



SERVING MEMBERS FOR SIXTY YEARS

American Frozen Food Institute • 2000 Corporate Ridge, Suite 1000 • McLean, Virginia 22102

Telephone (703) 821-0770 • Fax (703) 821-1350 • E-Mail info@affi.com

<http://www.affi.com> • <http://www.HealthyFood.org>

August 30, 2002

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

Re: Docket No. 02N-0277 (Recordkeeping)

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) is pleased to provide initial comments with regard to FDA's upcoming 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 Act or statute). AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 550 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 million. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationally and internationally.

The 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."

1. Food Industry and Agency Have the Same Goals

In implementing the records maintenance provision of the Act, AFFI urges the agency to keep squarely in focus the extraordinary circumstances that

02N-0277

c9

Dockets Management Branch (HFA-305)

August 30, 2002

Page 2

prompted Congress to adopt it. September 11 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 our food supply, had to be evaluated and addressed. The Act is the result.

In light of this background, the records maintenance provision, like the other food protection provisions of the Act, is properly regarded as a tool to assist the agency in combating malicious attacks on the safety of the U.S. food supply. Thus, the agency's goal in promulgating regulations should be to work with the food industry as efficiently and effectively as possible to address credible threats without imposing undue burdens. In short, 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. Leverage Existing Recordkeeping Systems

Companies already keep extensive records to facilitate product traceback, recalls, etc. FDA should permit companies to rely upon these records, along with whatever additional records, if any, they believe may be necessary, to ensure that the Act's mandate, namely identification of the immediate previous sources and subsequent recipients of food (so-called "one up/one back"), is met.

Because the Act makes failure to keep the records covered by FDA's regulations a prohibited act, companies would have every incentive to review their existing systems and ensure that their records are adequate to accomplish "one up/one back" identification. Failure to do so would subject the company to possible enforcement action by the agency, including criminal penalties.

The one up/one back standard, however, must be interpreted reasonably by the agency, in accordance with the "real world" constraints of our food supply. First, company records should be acceptable to the agency in whatever form they are kept, including electronically, as long as they can be made available to FDA upon request within a reasonable period of time. Second, for purposes of "one back", company records identifying all of its sources (i.e., suppliers, growers) for a particular ingredient in a food should be sufficient. Linking individual suppliers and growers to end products, and maintaining that identification throughout the

processing and distribution chain, simply is not possible given the complex scope and fast pace of our commercial food supply.

For example, food processors commonly store raw materials like corn syrup and flour in tanks and silos. These tanks and silos are not dedicated by supplier but rather are "topped off" as supplies run low, resulting in the routine commingling of raw ingredients from a number of suppliers. Moreover, It is AFFI's understanding that even flour or grain silo crowns do not uniformly dissipate, resulting in uneven distribution of ingredients. Changing this longstanding system to require dedicated supplier storage to facilitate supplier-specific one-back recordkeeping would involve astronomical financial costs and logistical burdens for the entire food industry.

It is important to remember, moreover, that a reasonable approach to "one back identification," like that advocated by AFFI, would in no way undermine the effectiveness of the records maintenance provision. In the event prompt action was ever necessary to protect the public, a food manufacturer could quickly and efficiently identify and recall any products potentially affected by credible threats to the safety of raw materials. Lastly, AFFI believes FDA must fully understand the current industry practices and logistics for managing ingredients prior to making any proposal that would require substantial changes in the current system.

3. Duration of Records Retention

The Act permits FDA to require food companies to maintain one up/one back records for up to two years. AFFI believes the public policy goal behind the records maintenance requirement would be served by a minimum records retention period of two years from date of production. This period would ensure that records are available as long as a food reasonably could be expected to be in the food distribution chain, yet observe the statutory time limit.

* * * * *

In sum, AFFI urges the agency to promulgate a records maintenance rule that incorporates as fully as possible companies' existing recordkeeping systems. Records requirements developed by the agency "from scratch" would only duplicate current records systems at a cost that would far exceed any benefits. A

Dockets Management Branch (HFA-305)

August 30, 2002

Page 4

wealth of information about the food supply already resides in the hands of food manufacturers, distributors, etc. AFFI would be willing to assist the agency in understanding current ingredient logistics management and attempt to arrange for facility visits to further the agency's understanding. AFFI calls upon FDA to leverage this information to the greatest extent possible to advance public health protection against bioterrorism.

Sincerely,

A handwritten signature in cursive script that reads "Leslie G. Sarasin".

Leslie G. Sarasin, CAE

President and Chief Executive Officer