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The Food Safety People

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FOOD

PROCESSORS

ASSOCIATION

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July 13, 2004

VIA EMAIL

Dockets Management Branch
Mail Code HFA-305
Food and Drug Administration
Rm 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 2002N-0278 Reopening of Comments Period on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Joint Food and Drug Administration and Customs and Border Protection Plan for Increasing Integration of Prior Notice Time Frames

Dear Sir or Madam:

The National Food Processors Association (NFPA) appreciates the opportunity to comment again on the interim final rule on provisions of The Public Health Security and Bioterrorism Preparedness and Response Act (The Bioterrorism Act). On August 30, 2002, and again on December 24, 2004, NFPA submitted comments urging a seamless integration with existing systems to minimize unnecessary, multiple or redundant notifications. On March 5, 2003, NFPA submitted comments to the Office of Management and Budget (OMB) specifically related to the information collection aspects of the proposed rule. On April 3, 2003, NFPA identified burdensome and ineffective requirements of FDA's proposed rules and suggested reasonable alternative solutions to reduce the impact on trade in food products. Today's comment takes into consideration the experience of food companies during the first six months of the phased in implementation of prior notice and highlights some remaining concerns that will have adverse implications on trade and business operations, if not resolved. NFPA offers possible solutions to facilitate compliance with the new rules and trade in food products.

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

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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 are affected by the rulemaking that has been mandated under the Act.

General Comments

NFPA's earlier comments strongly supported the ongoing dialogue with the Bureau of Customs and Border Protection (CBP) to integrate federal reporting requirements and allow food importers to submit prior notice information through the Automated Commercial System (ACS). NFPA continues to urge FDA to work to integrate and coordinate time frames. The integration of time frames is particularly important for shipments by truck originating at close border points.

NFPA also urged FDA to recognize and facilitate trade for low-risk shippers, citing existing CBP programs like Customs Trade Partnership Against Terrorism (CTPAT) and Free and Secure Trade (FAST). Recognized benefits for partnering with the trade community will advance U.S. security goals while allowing better targeting of agency enforcement resources. NFPA responds to FDA's questions in the following comments.

Finally, NFPA emphasizes significant concerns related to the mandatory elements required to provide prior notice for imported food samples intended for research and development. NFPA strongly reiterates that a solution must be identified to allow U.S. food companies to import samples from unregistered foreign companies for product research and development (R & D). Lacking such a solution, food companies will be forced to discontinue certain aspects of research or relocate R & D facilities to other countries, putting U.S. food companies at a competitive disadvantage globally and eliminating many key research functions, positions and laboratories. NFPA has described several viable solutions to this dilemma that would not compromise FDA's statutory obligations.

Integration of Prior Notice Time Frames

On April 2, 2004 and again in May 2004, FDA published compliance summary information on prior notice. The summary indicates that over 150,000 prior notices were received each week since February; that number has been increasing. The summary also indicated that 88% of prior notice is filed through the ACS system. Therefore, it is clear that integration of time frames will reduce resource demands on the food industry, brokers and border officials. Consequently, NFPA strongly supports moving forward with data analysis and integration of time frames as proposed.

As noted previously, integration with CBP time frames for cross border truck traffic would be the most beneficial to the food industry. This would allow operators at close border points to load and verify truck loads and travel routes prior to submitting notice,

eliminating much of the “estimation” necessary for this type of shipment under current rules and potentially improving compliance data for truck carriers. NFPA also notes that food importers, cleared through the 801 (m) section of the Food Drug and Cosmetic Act, must still await “may proceed” clearance under the 801(a). As a next step, NFPA recommends that FDA evaluate possible integration of the 801(m) clearance and the 801(a) release to provide the food industry and consumers with the confidence of FDA approval of imported food entering domestic commerce.

Integration of time frames is a reasonable and achievable goal. The Bioterrorism Act of 2002 and the Trade Act of 2002 were enacted by Congress for the purpose of improving the safety and security of products and vehicles entering the United States. The Bioterrorism Act mandates FDA to choose timeframes that are “no less than the minimum amount of time necessary for the Secretary to receive, review and appropriately respond to such notification.” The Trade Act of 2002 mandates the collection of information to be used for ensuring “transportation safety and security” and mandates that regulations imposed shall take into consideration the extent to which the technology necessary for parties to transmit and the Customs Service to “receive and analyze data in a timely fashion.” In addition, under the Trade Act, the Secretary is required to balance the timing for transmittal of information with the “likely impact on flow of commerce.” In order to maximize the limited use of regulatory resources and to reduce the redundancies of reporting requirements, FDA and CBP appropriately entered into an understanding to enable shared enforcement of the provisions of the prior notice requirements.

Taking into consideration the similar statutory provisions, utilization of identical technology (for 88% of the entries), and often the same personnel resources, NFPA questions the need for different time frames for the two agencies to receive and react to similar information. As NFPA understands, the initial targeting process is computer based. Prior notice reaction times may depend upon computer load and volume of submissions, but identification of suspicious products to be “held” for further evaluation would presumably be a matter of moments rather than hours. NFPA is confident that “safety and security” analysis on all product categories could be achieved within an identical time frame.

As FDA suggests, better evaluation of factors related to prior notice submissions since December 12 is important. FDA indicates that the “evaluation of whether to reduce the timeframes for prior notice review will depend on the level of compliance industry achieves during the assessment.” FDA’s recent compliance summary indicates “very few” entries had no prior notice, signaling a good attempt by food importers to comply. The summary also highlights very low compliance rates on specific data elements such as carrier data on land/truck submissions and manufacturers’ registration numbers on all shipments.

The food industry previously detailed the problems related to obtaining specific data within a specific time frame (or, in some cases, at all). FDA should consider these factors when evaluating industry compliance, and whether the compliance rates and accuracy would improve under the CBP time frames. FDA should also evaluate other reasons for non-compliance, such as the need for additional discretion on data and education.

FDA has indicated, in publishing the interim final rules, that the discretionary enforcement period would emphasize outreach and education. NFPA strongly endorsed that approach believing it appropriate and necessary for improving compliance and preventing trade disruption. Nevertheless, following the first six months of this “educational” period, the feedback to the industry has been seriously lacking. The “summary” information released in April provides general information about the pattern of submissions and the level of compliance but no details about errors or inaccuracies that would be useful for improving an importer’s reporting procedures. Companies can only assume that, lacking other information, that their prior notice submissions are complete and accurate. Industry remains concerned about “surprises” on August 12 that may detain their products at the border or disrupt trade due to noncompliance by other importers. In this regard, NFPA urges better and more open communication with industry including (but not limited to): an industry/agency working group, improved technical staffing on the “hotline,” and prompt information to submitters regarding inadequacies or inaccuracies in notice.

NFPA urges FDA to extend the discretionary enforcement period until detailed analysis and industry feedback can be provided on submissions for each mode of transportation and each reporting system. NFPA would also support taking steps to phase in integration by mode of transportation to avoid unnecessary “holds” on food products at the border that would disrupt trade.

Reopening of Comments Period on Prior Notice

Samples for Research and Development

In all previous comments, NFPA has stressed that requiring manufacturer registration numbers for imported samples for research and development will undermine a manufacturer’s ability to conduct legitimate business operations and reduce his ability to compete globally. NFPA disagrees with FDA’s interpretation of the statutory mandate in this regard. NFPA points out that the regulations developed under the Bioterrorism Act for facility registration regulates food intended for consumption within the United States. FDA has interpreted the prior notice rules to apply more broadly to imported “food” for all purposes, thus creating an impossible situation for U.S. food companies importing products for research purposes from foreign facilities that never intend to do business in the United States.

The lack of flexibility regarding registration numbers has also adversely affected the ability of U.S. companies to recall exports. For example, FDA regulated products like soups and extracts were rejected by foreign countries following the identification of BSE in the United States. These products were detained in various holding facilities pending direction from suppliers. Storage facilities that would not normally be shipping to the U.S. would have no obligation to register. Consequently, importers were unable to satisfy mandatory prior notice requirements to promptly recall this product to the U.S.

NFPA has urged FDA to provide an exemption from prior notice for products that are not destined for commercial or retail consumption within the United States, particularly for products intended for research and development. FDA has exempted food sent as personal gifts. In FDA's recent Questions and Answers Edition 2, FDA justifies that exemption as follows; "FDA recognizes that in these circumstances, the sender who purchased the food as a gift may not have the manufacturer/producer registration number." Likewise, NFPA requests that FDA recognize, in circumstances where research samples have been purchased at retail, the sender may not have the registration number, or, under FDA's rules, the company may not be required to be registered.

In fact, food safety and security considerations are even better satisfied in the context of food samples than with respect to food gifts. While the ultimate consumer of food gifts will not likely be traceable, the distribution of food samples for research and development purposes will necessarily be controlled and tracked in order for the samples to serve their commercial purpose. In the unlikely event that such a food sample becomes associated with a serious health risk, distribution can be shut down quickly, and anyone who may have been exposed to the product can be notified promptly.

In earlier comments, NFPA referred to the interim final rules and FDA's conclusion that it is appropriate to exclude food contact materials. In reaching this determination, FDA conducted an analysis pursuant to *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842 (1984), asking first whether Congress had directly spoken to the precise question of the definition of food. Finding that Congress was silent as to the meaning of "food" in the Bioterrorism Act, FDA concluded that the term was ambiguous. FDA then conducted a Chevron step two analysis to determine a permissible construction of the term, and concluded that food contact materials could be excluded.

The same Chevron analysis readily can be applied to the issue of providing registration numbers for samples. The first question is whether Congress has spoken to the issue. The Bioterrorism Act requires a prior notice submission to provide "the identity of each of the following: The article, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of entry." The statute does not prescribe how the identity of the manufacturer must be provided, and therefore Congress has not spoken to this issue. Accordingly, FDA is entitled to deference in crafting a permissible construction of the statutory requirements. Just as the agency determined

that manufacturer registration numbers need not be provided for food sent as gifts, FDA could likewise allow the manufacturer of samples to be identified by means other than the registration number.

NFPA stresses that the Bioterrorism Act requires a prior notice submission to identify the manufacturer. The statute does not mandate a manufacturer's registration number. Consequently, NFPA asserts that a prior notice for food samples would be deemed legally sufficient using any of the following alternative solutions:

- FDA could provide an alternative prior notice in a simplified version (that does not require manufacturer registration numbers) for products that are shipped to the U.S. and not intended for public consumption or sale;
- The manufacturer's registration number could be replaced by other identifying information such as the manufacturer's name and address;
- The manufacturer's registration number could be replaced by the registration number of the importing manufacturer who is ultimately responsible for the shipment and final use of the product;
- FDA could require registration numbers for **either** shipper or manufacturer. This alternative would provide FDA with information to enable enforcement of foreign facility registration without imposing unnecessary and unobtainable information burdens; it would also allow a U.S. manufacturer to recall product to the U.S. when necessary without unnecessarily registering a "shipper" or allow U.S. companies to ship samples from sales offices abroad.

At most, any of these alternatives would require only a simple technology adjustment to identify a specific shipment category: samples for research and development.

The prior notice regulation could easily be amended to accommodate this change merely by addressing food samples as well as gifts in section 1.281(a)(6), to read as follows: "If the article of food is sent by an individual as a personal gift (e.g., for non-business reasons) to an individual in the United States, or is imported as a sample for research and development purposes, you may provide the name and address of the firm that appears on the label under 21 C.F.R. 101.5 instead of the name, address, and registration number of the manufacturer."

As stated, failure to accommodate this specific situation will make legitimate food research and product development impossible within the United States. The requirements will force domestic firms to move research and development operations to other countries, such as Canada, where consumer attitudes and tastes are similar and where research samples can be delivered without unnecessary barriers. U.S. laboratory facilities that currently test products for foreign manufacturers will be unable to continue providing analytical service to their customers. Lacking flexibility in the registration requirement, U.S. companies, in some instances, will be unable to recall products to the U.S. for analysis when a potential problem is identified. Finally, because of the usual delays and

problems related to providing information for shipments of samples, companies report that commercial shippers have resorted to assessing a \$10.00 FDA/Customs clearance fee. In fact, samples that are not intended for consumption should be deemed low risk products and processing at border points should be facilitated.

The statute expressly provides that FDA may consider the types of food imported into the United States and the effect on commerce when determining the specified periods of time required for prior notice. While these considerations are addressed in the context of the prior notice timeframe, they reflect the fact that Congress placed great importance on ensuring that the regulations do not force changes in existing import practices that are not justified by commensurate increases in the safety and security of the food supply. Identification of the manufacturer of food samples by means other than the registration number would address the particular circumstances surrounding importation for this type of food and would satisfy the many considerations behind the Act's prior notice requirement.

In addition to the negative impact on American business, NFPA asserts that by stifling product development and research as well as laboratory analysis of food products from global sources, FDA undermines the intent and objective of the Act: to improve the security and safety of the U.S. food supply. Product analysis that could identify possible food safety problems will become more difficult.

Recognized Benefits for Low-Risk Shippers

Also in previous comments, NFPA urged FDA to rely on CBP's existing targeting programs and to recognize security systems already in place that identify low-risk shippers and pointed out that many food companies are participating in Customs Trade Partnership Against Terrorism (CTPAT) and are using the Free and Secure Trade (FAST) carrier transport across the Northern borders. These companies have realized benefits through improved clearance times at the border and improved communication from CBP when a problem arises or random or repeated sampling occurs. These successful public/private partnerships have allowed CBP to take a risk-based approach to improve security, while maximizing the use of limited Agency resources.

NFPA appreciates FDA's consideration of these programs and strongly agrees that food products should be eligible for full-expedited processing and transmission benefits allowed with C-TPAT and FAST. In addition, NFPA encourages FDA to consider low risk status to expedite 801(a) deliberations.

In response to FDA's specific questions:

CT-PAT / FAST

1. NFPA strongly agrees that food products should be eligible for full-expedited processing and transmission benefits allowed with C-TPAT and FAST. A

memorandum of understanding between FDA and CBP would be appropriate to allow the sharing of necessary information with the understanding of the applicant. Time frames for FDA low risk programs should be consistent with those used by Customs. Risk based assessment entails both random and “targeted” inspections of border entries. CTPAT approval removes several of the usual “targeting flags.” Consequently, CTPAT participants have benefited by a decrease in “targeted inspections.” Even more significant, CTPAT approval establishes a communication contact between applicant and CBP that is used for intervention in border inspections facilitating resolution. FDA facilitator of “may proceed” decisions could use a similar approach.

2. In assessing low risk status, FDA should rely on CBP’s successful programs and avoid “recreating the wheel” or imposing new and potentially inconsistent criteria on food companies.

Flexible Alternative Questions

1. FDA asks if flexible alternatives would be needed for food imported by other agencies. NFPA is working with other agencies to facilitate the safe import of food products. NFPA notes that prior notice for food is not required by USDA.
2. Voluntary participation in CBPs programs has been a key contributor to their success. CBP has provided “common sense” guidelines for application and has relied on applicants to develop a plan for supply chain security that is designed to address the critical control points for specific product and production facilities. Gaining approval under CBPs scrutiny is rigorous and time-consuming.
3. Companies eligible to participate in low-risk programs should have an updated registration; verification of that registration would be useful in determining low-risk status.
4. Inspections and reviews of companies in the supply chain of a CTPAT participant should be limited to verification of information provided in the approved security plan unless such inspections are warranted under other FDA requirements or procedures.
5. Unless, FDA can identify food specific factors related to supply chain security systems not currently assessed under the CBP evaluation process, there would be no need for FDA to impose additional criteria to allow importers to also achieve low risk benefits under prior notice. If additional “food” criteria are deemed necessary by FDA to augment the CBP programs, these criteria should be flexible enough to accommodate the specific company/product needs and not undermine programs already approved by CBP. FDA asks if food product category should be considered in eligibility for low-risk status. CBP programs allow the applicant to design a security program around the company needs. CBP then reviews the plan according to Agency guidelines. NFPA sees no reason for a specific product category to be excluded from eligibility if the applicant can demonstrate a secure supply chain.
6. FDA asks if time frames should be phased in. NFPA believes that phasing in time frames consistently with CBP would be appropriate. As noted previously, cross

border truck traffic would achieve the biggest benefit from integration of time frames.

7. FDA specifically asks if training programs for submitters and transmitters and brokers should be offered. NFPA believes that additional training programs may be appropriate following a detailed analysis of compliance issues where training could be targeted to specific problems and their solutions. Priority should be given to identifying and training entities that have only recently begun filing with CBP or FDA because of the new prior notice requirements.

Simplify the Prior Notice Systems Interface (PNSI)

After some months of experience with prior notice, companies continue to report technical difficulties in using the PNSI, including the inability to access reliable technical advice through the hot-line. In addition, they indicate that the system is unnecessarily complex in that it requires the complete recreation of all data for each prior notice even when shipments are repetitive with minimal variables in information. NFPA recommends, that the PNSI should allow submitters to save and store data for replication or provide for self-populating fields and that better technical support should be made available to submitters.

Extend Discretionary Enforcement Period

Finally, NFPA strongly urges FDA to extend the discretionary enforcement period until December 12, 2004. This is particularly important for those importers who work with seasonal products that are only imported in late summer or fall. Providing a full year for education and outreach assures that those importers of commodities shipped only during specific months are provided an equitable opportunity to learn the process. FDA's most recent compliance information indicates that this time has been productive for educating educate food traders and regulators and has provided an opportunity to evaluate review and response time and to identify elements affecting the accuracy and timeliness of filing and response. However, NFPA believes that the very low compliance rate of carrier data on truck entries indicates the need for additional education and outreach.

As indicated previously, most food companies have received no feedback from FDA or CBP on prior notice submissions and the analytical data is not yet sufficient to determine the degree of accuracy or reasons for incomplete data. Some sources indicate that border officials have provided confusing and inconsistent instructions. Other sources indicate extreme confusion among foreign suppliers.

More education is appropriate for submitters, transmitters, brokers and carriers following a detailed analysis of compliance issues including some aggressive feedback to submitters that are experiencing compliance problems. The detailed analysis should be made available to all stakeholders. Training programs can only provide added value after a detailed evaluation of data identifies existing problems and their solutions.

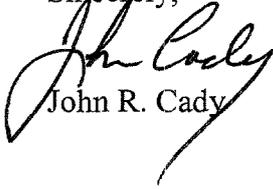
Summary

NFPA is committed to the important goal of protecting the nation's food supply against intentional contamination and welcomes the opportunity to work with FDA during the next months while rules are implemented and finalized. NFPA commends FDA and CBP for building a cooperative relationship and for continuing to integrate notification systems to minimize the disruption to trade and business operations.

However, NFPA is extremely concerned about FDA's inability to identify a reasonable solution to accommodate entry of samples for research and development. Product research and development is critical to business success and to achieving the common goal of safe, high quality foods. Innovative food products also build U.S. exports. Lacking a satisfactory accommodation for imported research samples, this critical component of the domestic food industry will be largely forced "offshore" or potentially out of business.

Thank you for your consideration of these comments.

Sincerely,



John R. Cady