



NFPA
The Food Safety People

NATIONAL

FOOD

PROCESSORS

ASSOCIATION

July 8, 2003

4303 '03 JUL -8 P2:12

Dockets Management Branch
 (HFA-305)
 Food and Drug Administration
 Room 1061
 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 of 2002. (68 *Federal Register* 25188; May 9, 2003)

John R. Cady
*President and
 Chief Executive Officer*

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits these comments on the proposed regulations to implement the provisions of the Bioterrorism Preparedness and Response Act (hereinafter the "Act") of 2002 related to establishment and maintenance of records. NFPA previously submitted comments on the economic impact of this proposal to the Office of Management and Budget (OMB) and FDA on June 9, 2003 (attached).

1350 I Street, NW
 Suite 300
 Washington, DC 20005
 202-639-5917
 Fax: 202-637-8464

The National Food Processors Association (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. In view of the fact that, as proposed, NFPA members will be significantly impacted by this regulation we have prepared these comments to present our views and recommendations to ensure the intent of Act and the benefit to the public are realized.

WASHINGTON, DC
 DUBLIN, CA
 SEATTLE, WA

NFPA commends FDA for attempting to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) within such a short time frame. We encourage FDA to consider our comments in developing an effective and workable approach to implementing the records provision of the Act.

02N-0277

067

Serving Genuine Public Health Needs

Food processors take seriously their responsibility for producing and delivering safe food to consumers. To this end, the food industry has worked hard to develop a food safety system in the United States that is second to none. The food industry's existing systems are highly successful, effective, and well targeted for removing unsafe food from distribution promptly. These systems have been carefully constructed and maintained over many years. The Agency's recognition of the ability of industry to respond in a timely way in the absence of detailed information and records is presented in the case of commingled ingredients presented in the preamble to the proposed rule. In that example, the ability to track lot by lot is described as unnecessary and, in many cases, impractical given the complex and diverse range of circumstances presented across the U.S. food supply and distribution systems.

NFPA encourages FDA to recognize that the priority objective under circumstances where immediate action is needed to protect the public health due to a threat of serious adverse health consequences or death from a food source is the removal of potentially compromised product from store shelves and warning the public as appropriate. Accordingly, NFPA urges FDA to focus record keeping requirements on the identity of sources and recipients, as Congress directed, and to accept existing company records for investigative purposes, even if existing records require some explanation. It would be unfortunate if industry and FDA security and food safety resources were inefficiently applied or diminished due to unnecessarily detailed and burdensome records maintenance and access requirements. The information from existing records should provide an additional contribution to FDA's ability to act with certainty and accuracy to reduce potential confusion about which products in the food chain are affected and which are not. The proposed rule should focus on identifying the immediate previous source and subsequent recipient of a facility's products rather than attempting to make FDA capable of tracking finished products and ingredients without industry involvement.

NFPA strongly believes that the FDA proposal does not adequately recognize the existing food and food ingredient tracking and recall systems that companies currently maintain. NFPA believes the FDA proposal is unnecessarily burdensome, and is unlikely to enhance a system that is already both efficient and effective. NFPA believes that public health protection would be better ensured by recognizing that companies maintain effective systems that enable companies to trace sources of incoming ingredients and the distribution of outgoing product (one step back/one step forward) that can be effectively and efficiently utilized in an emergency situation.

Necessity and Utility of Proposed Access and Maintenance of Records

In the preamble to the proposed rule, FDA indicates the purpose of records access and maintenance is to allow FDA to significantly improve its ability to respond and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food. To accomplish this purpose, the food industry needs to be diligent in locating and providing information about the suspect food for FDA to examine. The

Agency notes that this information is one of several tools that will enable quick action in responding to a threatened or actual terrorist attack on the U.S. food supply.

Most companies already have procedures and operational structures to facilitate the expeditious handling of food product emergencies and to rapidly retrieve information about their products and the ingredients used to make these products. NFPA believes that FDA, with the proposed regulations, is seeking a level of product and ingredient tracking detail that will definitely not only be burdensome, but more importantly, unnecessary to achieve the stated purpose of the Act. NFPA suggests greater reliance on existing industry systems and experience.

We propose that FDA's approach should not be mandatory lot-level tracking of ingredients through the food chain, but rely on the company's ability to provide source information on ingredients, where appropriate. FDA should have sufficient information on suppliers and other manufacturers that may be affected. NFPA believes that the efforts for the detailed level of lot tracking proposed by FDA would be unnecessary and impractical for record keeping between sources and recipients, and between various transporters.

FDA should consider what effect the proposed record maintenance provisions will have on operations for distribution of products to the retail level. Food transporters and retailers work at a product/volume level of information and do not maintain detailed information at a lot code level of detail. It is not practical and of questionable technical feasibility or value for transporters and retail operators to monitor the large number and variety of products in the US food system at a production lot level.

NFPA believes that to impose lot level tracking would be a severe and impractical burden on the current distribution system. The current practice of product recalls through written notification to all possible retailers receiving product to recover specific products with specific lot codes is working well and is the most efficient and practical way to identify and remove product from the distribution system. To require additional tracking information by lot code identification is well outside the capability of the existing systems in the food manufacturing, transportation, and retail industries and unnecessary for achieving the objectives of the Act. NFPA notes that lot-level tracking as proposed by FDA is not specified in the Act.

Discussion Areas

Responsible Individual/Contact Updating

NFPA believes that this contact information should be provided through the registration process, not through an additional requirement in these proposed rules, which would be duplicative. The vast majority of the regulated industry would be subject to the registration requirements. Given that the need to contact a facility will have a high degree of urgency, NFPA believes that information regarding a specific individual may lead to delays and potential confusion in an emergency situation. NFPA estimates that many suppliers and facilities would have frequent changes in "responsible individual" during operations. Many U.S. food corporations have

reorganized significantly within the last five years, with several changes to personnel, titles, locations, and trade names. The proposed rules would require constant updating of this information on a frequent basis to maintain accuracy of the information. NFPA believes the critical information needed here is not the “responsible individual,” but emergency contact information. This information is more likely to ensure the right person will be contacted in a timely manner.

Official Records Request and Confidential Information

The delegation of authority for instituting a records access request also merits close consideration in view of the broad nature of the statutory language. As for the “officer or qualified employee of FDA” who could order the review, that person potentially could be an FDA field investigator, another government employee commissioned by FDA, an FDA employee with security clearance to receive national security information, or possibly some other person. We believe any records request should require prior approval from an “authorized FDA representative”, as defined § 1.377 of the proposed rule, Administrative Detention of Food for Human or Animal Consumption (68 FR 25241). Clear procedural safeguards are needed to ensure that this authority is implemented in a consistent, coordinated manner. We also interpret the proposed regulation to indicate that the authorized FDA representative would present any and all requests in a written format. The written document should include a summary of the threat basis so that companies can begin to conduct parallel investigations and take actions accordingly.

The Act directs the Secretary to take appropriate measures to ensure that any trade secrets or confidential information that may be obtained in a records request is not disclosed to unauthorized personnel. NFPA members want to reiterate that recipes need to be protected under this assurance and note that if FDA requests a list of ingredients as well as quantities of ingredients that the actual recipe could possibly be “reverse engineered” by someone with that level of detailed information. We believe FDA should develop and inform the public of procedural safeguards to obtain the information needed without jeopardizing confidential business information.

4- and 8-Hour Response Timeframes

NFPA has considered the proposed 4-hour requirement to make records available and consider this, in almost all cases, to be of questionable utility. In many or most cases, there would be time zone differences perhaps shifting the requirement to 8 hours. FDA should be most interested in the information from those records and not physical access to the records themselves. The company can provide FDA with this information in a timely manner for the Agency to proceed with their food security activities, without the physical records. If a visual review of records is necessary, this can occur at a later investigation. Many firms do not use electronic media for records maintenance and would be required to manually access paper records to obtain the information.

NFPA proposes the records access time requirements need to be timely but practical. The proposed rule could stipulate that records should be available as soon as possible, but within a time frame not to exceed 24 hours or other time frame appropriate to the scope of the records being sought. FDA's own past recall experiences has shown firms typically produce records/information in 2 to 3 days. We believe it is a desirable goal to reduce this time but only within a 24-hour framework. FDA should recognize that it is in the best interest of all companies to act as quickly as possible to recover products and therefore companies will strive for, and achieve, timely response. What is timely will depend upon the particular circumstances of an event and the scope of the information request.

Cost and Burden of Proposed Regulations

To determine the economic impact of the proposed regulations, FDA has made many assumptions. Attached are the comments NFPA submitted to OMB regarding our specific concerns on the economic analysis used to estimate the level of burden on the industry. Since FDA does not have a direct estimate of the proposed record-keeping burden, FDA is relying on their previous analysis of recordkeeping, using Juice HACCP recordkeeping requirements as a basis for estimating time required. NFPA does not believe the use of these recordkeeping estimates is appropriate. As we noted in our comments to OMB, of the products regulated by FDA, only seafood and juice products have required HACCP regulations. NFPA argues that much of the rest of the FDA-regulated industry would require both different and possibly more resources to achieve HACCP proficiency; therefore, using the juice HACCP model substantially underestimates the economic burden.

NFPA believes that the Agency has underestimated the number of record handlers by underestimating the number of transportation vehicles required to handle records. Company-employed or independent transporters operate between distribution points and the retail level. They conduct business on a product/volume basis to service supermarkets down to small retail outlets. They do not have the means or capability to track products at the lot level. To advance to this level of product tracking would require a significant technology advance and expense for these operators. NFPA estimates lot-level tracking capability would require on the order of 5 to 10 years development time and cost tens to hundreds of millions of dollars for redesigning and implementing new systems.

The cost-benefit justification and feasibility of the chain-of-custody system is unproven and remains in doubt. The legal and economic burdens imposed on the food industry by the proposal will be huge and cannot reasonably be justified where the need cannot be established, especially in view of the fact that the effectiveness of existing industry systems for responding to public health risks from adulterated food already are established.

NFPA urges FDA to reexamine the records storage approach and the proposed definition for perishable products. In practical terms, including only seven-day shelf-life products would cover very few regulated products and, in effect, cause the records retention burden to be shifted to most all products from a one year to a two-year retention burden. We propose that records

retention be based on a simple partitioning of shelf perishable and shelf stable products. In these terms, records should be retained for products with a shelf life up to 90 days for a one-year period. For products having a shelf life greater than 90 days, the company would retain records for a two-year period from the time of manufacture. This simplified partitioning approach will facilitate ease of record retention and disposal.

FDA assumes that the additional records storage cost for the industry would be zero. Many FDA regulated products are not currently under HACCP rules and therefore may not have ongoing records storage practices that would allow no additional cost to accommodate this proposed rule. The records storage burden is greatly increased when one considers the resources needed for lot level tracking of ingredients and finished products. We believe that a significant number of food processors would incur substantial additional or new costs to develop or implement record storage, retention and retrieval systems to comply with the rules as proposed. NFPA recommends that FDA review the costs associated with storage and recovery of retained records.

NFPA believes that FDA needs to review the strategy and outcome (benefit) of the proposed rule. FDA provides examples of several prominent product recalls and states the Agency is unable to quantify the benefit, indicating that the cost of a deliberate contamination to the food supply would be high. FDA needs to estimate the potential benefit of the proposed rules in reference to the existing tracking and recall capability of the industry. The benefit factor here is how much more quickly, if at all, could the industry respond to FDA's request for records than industry is capable of doing today. An improved response time of an efficient recall system could result in removing product more quickly and thoroughly from the market and potentially reducing illness and/or injury. A burdensome exercise to produce records for FDA to review could slow and hinder the objective of recalling suspect product. FDA should consider what an anticipated response time and records recovery saving time might be anticipated with new regulations in place, and also how this time savings (if it is realized) translates to reduced illness, injury, and enhanced product recovery. The potential of a quicker industry response could be measured and compared to the existing information retrieval and recall systems in place, as could a slower response due to a records gathering exercise.

Pipeline Provisions for Ingredients

Many NFPA members that have ongoing operations will have some ingredients on site that have been purchased and housed in facilities for sometime prior to the implementation of these regulations. In these cases, it would be a significant manpower burden (or perhaps not possible at all) to obtain or attempt to recreate all the required information on the source of those ingredients. NFPA suggests that there should be a "pipeline provision" that allows the use of NA (not available) in place of information where ingredient records, as required in the final rule, were not maintained. We recognize that these ingredients have been used in food production without incident and it would be unlikely they would be involved in an act of terrorism.

Outer Packaging

Docket No. 02N-0277
NFPA Comments to FDA
July 8, 2003
Page 7


NFPA believes that food packaging materials beyond immediate food-contact packaging that is defined as "food" in the FD&C Act should not be included under the scope of these proposed rules for maintenance of records.

Implementation of Final Rules

FDA proposes that the final rules be implemented by the industry at various times according to the size of the firm. With the scope of the FDA proposal, it is not possible to expect the industry to meet the timing of 6, 12, and 18 months as proposed by FDA. A more reasonable timetable should be considered that would be less costly and have a more realistic chance of successful compliance. At a minimum, NFPA proposes that FDA consider an implementation time of 18 months across the board.

Thank you for the opportunity to comment on this important issue. We stand ready to assist FDA with the outcome of a rule that fully protects the food supply and the public against acts of bioterrorism and is workable for government and industry.

Sincerely,


John R. Cady



June 9, 2003

4304 '03 JUL -8 P2:12

Attn: Stuart Shapiro
Desk Officer for FDA
Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)
New Executive Office Bldg
Room 10235
725 17th St NW
Washington, DC 20503

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

RE: Docket No. 02N-0277. Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (68 *Federal Register* 25188; May 9, 2003)

Dear Mr. Shapiro:

The National Food Processors Association (NFPA) submits these comments on the economic burden of information collection aspects of the above-cited proposed rule. NFPA will submit more detailed comments to FDA on the proposed rule at a future date.

The National Food Processors Association (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.

In this discussion, NFPA will address the areas in which FDA invites comments to the Office of Management and Budget (OMB) on the economic impact of the

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

WASHINGTON, DC
DUBLIN, CA
SEATTLE, WA

C

proposed regulations. We submit that NFPA members will be significantly affected by the final regulations and we will utilize both facts and data from our members to validate this view when we present more detailed information to FDA on the economic impact of these proposed regulations. At this time, we will also provide a copy of those comments to OIRA-OMB.

Summary of Comments

NFPA commends FDA for attempting to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) within such a short time frame. The stringent time constraints imposed upon this proceeding, however, only increase the importance of incorporating into the final rule reasonable recommendations from the regulated industry. NFPA has carefully evaluated the implications of the proposed rules. We attempt to offer alternative approaches that we believe are constructive. We ask both OIRA-OMB and FDA to consider our comments, realizing that we share the government's goal: protecting the safety and security of the U.S. food supply.

NFPA believes the food industry has been successful in carrying out its responsibility of protecting public health by having appropriate and effective recall plans in place to quickly and efficiently remove affected product from the market. While we recognize that the new Bioterrorism Act calls for the establishment and maintenance of records, we do not feel that FDA should be so prescriptive in their approach to achieving this objective as to add excessive burden on the food industry. FDA's role here should be to request and obtain the information needed to deal with a credible bioterrorism threat and not one to impose burdensome requirements that do not substantially assist firms in their tracking and recall efforts, or that do not allow the FDA to move more quickly and efficiently to protect public health.

NFPA believes FDA significantly underestimates the economic impact of the proposed rules for records establishment and maintenance. Our discussion below considers why we believe the regulations: (1) will introduce a higher burden than estimated; and (2) are not practical or manageable and therefore cannot be implemented without imposing unnecessary high costs. The reasons for our differences of opinion and recommendations are explained below.

Necessity and Utility of Proposed Access and Maintenance of Records

In the preamble to the proposed rule, FDA indicates the purpose of records access and maintenance is to allow FDA to significantly improve its ability to respond and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food. To accomplish this purpose, the food industry needs to be diligent in locating and providing information about the suspect food for FDA to examine. The

Agency notes that this information is one of several tools that will enable quick action in responding to a threatened or actual terrorist attack on the U.S. food supply.

The information from records should provide an additional contribution to FDA's ability to act with certainty and accuracy to reduce potential confusion about which products in the food chain are affected and which are not. The proposed rule focuses on record keeping and maintenance requirements to identify the immediate previous source and subsequent recipient of a facility's products. The premise of the proposed rule appears to be that FDA must become independently capable of tracking finished products and ingredients. However, this information will be used by the companies involved and by FDA in their response to an event to determine if other food companies may also need to recover product.

Many companies already have procedures and operational structures to facilitate the expeditious handling of food product emergencies and to rapidly retrieve information about their products and the ingredients used to make these products. NFPA believes that FDA, with the proposed regulations, is seeking a level of product and ingredient tracking details that will definitely not only be financially burdensome, but more importantly, unnecessary to achieve the stated purpose of the Act. NFPA suggests there may be alternative approaches that are less prescriptive and burdensome on the industry, that can achieve the same outcome of information recovery and that can work within the operational structures of most facilities.

To meet the requirements of the Act, we propose that a facility could develop and put into practice procedures to manage information on product composition and to implement a recall if required. In general terms, companies would develop their procedures to accomplish two principal purposes: 1) to produce tracking information on the source of ingredients of a suspect product; and 2) to implement a recall of suspect product. The company procedures would have an output that would allow FDA and the company to identify suspect ingredients within the food chain and allow the company to quickly recover the implicated product. The approach should not be mandatory lot-level tracking of ingredients through the food chain, but rely on the company's ability to provide source information on ingredients, where appropriate. FDA should have sufficient information on suppliers and other manufacturers that may be affected. Greater focus on a company's recall plan and recovery structure, which already exists and is a proven and efficient way to remove product from the market, is more appropriate than what is proposed by FDA.

NFPA believes that the estimates for the detailed level of lot tracking proposed are extremely low for both record keeping between sources and recipients, and between various transporters. As an example, both OIRA-OMB and FDA should consider what effect the record maintenance provisions of the Bioterrorism Act will have on operations for distribution of products to retail level. Specifically, these distributors work at a product/volume level of information and **do not** maintain lot level tracking into the retail outlets. NFPA believes that to impose lot level tracking would be a severe and impractical burden on the current distribution system. The

current practice of product recalls through written notification to all possible retailers receiving product to recover specific products with specific lot codes is working well and is the most efficient and practical way to identify and remove product from the distribution system. To require additional detailed information, such as lot code identification, is well outside the capability of the existing systems in the food manufacturing, transportation, and retail industries. In summary, NFPA believes the burden to industry will be vastly greater than estimated. In addition, lot level tracking as proposed by FDA is not specified in the language of the Bioterrorism Act.

Given that the need to contact a facility will have a high degree of urgency, NFPA believes that facilities or their parent companies should be given the option of identifying relevant emergency contact information (phone number – cell or land line; email) without necessarily identifying a specific individual (Person) by name. Any given facility or parent company taking responsibility for an emergency contact system should not be bound by the specific information required in FDA's proposed reporting framework seeking the name of the responsible individual when in fact, FDA only needs the emergency contact information. With changes occurring within companies and the mobility of the staff, providing contact information would be more efficient and require fewer resources than to maintain a listing of responsible individuals (Person) as the contact point.

Accuracy of FDA's Estimate of Burden

Basis for Estimating Cost

To determine the economic impact of the proposed regulations, FDA has made many assumptions. In particular, since FDA does not have a direct estimate of the proposed record keeping burden for the Bioterrorism Act, FDA is relying on their previous analysis of the recordkeeping, using Juice HACCP recordkeeping requirements as a basis for estimating time required. NFPA objects to the use of these recordkeeping estimates. We do point out that of the products regulated by FDA, only seafood and juice products have required HACCP regulations. NFPA would argue that much of the rest of the FDA regulated industry would require both different and possibly more resources to achieve HACCP proficiency, and therefore using the juice HACCP model as the cost basis would underestimate the burden.

Given the need for higher-level personnel involvement, due to complexities of the proposed rule, the actual average wage rate for all company personnel involved in records activities likely would exceed the per hour weighted average wage rate estimate used by FDA and may be closer to \$33 per hour.

Description of Record Handlers

In its quantification of reporting burden, FDA estimates that approximately 187,000 foreign firms and 425,000 domestic firms would be impacted by these proposed regulations. NFPA believes this estimate is low. Individual transporters, not only transportation firms, will hold food while it is in transit and transportation vehicles do not appear to be exempt from the scope of the regulation. NFPA believes that the Agency has underestimated the number of record handlers by underestimating the number of transportation vehicles required to handle records. Company employed or independent transporters operate between distribution points and the retail level. They do business on a product/volume basis to service the groceries and retail outlet stores. They do not have the means or capability to track products at the lot level. To advance to this level of product tracking would require a significant technology advance and expense for these operators. NFPA estimates lot-level tracking capability would require on the order of 5 to 10 years development time and cost tens to hundreds of millions of dollars for redesigning and implementing new systems.

Cost of Chain-of-Custody and Maintenance Burden

The cost/benefit justification and feasibility of the chain-of-custody system is unproven and remains in doubt. FDA estimates that the average annual costs of compliance with the proposed recordkeeping requirements would be \$383 in the first year of implementation, \$828 in the second year, and \$361 for every year thereafter. These figures include the estimated costs of learning about the new requirements, redesigning the current format of records to include all information required by the rule, and preparation for records access within the timeframes specified. These relatively low estimates are largely the result of the Agency's questionable assumption that the proposed requirements would not substantially deviate from current industry practice, in terms of the content of existing trace back records and current records maintenance and access procedures. The legal and economic burdens imposed on the food industry by the proposal appear to be huge and cannot reasonably be justified where the need cannot be established, especially in view of the fact that the effectiveness of existing industry systems for responding to public health risks from adulterated food already are established.

Initial Startup Costs

The Agency's cost estimates are understated and based on assumptions that do not reflect typical operating practices. In the proposed rule, FDA estimates the time it would take for a respondent to read, understand, collect information, and complete the required records rule. Estimates of 3½ hours per facility, is dependent upon whether the respondent has access to the Internet and whether the respondent is fluent in English. FDA provides limited justification for this estimate other than to explain the variables introduced by differences due to Internet access and English fluency.

To research and understand the rules, any company would need far more than the one (1) hour FDA factored into the economic impact assessment. The proposal alone is 52 pages of fine print in the *Federal Register*. A FDA explanatory video would take another hour or so to watch. No time was allocated for the task of evaluating the implications of the proposed rules to current business systems or for preparing comments. When the final rules are published, assuring compliance will involve reading and understanding the final rules, as well as any accompanying question and answer documents or videos.

Records Storage Time and Cost

NFPA members do not agree with the records storage approach and the proposed definition for perishable products -- having a shelf life of seven days or less. In practical terms, including only seven-day shelf-life products would cover very few regulated products and in effect, cause the records retention burden to be shifted to most all products from a one year to a two year retention burden. We propose that records retention be consistent with a product's actual shelf-life as determined by the company and the proposed perishable definition be changed. NFPA recommends that records be available for FDA's access for one year for defined shelf-life products (products that are not shelf-stable) and that for shelf-stable products, records would be available for a two-year period from the time of manufacture.

FDA assumes that the additional records storage cost for the industry would be zero. Many FDA regulated products are not currently under HACCP rules and therefore may not have ongoing records storage practices that would allow no additional cost to accommodate this proposed rule. NFPA estimates that the cost for off-sight storage and recovery services for records storage is about \$2.50 to \$3.50 per cubic ft/yr. Many services offer 24 hr availability yet these must be physically located and retrieved by a company employee. The records storage burden is greatly enhanced when one considers the resources needed for lot level tracking of ingredients and finished products. We propose that a significant number of food processors would incur additional costs due to records storage, retention and retrieval costs in implementing the proposed rules. NFPA recommends that FDA review the costs associated with storage and recovery of retained records.

Four Hour Access Requirement

NFPA has considered the proposed 4-hour requirement to make records available and consider this, in almost all cases, to be an unmanageable task. In some cases, there would be time zone differences perhaps shifting the requirement to 8 hours. However, even 8 hours does not give many companies enough time to gather the records for FDA. FDA should be most interested in the information from those records and not the records themselves. The company can provide FDA with this information in a timely manner and it is the information that FDA needs to proceed with their food security activities, not the physical records. If a visualization of

records is necessary, this can occur at a later investigation. Many firms do not use electronic media for records maintenance and would be required to manually access paper records for the information. Many firms have multiple facilities, especially through mergers and acquisitions that have different data systems that are not integrated in a manner to recover the required information in such a rapid manner as proposed. Compliance with the current proposal would necessitate building a new records system, requiring substantial capital and time investment. NFPA proposes the records access time requirements need to be timely but practical. The proposed rule could stipulate that records should be available as soon as possible, but within a time frame not to exceed 24 hours. FDA's own past recall experiences has shown firms typically produce records/information in 2 to 3 days. We believe it is a desirable goal to reduce this time for both domestic and/or foreign facilities, but only within the framework of 24 hours. FDA should recognize that it is in the best interest of all companies to act as quickly as possible to recover products and therefore companies will strive for, and achieve, timely response. NFPA suggests that after these rules are implemented, FDA work with companies to conduct validation exercises to determine the actual response time of companies and build a knowledge base to determine if: 1) less than a 24hr limit is needed; and 2) what regulated companies are capable of achieving.

Contact Information Updating

NFPA estimates that many suppliers and facilities would have frequent changes in "responsible individual" during operations. Many U.S. food corporations have reorganized significantly within the last five years, with several changes to personnel, titles, locations, and trade names. The proposed rules would require constant updating of this information on a frequent basis to maintain accuracy of the information. NFPA believe the critical information needed here is not the "responsible individual" by name, but the emergency contact information. This information is less likely to change and listing 2 or 3 emergency contact phone numbers (perhaps with position titles) is a more realistic approach to ensuring the right person will be contacted in a timely manner. NFPA believes that this contact information should be provided through the registration process, not through an additional requirement in these proposed rules, which would be duplicative. The vast majority of the regulated industry would be subject to the registration requirements.

Pipeline Provisions for Ingredients

Many NFPA members that have ongoing operations will have some ingredients on site that have been purchased and housed in facilities for sometime prior to the implementation of these regulations. In these cases, it would be a significant manpower burden (or perhaps not possible at all) to obtain or attempt to recreate all the required information on the source of those ingredients. NFPA suggests that there should be a "pipeline provision" that allows the use of NA (not available) in place of information where ingredient records, as required in the final rule, were not maintained. We recognize that these ingredients have been used in food

production without incident and it would be unlikely they would be involved in an act of terrorism.

Business Impact

NFPA is concerned that the proposed regulations would impose an unnecessary cost burden across all the food industry, regardless of size. Many operations do not have the resources, both equipment and personnel, to accommodate the additional records establishment and maintenance requirements of the proposed rules. Many would not have an existing recordkeeping requirement program and records storage procedures in place that could easily be expanded to include the provisions as described by FDA to meet the requirements of the Act. Many businesses, large and small, would lack the computer systems and resources for tracking, to the level proposed, of incoming ingredient details. Also, with limited personnel, there would be a negative cost impact, at all businesses, in hiring additional staff to accommodate the rules as proposed.

Implementation of Final Rules

FDA is proposing that the final rules be implemented by the industry at various times according to the size of the firm, following the publication of the final rule. With the scope of the rules as proposed by FDA and with special attention to the requirements for lot level tracking of ingredients and tracking finished products, it is not possible to expect the industry to meet the timing of 6, 12, and 18 months as proposed by FDA. A more reasonable time schedule should be considered, that would be less costly and have a more realistic chance of successful compliance. At a minimum, NFPA proposes that FDA consider the following implementation times following the publication of a final rule (18 months for large businesses, 30 months for small and 42 months for very small businesses).

Benefits of Proposed Rules

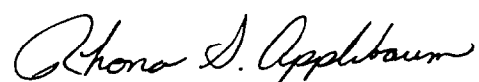
NFPA believes that OMB and FDA need to review the approach to estimating the benefit of the proposed rule. FDA gives examples of several prominent product recalls and states they are unable to quantify the benefit, indicating that the cost of a deliberate contamination to the food supply would be high. FDA needs to estimate the potential benefit of the proposed rules in reference to the existing tracking and recall capability of the industry. The benefit factor here is how much more quickly could the industry respond to FDA's request for information than they are able to do today. This improved response time could result in removing product more quickly and thoroughly from the market and potentially reducing illness and/or injury. As an example, FDA could estimate one or two food terrorist events in a year and determine what the reaction time and records recovery saving time might be with new regulations in place, and also how this time-savings translates to reduced illness, injury and enhanced product recovery. The

Docket No. 02N-0277
NFPA Comments to OIRA-OMB
June 9, 2003
Page 9

potential of a quicker industry response could be measured and compared to the health and security benefits of recovering product more quickly within that response time.

Thank you for the opportunity to comment on this important issue. We stand ready to assist both OIRA-OMB and FDA in perfecting the information collection provisions of this rule.

Sincerely,

A handwritten signature in black ink that reads "Rhona S. Applebaum". The signature is written in a cursive, flowing style.

Rhona S. Applebaum, Ph. D.
Executive Vice President and Chief Science Officer
National Food Processors Association