American Bakers Association

Serving the Baking Industry Since 1897

December 19, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0278; Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
68 Federal Register 58893 (October 10, 2003)

Dear Sir/Madam:

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 purpose of this letter is to voice our comments and questions in response to the Agency's interim final rule regarding prior notice of imported food.

While ABA appreciates the efforts FDA has made to make this rule workable for industry, there are still several questions and strong concerns that remain. In our comments below, ABA has outlined these concerns for FDA's consideration.

FDA Communications with Industry after October 10, 2003

Communications from FDA to industry from the publication date of the interim final rule on Oct. 10, 2003 through Dec. 12, 2003 were extremely poor. Substantive questions from ABA and its member companies on specific inquiries were unanswered after repeated calls to FDA regarding how industry could comply with this regulation. Calls to the FDA Furls help line, and e-mails to furls@fda.gov with questions on how industry could submit prior notice were replied to with either a "call back" message or a standard form reply that included no substantive answers to specific critical questions asked by industry.

While ABA welcomed FDA's issuance of its "compliance policy guide", the Association was disappointed by the delayed issuance on December 11, 2003. This December 11 issuance date, one day before the implementation date, was entirely too late to address the

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legal questions for requirements on how industry should comply with prior notice as part of the law / Bioterrorism Act of 2002 law (BTA). Such FDA guidance and communications should have been part of the Oct. 10, 2003 interim final rule on prior notice.

Foreign food industry exporters were placed in a seriously compromised position whereby legally their products could have been (and still may be) refused entry into the U.S. because FDA did not provide timely notice of how to comply. This fact remains a serious issue for food exporters shipping products into the U.S. as the BTA law requires compliance, even though FDA may not be prepared to or may chose not to enforce the law/regulation. In fact, ABA notes that this compliance policy guide is prefaced with the statement "contains nonbinding recommendations." FDA has placed foreign suppliers for food products in an inexcusably compromised business position whereby foreign manufactures must rely on the voluntary discretion of FDA for the unimpeded transport of their products into the U.S. This is completely unacceptable.

Scope

ABA believes that the inclusion of trade and quality samples falls outside of the intent of the Bioterrorism Act of 2002 for purposes of prior notice. Quality assurance and quality control samples are sent to a small and distinct group of people in a limited quantity. Such samples would not be a tool to terrorize the public. Further, if quality assurance samples or quality control samples were tampered with or adulterated, there are already federal anti-tampering laws that would apply. Prior notification for samples would not improve the government's response if the samples were adulterated since the distribution is already contained. ABA believes in the case of trade and quality samples, the notification process would burden both industry and government with additional work to process prior notifications with no added public health benefit.

Trade Barriers

Just as ABA outlined in its previous comments submitted to FDA on April 3, 2003, regarding the prior notice proposal, the interim final rule's prior notice requirement still effectively imposes a "trade barrier" on foreign food exporters supplying food products to the U.S. Clearly, this requirement places an undue competitive disadvantage on foreign suppliers versus U.S. domestic suppliers. Many ABA member foreign owned companies have received numerous requests from U.S. customers to locate U.S. domestic sources for products they supply from foreign sources, strictly based on the threat of restricted supply from foreign sources resulting from the prior notice requirement.

Additionally, ABA foreign owned member companies require information from FDA to enable their automated order entry system to also automatically submit the required information to the FDA Prior Notice System Interface. Requests submitted to FDA for this information have thus far been unanswered. Automation of this process is critical for these businesses, as the current system requires additional personnel resources to prepare prior notice documents. These additional resource requirements result in additional costs that make it more difficult for foreign owned businesses to remain competitive with U.S. based suppliers.

Requirements for U.S. Agents for Foreign Manufacturers are Unclear

Requirements for U.S. Agents for foreign manufacturers are still unclear. This requirement has resulted in significant expense to businesses that may in fact be unnecessary. Clarification should be added to the final rule to state that foreign manufacturers may use any suitable U.S. agent as a contact for their business, and provide mailing address, phone and fax numbers for contact purposes. It should be clarified that the U.S. Agent is not required to be available 24/7 if a separate emergency contact is also provided.

Additionally, it should be clarified that only the emergency contact for foreign manufacturers should be available 24/7, and that this person or persons may be located outside the U.S. as long as they are available 24/7.

Release Forms – Border Issue

Currently, FDA has a practice of requiring food shipments that cross the Canadian/Mexican borders into the U.S. to be held without distribution until a release form is issued if an FDA inspector is not on duty. In the past, these release forms were issued within 24 hours, but recently the process has taken significantly longer, taking up to one week, greatly disrupting commerce and in some cases interrupting production in facilities. It appears to ABA that the new prior notice would give FDA border inspectors the information needed and therefore, the older practice of release forms should be eliminated as it is redundant and obsolete in light of the new interim regulation.

In closing, ABA notes that FDA can continue to count on the full support of the baking industry in its mission to protect the American public and supply them with a safe and wholesome food supply. The livelihood of the baking industry is predicated on the delivery of these products. ABA and the entire food industry wants and should be

considered partners in this mission, not as outsiders, if the system is to work effectively and efficiently.

ABA appreciates this opportunity to comment on FDA's prior notice of imported food final interim rule. The Association is hopeful that the detailed concerns outlined will be useful to FDA as the Agency moves forward to finalize policy on this issue. 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,

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