



March 5, 2003

Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th St. NW Room 10235
Washington, DC 20503

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

ATTN: Stuart Shapiro, Desk Officer for FDA

RE: Docket No. 02N-0278 RIN 0910-AC41, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 FR 5428, February 3, 2003)

Dear Mr. Shapiro:

The National Food Processors Association (NFPA) welcomes this opportunity to provide comments specifically regarding the information collection proposed under the above referenced "Prior Notice" requirements of "The Bioterrorism Act" (the Act). NFPA will submit subsequent comments to FDA on the substance of the proposal. Under the Act, the Secretary is required to implement final regulations addressing Section 307 by December 12, 2003. On August 30, 2003 NFPA submitted comments to the Food and Drug Administration (FDA) urging a seamless integration with existing and pending import notification requirements with the goal of minimizing or eliminating unnecessary, multiple or redundant notification. NFPA submits that the FDA proposal fails to meet that goal and that the information collection requirements are more burdensome than necessary; the prior submission form is long, confusing and duplicative.

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 import ingredients for further processing and export finished processed food products globally and will, consequently, be affected by this rulemakings.

Since September 11, 2001, the food industry has taken active steps towards protecting the nation's food supply. NFPA is providing the leadership for the

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Food Security Alliance, a coalition including over 130 organizations representing all levels of the food chain. NFPA is striving to work closely with the Food and Drug Administration (FDA) as regulations are being developed to respond appropriately to the security mandates of the Act without undue disruption to trade.

General Comments

In general, NFPA believes that the proposed prior notice requirements extend beyond that which is necessary to adequately respond to an incident of intentional contamination related to imported food and exceed the specific Congressional mandate of The Bioterrorism Act. NFPA believes that FDA has failed to adequately take into consideration “the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported...” as recommended by Congress.

Specifically related to this comment submission, NFPA believes that the detailed data submission requirements as proposed by FDA that have been elaborated on the proposed form exceed those necessary to satisfy the intent of the Act. NFPA believes that the economic burden of the information collection provisions has been underestimated and that the operational practices of food trade has not been adequately taken into consideration. NFPA believes that the objective and, specifically, the mandate of the Act can be achieved in a simplified manner that reduces the burden on the food industry and the related disruption to trade in food products. Furthermore, NFPA believes that that proposed rules, including the submission form, do not provide adequate guidance to importers for completion of the data submission; clarification is necessary in several areas. Most significantly, NFPA believes that the reporting burden could be further lessened by reducing the required prior notice period, subsequently reducing the number of necessary amendment and update. NFPA will file subsequent comments substantiating that view.

Scope

Section 307 of the Act amends Section 801 of the Federal Food, Drug and Cosmetic Act mandates importers to provide notice to the Food and Drug Administration (FDA) including the “identity” of the: article, the manufacturer, the shipper, the grower (if known in the specific time notice is required), the country of origin, the country of shipment and the anticipated port of entry for the article. The specific data elements of the Act provide FDA with sufficient information to identify incoming shipments.

FDA, in developing the proposal has expanded the congressional mandate to include additional information to “facilitate product tracking,” obtain information to “assist FDA and other authorities in determining the source and cause of problems and in communicating with affected firms,” and to help “use foreign inspection resources more

effectively.” While NFPA empathizes with FDA’s intent to utilize this new information source for seemingly broader purposes, Congress was clear that an appropriate balance must be achieved between those needs and the implications on trade including the operational practices of food businesses.

NFPA also notes that product tracing for the purpose of recall is the responsibility of the food manufacturer and that information about consignees and customers is often deemed proprietary. The purpose of prior notice is to allow FDA to identify and hold (if deemed necessary) product prior to entry into domestic commerce. To achieve this purpose, information regarding origin and shipment is pertinent; final destination within the U.S. is not.

Prior Notice Submission – Form and Format

In general, NFPA believes that the information collection as proposed through this submission form is overly burdensome, excessively long and unnecessarily extensive to accomplish the identified objective. Many of the data elements are beyond the scope and mandate of Congress; others are unnecessary to meet the stated purpose of the FDA regulations. Some data elements cannot be easily completed within the designated time allowed. Finally, it is unclear if the fields are mandatory or voluntary. In several cases, the information indicated as mandatory will not be applicable or available.

In addition, NFPA notes that prior notice requires electronic submission of data. The publication has provided a paper form that cannot actually be used for this purpose. Consequently, it is impossible to accurately evaluate the burden imposed on the submitter that will depend largely on the technology available including: interactive accessibility, capability of multiple submissions, automatic population of fields and ability to recall for subsequent submissions.

It is not clear if a submitter can return to a submission to make an amendment or update without filing an entirely new submission. In that regard, it has been suggested that a submission form should be assigned a unique control number that would allow the importer to recall the original submission to update the information with a few keystrokes. In that case, the control number should be automatically assigned and located at the top of the submission form.

The order of the submission information on the form appears to bear no relevance to the importance of the information necessary to make risk based decisions of cargo requiring FDA inspections. Nor is it arranged to accommodate logical data entry. NFPA asks FDA to consider the critical elements of information and re-order the submission form in a manner to best facilitate determinations on in-bound shipments by FDA and data entry by the submitter. For example, it may be helpful to place arrival information on page one (1) in order to prioritize and sort data by attention needs. Common sense dictates that

information about the importer and product and other known mandatory information should have priority placement. Reducing the confusion will reduce the reporting burden.

NFPA encourages FDA to provide for self-populating fields wherever possible to reduce the administrative burden for submitters as well as the possibility for errors. For example, the entry of a registration number should allow for automatic completion of all other data related to the manufacturer or distributor.

Finally, the proposal fails to consider “low-risk” or “known” importers. This would include importers accepted into U.S. Customs Trade Partnership Against Terrorism (CTPAT) program and those utilizing Free and Secure Trade (FAST) transport across borders. It may also include importers making recurring identical shipments across borders. However, FDA has stated that it continues to consider opportunities to recognize low-risk importers and to cooperate with U.S. Customs and the food industry in this regard. For that reason, NFPA suggests that the first page of this form should include a field in which to identify “CTPAT” low-risk status information.

NFPA submits the following comments on each of the data fields:

1. Paperwork Reduction Act Submission

NFPA believes that FDA has underestimated the reporting burden for this submission. Furthermore, there are inconsistencies between the form and the proposal in that FDA has estimated the prior notice form will take one hour to complete (e.g. 45 minutes by the administrative worker and 15 minutes of management time). The form estimates the reporting burden to average 0.5 –1.0 hour. See subsequent comments on Analysis of Economic Impacts.

2. Amendment on product identity and update.

NFPA members are very concerned about the limitations and restrictions on amendment and the proposed time frames. These issues will be addressed in subsequent comments to FDA.

Specifically related to the submission form:

- The preamble to the proposal also allows for amendment to product quantity but is not sufficiently clear about permitted quantity amendments. NFPA notes that Section § 1.290 provides for amendments to product identity, including quantity and growers and that food companies do not consider quantity to be product identity. However the ability to amend quantities is important to the food industry. The form provides no field to amend product

quantities or growers (that may become known after filing). NFPA intends to submit substantive comments justifying the need to allow amendments for several other purposes. Consequently, NFPA suggests a single field “amendment” would be more appropriate.

- An importer may often know in advance that an amendment will be filed; a field has been provided at the end of the form to accommodate this situation, “amendment to follow.” NFPA believes that field should be placed in the first page area.
- A field is provided to “cancel” the submission; fields should also be provided to “cancel” an update or amendment.

3. Mandatory/ Mandatory if applicable

These fields require further explanation. It is completely unclear to which elements “mandatory if applicable” refers. In addition, it is very clear that if all the data elements on the left portion of the form are mandatory, the submitter will be unable to complete them resulting, it is assumed, in an incomplete prior notice and unnecessary rejection. Subsequent comments identify fields NFPA believes should be clearly indicated as “voluntary.” Again, confusion regarding the mandatory elements of the form increases the reporting burden and possibility for error.

4. Submitters

NFPA suggests this area contains too many data fields. The proposal holds the importer or purchaser responsible for the submission and allows for the designation of a U.S. agent or submission by carrier for in-bond movement through the U.S. There is no reason for FDA to distinguish between a purchaser or an importer for this purpose. Therefore, fields should be provided for: (1) importer or purchaser; (2) U.S. agent or (3) In-bond carrier.

NFPA notes that a field is provided for an FDA registration number and agrees, that in some cases the submitter will not be registered with the FDA. For example, many food importers intend to delegate prior notice submission to Customs Brokers. In other cases, the submitter will not know (and be denied access to) the registration numbers of other entities identified on the submission such as the manufacturers and shippers. However, when FDA registration numbers are available and known, a keystroke entry of the number should be sufficient data for FDA purposes. The entry of the corporate name in the subsequent field will provide sufficient validation to assure FDA of an appropriate linkage. The proposal notes that “header” information will permit repeated information to be automatically entered. This is critical to efficient submission. In addition, FDA technology should automatically populate the

information fields following the registration number or, alternatively, link to the facility registration database should more detailed information become necessary.

The submitter fields should be immediately followed by the fields related to the importer, the responsible party for this submission.

5. Customs Information: Entry Type, Customs Code, Customs Entry Number

The Bioterrorism Act specifically mandates consultations between FDA and U.S. Customs Service. In comments submitted to FDA in August 2002, NFPA strongly urged FDA and Customs to work cooperatively towards seamless integration in order to avoid duplicative and redundant submission burdens on the trade. In fact, FDA indicates that substantive dialogue with Customs has transpired but still issued a proposal that precisely duplicates much of the existing data submission to Customs including the Customs entry, carrier and product code information. All of these elements are already provided to U.S. Customs that, as identified in FDA's proposal provides entry information to FDA via its Automated Broker Interface (ABI) of the Automated Commercial System (ACS) that is downloaded into FDA's Operational Administrative System for Import Support (OASIS) from which FDA currently makes decisions to hold food entries. In addition, Customs is proceeding concurrently along separate paths towards mandating electronic submission of manifest data **prior** to entry. This duplication of redundant information already supplied to Customs should be eliminated from the form unless specifically required by the Act.

Customs Entry Number: This number is not always available to importers at the identified time period. It will be particularly problematic for products arriving by air transportation in time to accommodate the prior notice time frames. In many cases, importers would need to request pre-assigned entry numbers through Customs Brokers, adding to confusion and possibly error. Consequently, this field should be a voluntary field. A unique identifier may also be helpful in this regard to allow the Customs Brokers to link prior notice submissions when the entry occurs.

FDA has provided a data field for "baggage" even though FDA has proposed that food products arriving in traveler's baggage should be exempt from prior notification requirements. NFPA suggests this field be deleted.

6. Article Held Under FDA Direction

This set of data fields should not be placed on the first page of the form. It confuses the submitter as he strives to complete the mandatory information fields, again adding unnecessarily to the reporting burden. The first line of the form

appropriately indicates that the submission involves a “held” article. NFPA is assuming that in most cases, the article has been held due to failure to submit timely or complete prior notice. In such case, the submission form would require completion with the additional information on the location of the hold. Therefore, it would be most appropriate to place that information at the end of the data submission or in a clearly identified section for completion by submitter “when appropriate.”

NFPA will file subsequent comments to FDA on “held” articles and related appeal process.

7. Product identity

The statute mandates information regarding the product identity but not in the detailed manner indicated on the submission form. NFPA will file substantive comments to state that this degree of detail is not necessary for the purpose of the proposal, cannot be achieved within the designated time frame and will correspondingly increase the need for amendments to submissions.

Regarding the form, FDA indicates that you must provide as much of this information as is available by noon the preceding day. If not available, you must indicate amendment to follow. FDA recognizes that some information may not be applicable including lot or code numbers or trade names. Importers have also expressed confusion about the definition of trade names and codes. NFPA does not believe this information is usually necessary to identify a product intended for entry and believes these fields should be identified as voluntary.

FDA Product Codes: This form should provide for the simultaneously submission of several products with different codes that may be arriving in the same shipment. Furthermore, similar products with different common and usual names may have the same FDA product code but will also be arriving in the same shipment. One submission should be able to accommodate a variety of products for the same importer.

Quantity: NFPA will provide subsequent comments stating the need to amend product quantities in order to accommodate existing operational practices. In order to minimize amendments related to product quantities, NFPA recommends that FDA allow for an estimate, a maximum or a range to satisfy the specific information related to quantity. NFPA stresses that this detailed information is not necessary for the purpose of this proposal (e.g. FDA does not need this information.) and will greatly increase the reporting burden for industry.

Measure: First, NFPA suggests that the size of the package is immaterial to identify the presence of intentional contamination or a food safety hazard. Second, NFPA notes that FDA uses “package size” in the proposal. Finally, NFPA believes this level of detail is not necessary to meet the statutory requirements. Unless FDA can clarify why this information is needed to satisfy the purposes of the Act, it should be eliminated or indicated on the form, as voluntary.

Lot identification: Food processors limit lot sizes in order to minimize the exposure in case adulterated product is later identified and a recall necessitated. Food processed on “second shift” may be immediately loaded into trucks for cross border shipment. Consequently, lot numbers would not be known until that afternoon (after the required prior notice submission). Again, this information is not necessary to satisfy the purposes of the Act; will necessitate ability to amend or significant operational adjustments by the industry consequently increasing the reporting burden significantly. These fields should be voluntary.

8. Manufacturer

Previous comments state that even though a food manufacturer is required to register with FDA; the submitter may not know registration numbers and the information may be denied to him. However, when the registration number is entered (as with the submitter), the name of the firm and the registration number should be sufficient data; technology should provide for population of the remaining data by FDA.

9. Grower

In many cases, especially when further processed foods or ingredients are imported, the growers will not be known. Furthermore, because the raw materials have been modified and transformed through processing, the identity of the growers becomes irrelevant. Consequently, these fields should be identified as “Growers, if known” appropriately corresponding to FDA’s proposal, and should be indicated as voluntary fields

The field questioning the number of additional growers is confusing and should be eliminated. In cases, where there may be a large number of known but ever changing growers but the extent of the reporting obligation in such a case is unclear.

In all cases, the information fields should be limited to name and location. Detailed information on growers is not necessary to satisfy the mandate of the Act or the purpose of this proposal.

Furthermore, the entire section on growers is out of order on the submission form. It should follow other more pertinent information related to the identity of the importer, the originating country and carrier.

10. Originating Country – Shipper – Country of Shipment

NFPA questions FDA's definition of country of origin and will submit subsequent comments on this issue.

NFPA also suggests these data elements are also out of sequence. More reasonable, the country of shipment would follow the originating country and precede the information about the shipper. Again a shipper with an FDA registration number should not be required to manually file all the following data elements.

11. Arrival Information

NFPA will file more substantive comments related to providing arrival information according to the proposed time frame. Specifically related to the submission form, NFPA suggests this set of data elements should be on page one (1), not Page three. The Port of Entry with Customs Code and anticipated arrival time should be sufficient for FDA purposes. Furthermore, the port of entry code should automatically populate the city, state information. In addition, NFPA notes a need to allow for alternative border crossings to prevent unnecessary backups at border points. Requiring importers to provide border-crossing information will prohibit truckers from entering through alternative crossings in close proximity to avoid backing up traffic at border points. The current practice facilitates cross border traffic and maximizes the use of resources and personnel at border points. NFPA recommends FDA eliminate the data fields for border crossing. Alternatively it should be voluntary or provide flexibility for more than one entry points or "update."

Particularly for sea cargo, the prior notice submission should provide an opportunity to link update information onto manifest data. In this manner, when a vessel changes entry information, a single "manifest update" by the carrier would simultaneously update all the prior notice information in the cargo without requiring individual "update" submissions by each importer. This process would maximize the use of available resources and reduce the potential for error.

12. Importer

NFPA points out that the importer is the party responsible for prior notice submission, yet he is not identified until page three (3) of the submission form following a great deal of other informational significantly less critical to targeting risk-based inspections. This data set also requires the FDA registration number if available and, consequently, NFPA also suggests that the following information elements are already available to FDA and should not require manual re-entry for this submission.

13. Owner, Consignee

Request for information regarding these parties is beyond the scope of the statutory mandate, and unnecessary for the purposes of this proposal. NFPA asks, “owner of what?” Why would an owner differ from an importer or purchaser? In which situations would this information become necessary? In addition, NFPA points out that consignees are often customers of the importer and may be considered proprietary information. Consignees are often third party warehouse or cold storage facilities.

Furthermore, FDA points out that “in order to minimize confusion” under 1.278 (d), it is the “carrier or the person who submitted the prior notice” who must make arrangements for the movement of the food and it is the purchaser, owner, importer, or consignee that is responsible for expenses. Consequently, only the two responsible parties are relevant to prior notice information requirements. NFPA encourages FDA to eliminate these alternative data fields from the form. Specifically, only the responsible parties, the necessary contact points for FDA to identify the product at entry should be included on the prior notice. Information about additional parties, places an undue burden on the submitter and goes beyond the scope of FDA’s information needs.

15. Carrier

NFPA agrees that information related to the carrier will be helpful to locate inbound cargo when a need for hold or inspection is identified. However, NFPA points out that the specific information requirements about Standard Carrier Abbreviation Code will not likely be available for inbound truck loads until after the truck has arrived for loading. It will often not be available for inbound air cargo. Because air cargo is frequently “bumped” to other carriers for weight distribution reasons, importers may not even know carrier information until after entry. Consequently, if FDA remains firm on the prior notification time frames, opportunities to update or amend this information must be provided to meet operational practices and to assure timely delivery of perishable food products.

FDA has provided data fields for three carriers. Does this mean that one prior notice would be filed for a large shipment that filled 3 truckloads? If this is the case, how are these 3 identical truckloads linked through the prior notice, and subsequently at the border crossing?

For purposes of locating cargo at entry, the only pertinent carrier is that arriving at a U.S. port. NFPA suggests deleting these additional data fields. The information is not relevant for the purpose of this proposal.

16. Amendment to Follow – Cancel this Submission

These data fields are entirely out of sequence. Amendment to follow should, as indicated earlier be included in the first set of data fields identifying the intent of the submission. That set of data fields already includes “cancel.” How does the first “cancel” differ from “cancel this submission?”

Compatibility to Customs

FDA has indicated that the current data entry system duplicates the submissions to U.S. Customs ACS but that this duplication is intended to be eliminated when U.S. Customs Automated Commercial Environment (ACE) when it comes on line in 2005 with the capacity to handle FDA’s prior notice requirements. In that regard, NFPA urges the submission form and data to be reviewed by OMB to ensure compatibility to facilitate a seamless integration. The food industry looks forward to that opportunity when a few keystrokes can accomplish data requirements for both Agencies without reinventing the process and procedures.

Analysis of Economic Impacts

Research: NFPA believes that the economic impact of filing has been grossly underestimated. First, FDA estimates that the initial time to research prior notice requirements will be one hour (with internet access) of an administrative worker’s time. NFPA points out that this is a new and extremely complex and confusing new regulatory procedure. The consequences of error are extreme; potentially resulting in held or lost product perhaps down time of a production line and subsequent loss of business sales and revenue. The initial research into the proposal already has numerous corporate executives scrambling to evaluate operational changes necessary to accommodate this rulemaking. This proposed regulation is not a simple paperwork exercise; it is a complex reporting procedure that will entail significant management oversight prior to delegation to agents or administrative staff.

Entry Lines: FDA used OASIS data to conclude that 4.7 million entry lines for food were imported into the United States in FY 2001. FDA fails to consider that the new

regulations would mandate prior notice reporting for categories that may never have been filtered through OASIS under the previous system including the packaging components, and alcoholic beverages.

FDA estimates 4.7 million OASIS entries, averaging 2.6 lines each and notes that a prior notice will be required for each line. FDA then divides the entries by the lines to determine the number of prior notices. NFPA disagrees with this calculation; 4.7 million must be multiplied by 2.6 “articles of food” under the current proposal to determine prior notice, yielding a total of 12.22 million prior notices.

Form Completion: NFPA agrees that, once research is complete and a pattern is established, it would take approximately one hour to complete a full prior notice; 15 minutes for the manager and 45 minutes for the administrative worker. This calculation, however, does not take into consideration the time necessary to assemble and verify the detailed information on the proposed form. This will require prior communications with Customs and Carriers as well as the supplier, including verification of purchase orders and related contracts.

In addition, FDA has failed to appropriately take into consideration the time involved in amending and updating the information. Many importers from Canada and Mexico indicate that every prior notice will require amending and updating.

Many U.S. importers are likely to delegate prior notice filing responsibilities to Customs Brokers (agents). A preliminary estimate for a broker’s time would be \$50.00 to file and \$20-25.00 for each amendment or update.

Finally, the extent of manual data entry that will be required, and whether the form can accommodate several products in the same shipment will have a significant impact on the actual administrative time required to file.

Impact on Importers: FDA estimates that this regulation will affect 77,427 importers. FDA has failed to consider that this rule will also affect a large number of foreign suppliers and carriers who will have to adjust reporting procedures and scheduling to accommodate the time frame imposed by this new rule. In Table 24, FDA extrapolates (using the entry line assumption referenced above) that these importers will file an average of 23.3 prior notices annually. Under NFPA calculations (based on the current understanding of reporting requirements); FDA would receive over 12 million prior notices or well over 150 prior notices a year per importer. Clearly, many large importers will send several shipments across borders each day. A single shipping container with a variety of products, will also, under the proposal, require several prior notices. According to FDA’s calculations, an importer would receive less than two (2) articles per month on average (not a realistic number).

Summary

In conclusion, NFPA believes that the economic data are flawed and that FDA has grossly underestimated the burden on importers (and other affected parties) in prior notice submissions.

NFPA believes the data elements and fields on the submission form are excessive and extend beyond the scope and intent of the statutory mandate or that necessary to identify a product at entry. NFPA believes the form is confusing and that data fields are inappropriately sequenced. Mandatory and voluntary fields should be clearly indicated. This confusion adds significantly to the reporting burden. Several product identifiers should be permitted on each submission form. Finally, it is difficult to assess the electronic reporting burden from the paper format.

The following fields are beyond the scope of the mandate or the proposal, will unnecessarily increase the reporting burden and should be eliminated:

- Redundant fields to identify submitter
- Baggage
- Number of additional growers
- Border crossing information
- Owner
- Consignee
- Carriers 2 and 3

The following fields should be added:

- Cancel an anticipated amendment
- Tracking number for form
- Additional fields for several products in same submission
- Field to identify "low-risk" status.

The following fields should be clarified:

- Amendment (product identity)
- Mandatory if applicable
- Measure
- Cancel and Cancel this Submission

The following fields are not required to meet the statutory mandate or necessary to satisfy the objective of FDA's proposal. They should be eliminated. If FDA determines to retain them they should be identified as voluntary:

- Registration numbers
- Customs Entry Number

- Lot codes
- Trade Names
- Measure
- Lot Identification
- Grower
- Border Crossing
- Consignee

NFPA appreciates your consideration of these comments and will file subsequent comments on the substance of the FDA proposal in a timely fashion.

Sincerely,



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