



American Bakers Association

Serving the Baking Industry Since 1897

May 14, 2004

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Michael S. Craig
PGA Coordinator
Bureau of Customs and Border Protection
1300 Pennsylvania Avenue, N.W.
Room 52C
Washington, D.C. 20229

Re: Docket No. 02N-0278 – Comments On Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 -- Reopening of Comment Period (69 Federal Register 19763 (April 14, 2004))

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. The ABA and its members appreciate the opportunity to submit comments to the Food and Drug Administration (FDA) on the Interim Final Rule, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

ABA appreciates FDA's unprecedented approach to design a workable plan for prior notice for importation of food to allow the smooth flow of commerce across international borders to continue. The Agency's utilization of a graduated enforcement policy using discretion has assisted bakers as they become educated and accustomed to these new food security requirements.

This additional comment period is well timed, giving the industry an opportunity to share comments on new and continuing issues of concern regarding the new Prior Notice System (PN System) and offer constructive input on how to improve on the new system. As we expected, ABA members and their suppliers have experienced problems in the interface between the Bureau of Customs and Border Protection (CBP) Automated Broker Interface (ABI) and the FDA PN System. In some instances, the impact on companies has been severe and disruptive. Nonetheless, ABA believes that solutions to these problems are relatively simple and operational in nature

American Bakers Association
Docket No. 02N-0278
May 14, 2004
Page 2

and can/must be achieved at the computer interface level. Other issues ABA members are encountering are much more substantive and are reflective of systemic weaknesses in the PN System. ABA respectfully urges FDA to consider its comments below and incorporate ABA's recommendations into the final prior notice rule.

FDA Prior Notice System Interface (FDA PNSI)

ABA believes that FDA needs to enable automated data submission from submitters to the FDA Prior Notice System Interface (FDA PNSI). Currently, PN submissions require double entry of much of the information required by the FDA PNSI. Many companies have an automated order entry system that contains most of the information required by the FDA PNSI. Unfortunately, the FDA PNSI requires re-entry (double entry or double handling of data/information) for much of the same information that is already part of a company's automated order entry system. It is currently costing companies either (1) additional personnel resources to input the information in the FDA PNSI, or (2) costing additional charges from its customs brokers by the company sending the information required to complete a PN to the customs broker for them to enter in the Bureau of Customs and Border Protection (CBP) Automated Broker Interface (ABI) system. Companies must then wait on the customs broker to return the PN Confirmation Number which is required for the carrier to cross the border with a shipment. Currently, requests to FDA for such support (automated data entry in the FDA PNSI) have been responded to with comments that the FDA PNSI is restricted for security, and therefore, they have refused to work with exporters/importers to enhance the efficiency of the system. FDA needs to be more responsive to the industry's FDA PNSI issues for the system to work effectively, efficiently and in a fiscally responsible manner.

Reconciliation of New and Old Regulations

ABA also sees a need for the Agency to reconcile old regulations with new ones to avoid duplication of effort. Most notably is the 'Hold Intact Notice' issued by the broker when a food material passes through the border when FDA agents are not on duty. There should be a method of automatically issuing releases for low risk food materials produced by reputable manufacturers. Since FDA has prior notice of the material crossing the border, the Agency has an opportunity to notify the broker if they wish to sample or inspect shipment materials. If FDA does not avail itself of this opportunity in advance to identify shipments for inspection, sampling or detention, then ABA believes that FDA should allow the shipment be permitted to pass and be delivered without delay. Without the Agency's reconciliation of regulation duplications, the smooth flow of commerce will continue to be disrupted.

Broker Training

Additionally, ABA strongly encourages FDA to establish a broker training program to educate and enhance communications between the Agency and brokers who are encountering

issues when submitting many of the prior notices for imported shipments. ABA believes that such a training program would greatly improve fully electronic notice compliance levels.

ABA Endorsement of the National Coalition of Food Importing Associations (NCFIA)

Besides the comments above, ABA is in full agreement and endorses the comments submitted by the National Coalition of Food Importing Associations (NCFIA) for the reopening of the comments for Docket Number 02N-0278.

Specifically, ABA endorses NCFIA's comments regarding suggested changes for the final prior notice rule:

- ∅ Exemption for pre-purchase and trade samples imported for research/development purposes and laboratory and/or organoleptic analysis;
- ∅ Resolution of PN/ABI system problems so that CBP entry and prior notice need not be made at the same time. Resolution of this timing problem is especially critical because for many foods, prior notice must be submitted before entry can be made (e.g., for quota class merchandise subject to CBP "live entry" requirements) and current system configurations can make it impossible to comply with both CBP and prior notice requirements;
- ∅ Resolution of PN/ABI system problems so that CBP entry can be made for articles of food that are already in the United States;
- ∅ Provision for FDA to communicate refusals and rejections to the importer, and to the ultimate consignee, if different, and to the electronic filer, if different, as well as the carrier;
- ∅ Establishment of a system for swift resolution of technical and operational problems;
- ∅ Establishment of a system that validates data and resolves conflicts between CBP and FDA databases;
- ∅ Resolution of the problem of duplicate prior notice filings;
- ∅ Provision for correction of errors in prior notice submissions, so long as corrections are made prior to passage of the 2, 4 or 8-hour deadline;
- ∅ Improvement of the capacity of the FDA Prior Notice Internet System Interface; and
- ∅ Better FDA communication to, and involvement with, the importing community.

American Bakers Association
Docket No. 02N-0278
May 14, 2004
Page 4

Before FDA begins enforcing the prior notice requirements, ABA is interested in learning from FDA about inaccuracies and problems the agency is detecting in filed prior notices. It is suggested that FDA inform the filer electronically of the nature of any deficiencies in a filed prior notice. Alternatively, the agency could post on its website a description of the types of errors most commonly observed in prior notice filings.

Furthermore, it is recommended that after full enforcement has been in place for 90 to 180 days, that FDA re-open the comment period for an additional 60 days. With the benefit of a period of active FDA/CBP enforcement and surveillance, the food import community will be better able to offer informed comments to FDA on the PN System. FDA will also be in a better position to evaluate the degree to which the PN System is achieving its stated goals and any new problems. Only after this period of full enforcement and additional comment would FDA then issue a final rule covering prior notice of imported food shipments.

ABA also endorses NCFIA's responses to the specific questions raised in FDA's comment re-opening notice on the series of questions regarding the PN System, timeframes for the submission of prior notice, importations by government agencies, and consistency with other CBP programs, including Required Advance Electronic Presentation of Cargo Information, the Customs-Trade Partnership Against Terrorism (C-TPAT) and the Free and Secure Trade (FAST) program.

Further, ABA also supports NCFIA's comments to FDA regarding the flexible alternative questions that includes the key issue of exemption for pre-purchase and trade samples imported for research/development purposes and laboratory and/or organoleptic analysis. This is a serious issue for the baking industry.

ABA appreciates this opportunity to comment on the reopening of this interim final rule on prior notice for imported foods, which is of great interest to the wholesale baking industry. The Association is hopeful that the issues and concerns outlined above regarding a variety of prior notice issues will be useful to the Agency as it moves forward to finalize its policy in this area. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,



Paul C. Abenante
President & CEO
American Bakers Association