



August 30, 2002

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 02N-0277; Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Section 306 Maintenance and Inspection of Records for Foods: Regulations Concerning Recordkeeping.

Dear Sir or Madam:

The National Food Processors Association (NFPA) appreciates the opportunity to submit comments in anticipation of a proposed rulemaking on the above referenced section of the Public Health Security and Bioterrorism Preparedness and Response Act (Act) concerning the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food. NFPA recognizes that, under the Act, the Secretary is required to issue final regulations addressing Section 306 by December 12, 2003. NFPA is providing these comments to assist FDA in meeting that statutory deadline.

NFPA is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. NFPA members would be affected by the rulemaking that has been mandated under the Act.

General Comments

In developing the applicable regulations, NFPA urges FDA to consider several factors. NFPA believes this provision of the Act does not mandate the creation of new records that must be maintained by regulated businesses. Rather, NFPA

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1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5900

WASHINGTON, DC
DUBLIN, CA
SEATTLE, WA

believes the provision provides that existing records, which are currently used in the course of doing business, can be the records necessary for identifying immediate previous sources and immediate subsequent recipients of food, including its packaging.

Because of the diversity and complexity of the channels of trade for food, food ingredients, and packaging, the diversity in operational characteristics within the food chain, and the differing capacity for recordkeeping and maintenance within the food chain, NFPA recommends that FDA not take a prescriptive, or "one size fits all" regulatory approach. Rather, NFPA urges FDA to use a performance-based regulatory requirement that establishes what information is necessary for identifying immediate previous sources and immediate subsequent recipients of food, including its packaging, and that allows regulated persons the flexibility to use existing records, which could be inspected by FDA, if necessary.

NFPA urges the Agency to provide a description of what it intends to be able to accomplish as a result of the regulation as a means of helping industry evaluate current information systems and identify possible alternatives relevant to identifying immediate previous sources and immediate subsequent recipients. NFPA also recommends that FDA establish a plan and schedule for assessing the implementation of the requirements in order to determine if and what adjustments may be necessary with respect to the requirements in general as well as to the size of regulated companies.

The responsibility of a given person to establish and maintain records is subject to a significant limitation. The Act's legislative history indicates it was and remains Congress' intent that the authority to require the establishment and maintenance of records cannot be applied to activities or transactions to which the business is not a party. NFPA believes FDA should view this expression of Congressional intent to mean that regulated entities should be responsible only for information that identifies the immediate previous sources and immediate subsequent recipients for which existing documentation of business transactions, such as invoices, bills of lading, and purchase orders, are used.

What information is appropriate?

The ability of a given person to identify the exact immediate source of specific food will vary considerably. Factors affecting the specificity of identifying immediate previous sources include the commingling of foods or the manner in which foods and ingredients are handled or held prior to processing, how these foods and ingredients are introduced to the production process, and how foods are stored and distributed. FDA should recognize that in some cases information is available that would narrow the scope of immediate previous sources to a number of potential sources for a specific food, but would not necessarily identify the exact immediate previous sources.

The information required to identify the most likely sources and recipients of a food should be limited. The guidance provided in 21 CFR Part 7 Subpart C, "Recalls (Including Product Corrections) – Guidance on Policy, Procedures, and Industry Responsibilities", describes relevant information that could be required. Under 21 CFR 7.46, the information FDA would seek in the event of a firm initiated recall includes distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts. NFPA believes this is the appropriate information for identification of immediate subsequent recipients and is applicable to identifying immediate previous sources. NFPA does not believe that the transporter of food and its packaging between sources and recipients should be considered the immediate previous source or the immediate subsequent recipient.

What records should be established and maintained?

FDA should not require new, unnecessary, or superfluous records. Existing business records such as invoices, bills of lading, and purchase orders that identify immediate previous sources and immediate subsequent sources of finished goods and components should be accepted as the records for any necessary FDA inspection, under Section 306 of the Act. If such records are not adequate, businesses should have the flexibility to make necessary modifications in available records or establish appropriate records for their particular situation.

Any FDA inspection of records under Section 306 of the Act should be limited to the food where credible threats of serious adverse health consequences or death to humans or animals have been determined. Similarly, businesses should not be required to provide information and/or records that disclose sensitive business information, confidential or trade secret information such as pricing data, sales data (information on the quantity of product received), or product specifications and formulations.

Who should be required to establish and maintain records?

A food processor or manufacturer may conduct multiple functions (transport, hold, receive, import foods) within and among business units of the same company. NFPA believes the establishment and maintenance of records requirement should apply to the company with respect to external sources and recipients, but should not apply to transactions within company sources and recipients.

How FDA should consider the size of a business in promulgating regulations?

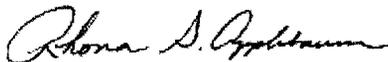
FDA should allow for a phasing-in of the requirements to establish and maintain records based on the size of regulated companies. NFPA recognizes that determining the application of the requirement based on size of companies may be difficult. NFPA suggests FDA seek additional information for making adjustments or modifications to the application of the regulatory requirement, based on business size.

How long should FDA require that records be maintained?

NFPA believes different recordkeeping maintenance periods are justified to accommodate reasonable periods in which foods may be in the channels of trade. However, required maintenance periods should be those that provide a workable means for businesses to manage needed records in a straightforward manner. NFPA recommends a required record maintenance period for perishable and non-perishable foods of one and two years, respectively.

NFPA thanks you for consideration of these comments, anticipates an opportunity to respond to FDA's regulatory proposals, and welcomes the challenge of working with FDA towards a safer and more secure food supply.

Regards,



Rhona S. Applebaum, Ph.D.
Executive Vice President
Scientific & Regulatory Affairs