



August 26, 2002

Joseph A. Levitt
Director, Center for Food Safety
and Applied Nutrition
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**Re: Public Health Security and Bioterrorism Preparedness and Response Act of
2002 Rulemaking Comments (Docket No. 02N-0277)**

Dear Director Levitt:

These comments relating to FDA's rulemaking pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Act") are submitted on behalf of the National Association of Convenience Stores ("NACS"). Founded in 1961, NACS is a non-profit trade association representing more than 2,000 retail and 1,700 supplier company members in the United States and abroad. There are over 124,000 convenience stores in the United States that provide consumers with convenient locations to quickly purchase a wide array of retail items including many foods and beverages. In addition, many convenience stores are small businesses that operate with tight profit margins on many of the products they sell -- in fact, over 70 percent of NACS members own ten stores or less. Increased compliance costs may erode profit margins and put significant pressure on convenience stores.

NACS members are supportive of efforts to improve bioterrorism security and are encouraged by some of FDA's positions. For example, we were pleased to hear FDA agree, during a stakeholder meeting held August 1, 2002, that it will not require retail establishments to collect and maintain information regarding individual consumers that buy their products. This is clearly the most sensible approach and avoids requirements that could prove to be extremely problematic both for retailers and consumers. We also were pleased to learn at the meeting that FDA staff is open to allowing flexibility so that businesses can comply with record-keeping requirements by maintaining records in electronic format. This is very helpful for NACS members who often do not have the storage space to keep voluminous paper records.

NACS is very concerned about the potential administrative burdens that could be imposed by FDA's regulations. In particular, the record-keeping provisions of section 306 of the Act could impose significant costs on small businesses unless the implementing regulations take

02N-0277

C 4

August 26, 2002

Page 2

a reasonable approach. In order to keep the burden of the record-keeping requirements reasonable, we would recommend the following:

- Small Business Exemption. We recommend that small businesses (as defined by the U.S. Small Business Administration) be given an exemption from FDA's record-keeping regulations. Section 306 of the Act directs the Secretary to consider the size of a business in promulgating regulations. A small business exemption is an important way to take into account business size.
- Limit Regulations to Food Businesses. We would also hope that the Administration would consider the size of the food sales and service component of a company as well. While food sales and service makes up an average 11.4 percent of convenience store sales nationally in 2001, many individual companies' food sales and service were a far smaller percentage of their business. Convenience stores sell many additional items, and while the food sales and service component is growing, it still consists of a small portion of the sales within this industry. NACS suggests that the Administration limit the regulations to those companies for which food sales and service comprise greater than 10 percent of their sales.
- Properly Define Restaurants. The Bioterrorism Security Act included an exception to its record-keeping requirements for restaurants, but did not define the term. Many convenience stores sell an array of prepared foods on their premises. The record-keeping requirements of the Act raise the same concerns for these convenience stores as they do for businesses that more clearly deem themselves to be restaurants. We believe the intent of the Act would be furthered if a restaurant were defined to be any business that prepares food at the same location where such food is sold to individual consumers, and where such food may be eaten. This definition would give an exemption to convenience stores that engage in the same food preparation processes (and have the same difficulties with record-keeping when many ingredients are combined in a prepared food item) as restaurants, while preserving the record-keeping requirement for stores that only sell packaged foods.
- Required Information. Currently, NACS members maintain contact information regarding their suppliers of food items including the names of the supplier companies, individual contacts, phone numbers and addresses. This information should be sufficient for FDA to satisfy its duties under the Act. This information would allow FDA to trace food back to the next step in the chain – suppliers of convenience stores. FDA regulations should require only this information and require that retailers make the information available upon a reasonable request from FDA.

August 26, 2002

Page 3

- Record Maintenance. FDA should give businesses the flexibility they need to store records in the manner they find most efficient. Whether records are kept in hard copy or electronically, on-site or off-site should not be FDA's concern. Instead, FDA should require that businesses have the ability to provide it with the required documentation within a reasonable time following a request.
- Limit the Records to Certain Types of Foods. Some foods may not cause a concern regarding potential bioterrorism because of packaging, transportation practices or other characteristics. NACS urges FDA to identify any such foods and exclude them from its requirements.
- Time Period for Record Maintenance. The Act gives FDA the authority to require that businesses maintain the required records for two years. This is longer than necessary to achieve the Act's purposes. Incidents of bioterrorism will manifest themselves much sooner than two years after the incident. Many retail businesses including convenience stores sell a large volume of many different kinds of food items. Particularly if the information required to be kept is more extensive than we have recommended, two years' worth of records may be quite voluminous for many businesses. NACS recommends that FDA require that records be maintained for one year unless FDA determines that there is a specific need for certain records (based on geography, type of food item or other characteristic) to be kept for a longer period of time.

NACS believes that these recommendations will help make FDA's regulations effective while avoiding potential harms to NACS members. Thank you for your consideration.

Sincerely,



Adam Witkonis
Manager, Government Relations