, at (202) 331-5900.

Sincerely,

Steven C. Anderson  
President and Chief Executive Officer

Cc: Steven F. Grover, Vice President, Health and Safety Regulatory Affairs  
Lee Culpepper, Senior Vice President of Government Affairs and Public Policy  
Allison Whitesides, Legislative Representative