



March 5, 2003

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-0276. Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
(68 Federal Register 5377; February 3, 2003)

Dear Mr. Shapiro:

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

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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 these remarks, NFPA will address the areas in which FDA invites comments on the information collection:

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- (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information would have practical utility;

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- (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (3) ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To substantiate our comments, particularly with respect to the estimates of reporting burden, NFPA currently is collecting data from its Members concerning their own estimates of reporting burden. Owing to the short comment period for filing with Office of Information and Regulatory Affairs, Office of Management and Budget (OIRA-OMB) on the information collection, NFPA does not now have sufficient data returns from Members to report in these comments. However, NFPA will submit such a report in our comments to FDA on this docket, and we will 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 a severely limited 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, including Members of NFPA. NFPA has carefully evaluated the implications of the proposed rules. In these comments, when we have objected to an approach proposed by FDA, we have offered alternative approaches that we believe to be constructive. We ask both OIRA-OMB and FDA to consider our comments, realizing that we share the government's goal: protecting the safety of the U.S. food supply.

NFPA has concerns about several aspects of the information collection associated with this proposed rule. One concern is related to the utility of collecting – or rather the futility of collecting – “FDA product code” categories for each registered food “manufacturer/processor” facility. NFPA urges the government not to adopt this approach.

NFPA also has concerns about the accuracy of estimates of reporting burden, and we present a detailed discussion below. NFPA is also concerned about the mechanics of gathering the registration data. While we agree that interactive registration over the Internet is likely to be efficient both for FDA and for companies registering a few facilities, we recommend that the Agency also accept transmission of electronic data

files, and allow for multiple, simultaneous registrations from a multi-facility registrant . Offering companies registering a large number of facilities options to process registration data electronically, will reduce entry errors and permit both the Agency and larger companies to accomplish the massive registration task as efficiently as possible.

The reasons for our recommendations are explained below in answer to the key questions that OIRA-OMB will be examining, as required by the Paperwork Reduction Act.

Necessity and Utility of Proposed Collection of Information

In the preamble to the proposed rule FDA indicates the purpose of facility registration, which the Agency notes 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. NFPA evaluated the utility of the proposed mandatory and optional information based on this stated purpose. Since facility registration is not intended to be the only source of information that FDA will use to respond to a threatened or actual bioterrorist attack, the registration information should provide a unique contribution to FDA's ability to respond, and not introduce uncertainty and potential confusion in conjunction with other sources of information.

Forthcoming proposed rules will focus on record keeping and maintenance requirements to identify the immediate previous source and subsequent recipient of a facility's products. Presumably, this information will also be used in FDA's response to an event. In this regard, it is not necessary for the registration database to be the sole source of information about food facilities. NFPA suggests that the appropriate emphasis for the facility registration provisions of the Bioterrorism Act should focus on establishing the appropriate information for locating and contacting a facility.

NFPA notes that FDA does not describe the sources or types of information, from facility registration and other provisions, that the Agency expects to access for responding to an event, or how this information will be integrated or combined to facilitate the Agency's response. FDA does indicate that facility registration information will help Agency and other authorities determine the *source and cause of the event* (emphasis added), and enable FDA to notify quickly the facilities that might be affected. NFPA believes that, as proposed, the registration requirements are not suited for determining the source or cause of the event, but rather for locating and contacting facilities that through some other means have already been associated with the event, thus facilitating further investigation.

With respect to notifying facilities that might be affected by threatened or actual bioterrorism events, NFPA does not believe that facility registration alone can offer a sufficiently accurate or effective means to identify a specific subset of facilities to be

contacted. NFPA believes that use of FDA product categories will be both inaccurate and ineffective for this purpose. NFPA believes that FDA should not attempt to pre-determine which facilities will be potentially affected by a particular event. Such an approach presumes FDA is adequately knowledgeable of the movement of products and ingredients among facilities to make such determinations. NFPA does not believe FDA has, or could possibly obtain, this level of detailed knowledge for the purpose of making large scale, facility-specific notifications. NFPA believes that the interest in and need to know about a possible terrorist action against the food industry will be substantial, and that FDA should not attempt to isolate potentially impacted facilities based on a questionable classification scheme.

The Bioterrorism Act gives FDA discretion to gather general food category data, but the law does not mandate collection of such information. The general food categories identified under 21 CFR 170.3 are to be used, if FDA determines through guidance that product category information for each facility is necessary. FDA has correctly acknowledged the problems associated with use of the outdated categories in 21 CFR 170.3, which were designed for applications regarding the regulation of food additive uses, and thus are not relevant for the facility registration information collection. Nevertheless, the Agency has tentatively decided to require submission of "FDA product code" categories, referencing the 170.3 categories, erroneously concluding, in our view, that tracking FDA product code categories

"...is necessary for a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency, because the categories will assist FDA in conducting investigations and surveillance operations in response to such an incident. These categories will also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected." 68 FR 5384.

The Agency's speculation that a potential threat to the food supply might be framed in terms of highly technical "FDA product code" category definitions is at best unrealistic.

The proposed categories bear no relationship to bioterrorism risk, and collecting information about the categories associated with each facility would not be useful in reducing threats to the food supply. The proposed product categories only add to the reporting burden of registrants. Use of the proposed general product categories for identifying potentially impacted facilities introduces huge uncertainties as to whether the appropriate facilities would be contacted or not, which may either lead to causing unnecessary concern or inadequate notification of affected facilities.

As a practical matter, the FDA product categories are difficult to understand and apply, even for specialists who deal with these sections of regulations daily. Some categories overlap each other, yet many foods fall into gaps among the categories; so, deciding which category FDA would deem correct can be quite difficult. Therefore, many food processors are likely to classify similar products differently or make mistakes in reporting category classification. Any product categorization would need to be self-evident, and any technique for determining a product category should be transparent to the registrant.

Under the FDA proposal, a firm must take the time and spend the money to determine the accurate "FDA product code" for each product formulation that the company makes, and then, from that detail, determine the "FDA product code" category. Alternatively, the company could guess the correct category based upon the FDA's descriptions on the form. The latter, more expedient, approach inevitably would lead to classification inconsistency, if not to a database full of useless information. Many food companies make hundreds or thousands of product formulations. In short, the "FDA product code" categories are simply no more useful in fostering the Agency's mission of maintaining the safety of the food supply than would be the 170.3 categories FDA properly rejected.

Moreover, company officials are required to certify that all registration information is "true and accurate." The preamble to the proposed rule informs the regulated industry that FDA will consider false information to be "a materially false, fictitious, or fraudulent statement to the U.S. government under 18 U.S.C. 1001, which subjects the person [submitting the information] to criminal penalties." 68 FR 5385. NFPA believes that no one should be subject to the remotest risk of criminal penalties for failing to discern the idiosyncrasies of the "FDA product code" system.

In the FDA training video on the proposed registration regulations, Agency personnel discuss the importance of using product category information for "targeted communication," a concept that appears to be based on the faulty premise that only facilities making one or a few of the identified FDA categories would need to know about a potential threat. 68 FR 5384-5385.

It is important to recognize that one food processor's product is another's ingredient. Most of the proposed FDA categories are for foods that are virtually ubiquitous throughout the food supply, like cheese, dried milk products, flours, and vegetable oils, and nearly all the product categories are used as ingredients in further processed foods. "Targeted communication" would address only primary ingredient manufacturers, not processors throughout the system that use those ingredients in other food products. Improperly targeted communication based upon the "FDA product code" categories would hinder, rather than foster, effective response to a potential threat as well as the associated FDA investigations and surveillance operations.

The proposed rules appropriately require submission of the emergency contact information FDA unquestionably needs for “a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency.” NFPA recommends that the Agency expand that section of the form, so that food companies can provide a back-up to the identified primary emergency contact person. Many companies have procedures and operational structures to facilitate expeditious handling of emergencies. NFPA suggests that FDA’s “targeted communication” objective can best be achieved through flexible, and company-determined contact information in this section of the registration form. This approach would be more effective in meeting that end than the product category scheme that FDA has proposed.

NFPA agrees that having a means to quickly and efficiently contact a facility will greatly facilitate FDA’s functions. However, NFPA believes the proposed information, which is individual specific, offers limited utility in some circumstances. The proposed rule requires information, including the name and contact information for the emergency contact, to be updated within 30 days of a change. Despite the best efforts of companies and facilities to maintain this updated information, it is reasonable to expect that, at any given point in time, some of this information will not be accurate. 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. 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.

FDA would not need to rely upon the emergency contact information alone. Both OIRA-OMB and FDA should consider what effect the record maintenance provisions of the Bioterrorism Act will have on the ability rapidly to notify affected sectors of the food industry of a threat. While the proposed rule implementing the record maintenance provisions has not been published, NFPA believes that the ingredient and product tracking records that companies doubtless will be required to maintain will facilitate FDA’s “targeted communication” objective.

In summary, collection of “FDA product code” category data is not required by the Bioterrorism Act, is unnecessary for the accomplishment of FDA’s mission, and is not useful as a practical matter. Tracking “FDA product code” categories for each facility would increase the cost of the registration system and divert resources that should be focused elsewhere, but would not improve the Agency’s capacity to protect the public.

Accuracy of FDA’s Estimate of Burden

Description of Respondents

In its quantification of reporting burden, FDA estimates that 205,405 foreign facilities and 202,046 domestic facilities would be required to register with the Agency. NFPA believes this estimate is low. It appears that, in the Preliminary Regulatory Impact Analysis, upon which the numbers of respondents are based, FDA fails to give appropriate weight or clarification to the number of very small facilities, including small local holding facilities, and transportation facilities. Transportation vehicles will hold food while it is in transit, and transportation vehicles do not appear to be exempt from the scope of the statute. Absent FDA's precise interpretation of the scope of the statute, NFPA believes that the Agency has underestimated the number of respondents.

Hour Reporting Burden

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 data, and complete the registration form. Estimates range from two hours to 12 hours per facility, depending on whether the respondent has access to the Internet and whether the respondent is fluent in English. FDA provides no justification for this estimate other than to explain the variables introduced by differential Internet access and English fluency.

To research and understand the rules, any company would need far more than the one hour FDA factored into the economic impact assessment. The proposal alone is 40 pages of fine print in the Federal Register. The FDA explanatory video takes another hour 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 Federal Register document, as well as any accompanying question and answer documents or videos. The "FDA product code" scheme is not used by industry, so companies first would need to learn the FDA system, and then will need to classify products by facility.

The hour estimates of reporting burden are predicated on the bulk of the registration being done by administrative workers. NFPA believes that this estimate has failed to capture accurately the time needed to assemble the data on the facility. The data required are likely to be beyond the familiarity of most administrative workers in a facility. A supervisor is likely to be needed to collect the registration information, which the administrative worker would enter onto the paper form or use to complete the electronic registration. Some of the data fields required and requested will need research and/or input from other persons, as well as validation checks.

FDA proposes to require management certification that the submission is accurate, but does not appear to have factored the time the manager needs to learn the Agency's requirements into the economic analysis. No systems development costs were included. The entire form, further, may take more than 15 minutes for a responsible party to review and certify. Furthermore, given the need for higher-level personnel involvement, the actual average wage rate for all company personnel involved in facility registration activities likely would exceed the \$33 per hour weighted average wage rate estimate used by FDA.

With respect to the reporting burden in time, NFPA estimates that the baseline response per facility likely would be 3 hours for the initial registration, for domestic facilities with Internet access, and other estimates should be increased accordingly.

Foreign facilities all must identify at least one U.S. agent. The registration form presupposes that a foreign facility will have one U.S. agent, when in fact it may have numerous U.S. agents, depending on the nature and business practices of the foreign facility. NFPA believes that FDA goes beyond the scope and intent of the statute in presuming to require changes in business practices, which would unduly constrain domestic commerce and international trade.

With respect to subsequent years' reporting, NFPA again believes that FDA has underestimated the burden. Product category information would change frequently, as manufacturers move product lines to achieve optimum use of their facilities. Thus, tracking FDA product categories would not only be difficult initially, for the reasons previously discussed, but would require monthly updates. Therefore, FDA has significantly underestimated the cost of constantly keeping the registration data up to date after the information is first gathered. The ongoing cost of maintaining the registrations would far exceed the initial registration cost. Moreover, processing constant minor registration changes related to changing food categories would not be a good use of FDA or industry resources.

FDA has estimated that 20 percent of facilities would have a material change in registration in one year. Put another way, FDA estimates that a facility is likely to have a material change in its registration information once every five years, on average. FDA does not draw a distinction in the proposed rule between "material" and insignificant changes to the registration information. Thus, it appears, as proposed, that even small changes to the registration information would be required to be reported to FDA within 30 days. Considering that some of these data involve personal information (name and title of personnel for emergency contact, addresses, telephone numbers, email addresses) subject to frequent change, or changes in product category information, it is unreasonable to estimate that a facility will change its information once every five years. Personnel changes in emergency contacts, person completing the registration, or authorized party

could be more frequent, given promotions, separations, relocations or changes in assignment of personnel. Companies often add and change product categories, or reorganize the corporation so that the trade name changes. These changes are fairly frequent. Several large U.S. food corporations have reorganized significantly within the last five years, with several changes to personnel, titles, locations, and trade names. FDA's assumption represents a serious underestimation. NFPA believes that a more realistic estimate is that 50 percent of facilities will have at least one change every year.

With respect to frequency of reporting, FDA estimates that any facility would likely change its registration information only once a year. FDA proposes to require that changes to registration information be executed within 30 days of a change, thus increasing the likelihood that a facility may have 12 annual opportunities to change registration information. Given that the need for changing registration information is triggered by any change in the facts, and that some of the data elements are likely to change frequently, NFPA believes that one change per facility per year is not a realistic estimate. A realistic estimate would reflect several annual changes per registered facility.

The reporting burden can be reduced if FDA were to change its proposed requirements that changes be made in 30 days. The longer the period permitted for changes, the less the burden on the registration system, and the less the reporting burden on respondents, with little or no degradation in timeliness of information.

The lack of a clear illustration of the electronic facility registration system makes it impossible to assess whether use of such a system adds to the time and complexity of reporting, or minimizes such burden components. There are many electronic data entry systems that might be built around the architecture of FDA's proposed reporting form; some systems could be quick and easy to use and some could be difficult and time consuming, but both could legitimately reflect the facility registration reporting form. NFPA urges both OIRA-OMB and FDA to ensure that the mechanics of electronic facility registration minimize the reporting burden.

Enhancing the Quality, Utility, and Clarity of the Information to be Collected

NFPA believes that FDA needs to ensure that the operation of the Internet-based electronic registration system is designed to accommodate the anticipated high level of activity. NFPA notes that no opportunity was provided to review the electronic data collection system, for the purpose of providing comments on information collection. Since FDA envisions the electronic data collection to be an integral part of the facility registration provision, NFPA believes that this lack of opportunity to review constitutes a serious shortcoming. NFPA would point out that hundreds of thousand of facilities will be required to register in an eight week time period, and any flaws in the electronic

registration system will cause serious disruptions to commerce and trade, as well as impede the industry's ability to comply with facility registration.

Minimizing the Burden on Respondents of Collection of Information

NFPA notes that the lack of detail regarding the Internet-based electronic registration system makes it difficult to evaluate overall reporting burden and assess whether FDA will have the adequate hardware and software to function as planned. NFPA has received several comments from Members that note the proposed data collection form is only available electronically as a PDF file, an artifact of Federal Register publication, and that this would not be a format that could be used for electronic filing. The illustrated form in the proposal is clearly that designed for non-electronic registration. NFPA imagines that the electronic form parallels the paper form. NFPA Members also have objected to their inability to evaluate an electronic data collection system.

There does not appear to be any provision for data security for original data entry and subsequent changes for the electronic data collection system. The registration number alone should not be sufficient to access the registration form securely in an electronic environment, since registration numbers will be required for prior notice of imports, and are likely to be part of the commercial documentation between parties. The best way for a company to ensure that its supplier or customer is appropriately registered is to require that information as part of a commercial transaction. This makes that information more vulnerable, from an electronic data security standpoint. FDA must have procedures in place to ensure that only authorized persons can access and change their facility's registration information.

FDA could reduce the burden of collecting the information, if multi-facility registrants were able to send a single transmission containing all of the required data, in lieu of entering the data interactively over the Internet, or could register several facilities simultaneously using several company computers. The interactive Internet data entry approach is probably excellent for many small manufacturers, but is too time consuming for large companies that must register hundreds of facilities. Assuming the one-hour FDA data entry estimate were correct, large companies could need 1,000 person hours to enter data for their facilities. It would take several full-time administrative personnel working 40 hours per week to complete such a task in the eight weeks that will be provided for compliance with the registration process. Thus, we suggest that the final rule include an option for a format for submitting electronic data files, such as XML documents, Microsoft Excel documents, or standard flat files. Additionally, we recommend that the Agency make provisions for a single registrant to stop entering data on one day and begin the task again another day, for interactive data entry. We also think the Agency will need to provide for a single registrant to enter data simultaneously from

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more than one desktop. FDA should allow for multiple electronic registration techniques to ensure that the facility registration system is sufficiently flexible to meet the needs of the wide range of registrants.

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 cursive script, appearing to read "Rhona S. Applebaum".

Rhona S. Applebaum, Ph. D.
Executive Vice President and
Chief Science Officer