



**SNACK FOOD
ASSOCIATION**
An International Trade Association

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VIA Electronic Mail and by Hand

July 7, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0277

**RE: Implementing Regulations of PL 107-I 88:
Docket No. 02N-0277, Section 306
(Maintenance and Inspection of Records for Foods)**

Dear Sir or Madam:

The Snack Food Association (SFA) is an international trade association representing snack food manufacturers and suppliers. SFA business membership includes, but is not limited to, manufacturers of potato chips, tortilla chips, crackers, corn chips, pretzels, popcorn, extruded snacks, meat snacks, pork rinds, snack nuts, party mix, fruit snacks, cereal snacks, snack bars, and various other snacks. Retail sales of snack foods in the U.S. total more than \$30 billion annually.

SFA strongly supports a rigorous food security system to protect the nation's food supply. Last year during Congressional debate on food security, SFA supported the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. However, we are concerned about some provisions of this draft implementing regulation published in the Federal Register of May 9, 2003. Specifically, SFA appreciates the opportunity to respond to the request for comments on Section 306: Bioterrorism Preparedness; Maintenance and Inspection of Records for Foods.

We would ask you to take the following points into consideration and make corresponding changes prior to finalization of this draft regulation.

What Records Must Be Kept. A serious concern is the maintenance of lot-by-lot distribution and receipt records from farm to retail. This proposal should not be mandatory as it would require expensive new tracking systems without improving food security protections. Instead, FDA should rely on existing records, including a

company's recall plans. Systems to track and isolate product already exist with product recall procedures. Relatedly, one-up and one-back tracking for intra-company transfers would be burdensome and unnecessary. In most cases, companies already keep such records under existing systems.

The emergency contact information required in the proposal should offer the facility more flexibility in expressing how the FDA can best contact it in the case of an emergency. Requiring an individual's name, e-mail, and telephone number will not account for business travel, schedule conflicts and changes in role responsibility. The facility should supply emergency contact information that allows the facility to react as quickly as possible in an emergency situation. Moreover, the identity of a "responsible individual" is redundant of the "emergency contact information" that must be identified through the facility registration requirement.

Transporter Requirements. Those who transport food would also have to keep records under the proposal similar to the requirements of the immediate previous source and immediate subsequent recipients. The preamble states that the "individual responsible" should be the person who is responsible for that vehicle and the food being transported. The "individual responsible" for practical purposes should not be the operator of the conveyance. Rather, it should be someone within the corporation who has overall responsibility for the vehicle and the food being transported. As an example, snack food distribution depends heavily on direct store delivery by route salespeople. The records requirement would be unnecessary for route salespeople as complex distribution systems already exist to track sales and distribution of product. A snack company's sales and distribution records would contain most, if not all, of the information required in the proposed rule.

Availability Requirements. Requiring all records to be available within 4 - 8 hours is not reasonable. Instead, the FDA should be focused on the information needed for the investigation—not the actual records. Again, systems to track and isolate product already exist with product recall procedures. These procedures are able to track raw materials through finished product delivery. This information can generally be provided with 24 hours of notice. Thus, SFA suggests the Agency limit its proposal to the information needed and set the time required for 24 to 48 hours.

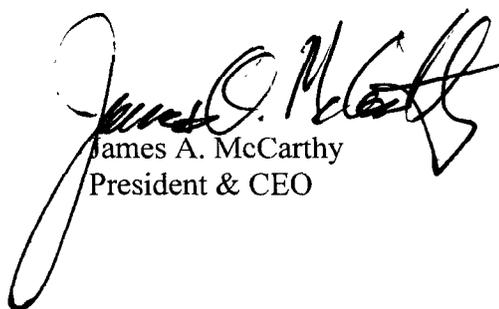
Consistent with the record keeping provision of the Bioterrorism Act, the proposal includes a provision that would specifically exclude recipes (i.e., the quantitative formula used in manufacturing food products), financial data, pricing data, personnel data, research data, and sales data from the information required by the regulation. SFA applauds this commitment to confidentiality. We would also urge FDA to use its existing authority to quickly develop guidance (as opposed to rule promulgation) establishing clear procedures for written demands for records and protection of records once in FDA's possession. FDA is urged to have these procedures in place to appropriately request and handle confidential records once this new records authority becomes available to FDA.

Retention Requirements. The proposal requires records for product with a shelf life of longer than 7 days to be maintained for 2 years. Many products are labeled with an expiration or "sell by" date for product quality reasons. Records should be maintained for 6 months beyond the expiration or "sell by" date or 2 years, whichever is shorter.

We appreciate the opportunity to comment on this proposed regulation and are committed to working with FDA and all government agencies to protect the food supply.

If you have any questions, please do not hesitate to contact us.

Respectfully submitted,



James A. McCarthy
President & CEO