SERVING MEMBERS FOR SIXTY YEARS

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July 8, 2003

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

Re: Docket No. 02N-0277; Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) is pleased to provide comments with regard to FDA's proposed rulemaking to implement the records maintenance provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. No. 107-188) (the Bioterrorism Act). AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 520 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than $60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationally and internationally.

The Bioterrorism Act calls upon FDA to establish requirements for the establishment and maintenance (for a period not to exceed two years) of certain records by those who manufacture, process, pack, transport, distribute, receive, hold or import food. The statute specifically limits the scope of the records that must be maintained to those that are needed "to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious health consequences or death."

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1. Food Industry and Agency Have the Same Goals

AFFI applauds the agency's tremendous effort in preparing a thoughtful proposed rule that, for the most part, remains focused on the extraordinary circumstances that led to its creation. September 11, 2001, represented a horrendous, unprecedented attack on our safety and security. In response, the possibility of future terrorist attacks on all aspects of our biosecurity, including the food supply, had to be evaluated and addressed. The Bioterrorism Act, including its records establishment and maintenance provision, was the result.

In light of this background, the records provisions of the Act are properly regarded as a tool to assist the agency in combatting malicious attacks on the safety of the U.S. food supply. AFFI is pleased that the agency has proposed a rule that, in general, appears to be designed to work with the food industry as efficiently and effectively as possible to address credible threats without imposing undue burdens. Industry shares FDA's interest in thwarting threats to food safety and should be treated as the agency's ally in the war on bioterrorism.

2. Use of Existing Records and Recordkeeping Systems

AFFI applauds FDA's tentative decision not to mandate any particular form for records maintained under the proposed rule, or the systems in which those records are kept. As AFFI noted in its initial comments to the agency, companies already keep a substantial quantity of business records, as well as records designed to satisfy other regulatory requirements. Allowing companies to leverage the information in these records to meet the "one up/one back" information requirements in the Act avoids additional, unnecessary costs for industry, without compromising the agency's public health mission.

3. Information Requirements

a. "Reasonably Available"

AFFI also applauds FDA's tentative decision to require that records kept under the proposal identify the specific source of an ingredient in a finished product only when that information is "reasonably available." Given the widespread practice of commingling commodity ingredients (e.g., corn syrup in tanks, and flour silos, etc.), identifying a single source/supplier for all ingredients in a finished food often is not possible.

The "reasonably available" language of the proposed rule, together with the agency's preamble discussion and example of a cookie manufacturer that commingles flour from several different suppliers, recognize this "real world" constraint. AFFI fully supports the agency's position that, in these and similar circumstances, a company should have records identifying all possible sources of the commingled raw material but would not be expected or required to identify a single supplier.

AFFI recognizes that what is "reasonably available" is a fact specific inquiry that will vary case-by-case. Nevertheless, the Institute believes both industry and agency personnel would benefit from additional guidance with respect to that which the agency would and would not consider "reasonably available" in various circumstances. The agency might consider providing this guidance through hypothetical case studies. The following description of some of the processing challenges faced by frozen produce processors might help form the basis of such hypotheticals.

For example, frozen fruit and vegetable processors generally process incoming loads as soon as they reach the facility. Thus, a processor of frozen green beans could be reasonably certain that Truckload X of green beans from Farm Y was processed into tote-bins 1-10 on a specific date. Based on that information, the company might also be reasonably certain that Farm Y product was packaged into Blend Z on a specific date.

However, given the perishable nature of the raw ingredients, changes in the harvesting and processing environment occur often, diminishing "certainty" about the source of ingredients in finished products. For example, mechanical breakdown of green bean blanching or sorting operations may necessitate commingling of perishable lots stored or transported to another facility for processing. Mechanical harvesting problems can delay shipment to the plant, necessitating priority processing that similarly may complicate efforts to pinpoint an individual producer in the event of a traceback. Finally, in grading and sizing cherries and other commodities, processors may separate incoming raw product into several receivers in which similar grade commodities are stored. The processor could not then pinpoint individual producers.

These examples illustrate the dynamic nature of the processing environment and, consequently, the complexity of managing records in the field. AFFI urges the agency to keep these and similar scenarios in mind in helping guide industry and agency personnel as to the information is considered "reasonably available."

b. Lot and Code Numbers

Although the proposed rule recognizes the "real world" practice of commingling bulk ingredients, it fails to recognize another widespread, equally significant commercial practice -- namely, retail stocking without recording lot or code numbers. In other words, it is common practice throughout the food industry to track food by lot or code number as it moves through warehouses in the distribution chain. Once food is removed from warehouses for individual retail store delivery, however, lot or code numbers are not tracked. This is true whether the food is removed from the warehouse and stocked on the retail shelf by the manufacturer's route sales delivery person (so-called "direct store delivery" or DSD) or by the retailer itself.

Nevertheless, the proposed rule seems to require lot or code number tracking all the way to the retail shelf. Specifically, manufacturers and processors' "one up" records, kept in accordance with proposed Section 1.345, would have to include "the lot or code number or other identifier of the food (to the extent this information exists)." Retailers' "one back" records, kept under proposed Section 1.337, would have to include the same information. Yet, for the reasons noted earlier, lot or code number information is not currently tracked to the retail level. Thus, the proposal as written would force companies to add that type of tracking to their business practices -- a fundamental and extremely costly change.

FDA has significantly underestimated the cost impact of this provision of the proposed regulation. By mandating the physical capture and maintenance of the lot and code numbers defined in the proposed regulation at each point of the distribution chain—from field to retail outlet—FDA has added significant time and capital burden to each of the many segments of the food production, procurement, processing, distribution and sales chain without providing any tangible improvement in or protection of the safety of the food supply.

For example, one AFFI member currently is in the process of testing and implementing a bar coding/scanning system to allow digital recording of the lot code number of each case of finished product produced at each of its production facilities. This project will require a capital investment of some $3,000,000 over a three or four year period. The company reports that from both a technical and a financial standpoint, it cannot install/implement this system within a shorter timeframe. Moreover, the company estimates the costs and time frame to capture the product date codes and other pertinent information at the receiving end of its distribution chain would be similar.

The company estimates it will cost $0.03 per product case to comply with the proposed regulations. Overall, the result is a $3,000,000 annual increase in expense. The company also estimates that the same costs would apply to the various common carrier transportation companies it utilizes to transport its products. This increase in costs will be borne by the company. At a minimum, this company estimates the cost to install and implement this system in the next few years will be $12,000,000.

The particular company in this example utilizes direct delivery, with a direct-to-store and a direct-to-consumer division. It has "mini-depots" located throughout the contiguous 48 states, and delivers products from production/distribution facilities directly to the "mini-depots". Manually recording lot codes during delivery/unloading at the "mini-depots" would be extremely inefficient and costly, without significant public health benefit. As stated by an official from the company, " We have an effective recall system, and when faced with a recall, recovery of any/all suspect product is our top priority. We question what efficiencies that would be gained by the proposal to require identification of lot codes."

Moreover, from the "mini-depots," by way of direct delivery, the company transports cases of finished product to retail grocery stores, convenience stores, and consumers' homes. It is unclear how this proposed regulation would apply to these route trucks, i.e., whether they are considered retail outlets or delivery/transportation trucks. Clearly, the burden of recording the lot codes of products loaded onto and off these trucks would be very significant.

As stated previously, the public health benefits of such a costly change are unclear. AFFI questions the agency's implicit assertion that tracking lot and code number information to the retail level will allow it to "target" its communications with the food industry and, presumably, move more quickly and efficiently to protect the public. In the event of a terrorist attack against the food supply, AFFI doubts the agency could or should attempt to identify the specific retail stores that received a given lot or code number of product and limit its recall communications/instructions to those stores and their customers.

AFFI submits that in the event a situation occurs in which food presents a threat of serious adverse health consequences or death, FDA likely will not have the luxury of time to conduct a detailed records review and still communicate with affected parties in a timely manner. Moreover, experience demonstrates that efforts to limit recall communications to specific lot or code numbers simply do not work. Customers routinely return all product, without regard to lot or code number. Indeed, in the event of a terrorist attack against the food supply, this may well be the most appropriate response.

Given the substantial costs associated with lot or code number tracking to the retail level, AFFI urges the agency to modify its proposal to require lot or code numbers in one up/one back records only when that information is reasonably available. The same rationale that underlies the agency's proposal to apply this standard in connection with identification of suppliers of commingled ingredients applies with respect to identification of lot or code numbers at the retail level.

c. Responsible Individual

AFFI also questions the wisdom and utility of the proposed requirement that company records identify a "responsible individual." The proposal does not include a definition for the term -- a gap that is sure to lead to confusion among the regulated industry. Moreover, as others have noted, individuals change jobs within and among companies very often, making it unlikely the "responsible individual" will have responsibility for the food at issue when FDA seeks to effect a traceback subsequent to the creation of the record. In light of these considerations, AFFI recommends that FDA eliminate the requirement that records identify a "responsible individual." FDA will have access to emergency contact information for all registered facilities through the food facility registration process. This information will ensure that the agency has rapid access to a knowledgeable,

"responsible" individual at all registered facilities, expediting any traceback activities.

4. Availability of Records

FDA's proposed requirement that records maintained under the proposal be made available to the agency within four hours of request (or within eight hours, if the request is made on the weekend) is reasonable. Because companies keep many of the records that will be relied on to comply with the rule on paper, however, AFFI asks that the agency clarify certain points in the final rule. Specifically, AFFI requests that the agency make clear that, although companies must make the records available within four hours, the agency does not expect companies to link the sources of each ingredient with every finished lot of product within that timeframe. AFFI asks that FDA acknowledge in the preamble to the final rule that very often more than four hours will be required to review and sort through the records, many of which are kept only on paper, to trace those links.

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AFFI appreciates the opportunity to comment on this important rulemaking and trusts that the agency will take the information provided by it and other stakeholders into account in formulating a final rule that strikes an appropriate balance between public health protection and the costs of compliance. In that regard, AFFI urges the agency to pay particular attention to the costs and benefits of tracking lot and code numbers to the retail level.

Please contact me if AFFI can assist the agency with additional information or perspectives that may be helpful in preparing a final rule.

Sincerely,

Leslie G. Sarasin, CAE
President and Chief Executive Officer