



American Bakers Association

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April 3, 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 5428 (February 3, 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 these comments is to voice our strong concern/opposition to the agency's recent prior notice of imported food proposal.

While ABA appreciates the efforts FDA has put forth in trying to develop a comprehensive and thorough approach to prior notice of imported foods, none the less, this proposal clearly goes too far in prescribing excessive requirements that would negatively impact the efficient delivery of ingredients and processed foods into interstate and global commerce. The impact of such a proposal would undoubtedly hinder the smooth flow of imports and would dramatically disrupt commerce as we know it today. Continuation in this direction as the rule is finalized, would be devastating to the businesses of bakers and their suppliers alike. ABA questions whether this proposal serves as an appropriate means to the stated goal and whether costs associated with such a proposal are outweighed by their usefulness in accomplishing the objectives of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

ABA understands that FDA's top priority must be to insure proper focus on the security of goods imported into the United States, as well as, security of those goods while moving through interstate commerce so that consumers can be assured of a wholesome and safe food supply. ABA is hopeful that its comments addressing issues of workability and rational, efficient transport of ingredients and finished bakery products will assist the agency as it moves forward to finalize this important policy.

Statutory Requirements

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ABA understands that FDA's proposed rule must meet the statutory requirements included in Title III of the Bioterrorism Act and Section 801(m) of the Federal Food, Drug and Cosmetic Act

(FDCA). These provisions require that prior notice of imports be submitted to FDA for the purpose of enabling the food to be inspected by the Agency at ports of entry into the United States. The rule is intended to enhance FDA's ability to deter, prepare for, and respond effectively to, bioterrorism and other public health emergencies that might result from imported food. ABA notes that, should FDA fail to meet its self-imposed deadlines to finalize a rule before the statutory deadline of December 12, 2003, the Bioterrorism Act provides that prior notice of not less than eight hours and not more than five days will go into effect December 12, 2003 and remain in effect until changed by FDA final rules on the subject.

Congressional Intent

ABA notes that within the report that accompanied the final Bioterrorism Act, there was language that appears to express an intent that food packaging and other food contact substances not be subjected to the prior notification requirements for imports, unless food is already packaged in it. Additionally, the language offered by Congressman John M. Shimkus (R-20-IL) to clarify the report language said,

“Section 307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances if, at the time of importation, they are not used in food.”

Based on this language, ABA strongly believes that FDA has gone beyond the congressional intent of the statute. The inclusion of food packaging and food contact substances such as equipment, replacement parts for machinery and sanitizing solvents greatly expands the breadth of the proposed regulation and will unduly clog the ports of entry with hundreds of thousands of additional imports to be examined. This additional reporting will burden not only industry but will disproportionately burden FDA staff and resources that simply will not be able to swiftly and effectively move these products through ports of entry into interstate commerce. Such a scheme will also require industry to carry the expense of additional insurance for perishable products and storage costs for goods awaiting clearance.

FDA projected numbers for the quantity of prior notice imports to be received per day (20,000) is a gross underestimate for food products and ingredients alone not to mention additional food contact substances that potentially could be captured under the proposal.

ABA is concerned that FDA's application of the prior notice of imports proposal to manufacturers of food contact materials, beyond food and ingredients, overreaches FDA's exercise of enforcement discretion. The congressional intent of this provision was clear that food packaging and other food contact articles are to be excluded from the prior notification for imported foods requirement. Traditionally, such items have been outside the scope of FDA's

prior approval authority under the food additives amendment, but it appears that FDA is now trying to set a precedent by treating all firms that manufacture materials that may contact food similarly, for purposes of prior notice. ABA estimates that this additional group of potential products would at the least quadruple the number of products that would need to submit prior notice and would saddle the already burdened notification field with tens of thousands of additional products creating an unmanageable workload.

Additionally, in the report language accompanying the Bioterrorism Act, Congressman Shimkus emphasized that it was the congressional intent for the Secretary of Health and Human Services (HHS) to exercise discretion to ensure that neither the requirements nor the timing of prior notice be more burdensome than necessary to provide for the ability of food port inspectional personnel, nor should such requirements become a barrier to the smooth flow of commerce. Further, the language directed the HHS Secretary to consider the effect on commerce of time periods; locations of various ports of entry; various modes of transportation and the types of food imported into the United States. Clearly, this language emphasizes that the congressional intent was for the HHS Secretary to exercise discretion in these areas. Undoubtedly, the restrictive time constraints included in FDA's proposal attempts to micro-manage trade and will subsequently slow imports and interstate commerce significantly, crippling the global marketplace.

Timing Mechanisms for Prior Notice

Based on the congressional intent for the requirements of the Bioterrorism Act outlined above, ABA supports the statutory language calling for an 8 hour minimum requirement and five day maximum for prior notice.

ABA believes strongly that the shortened early/late arrival timeframe that FDA discusses in its proposal (one hour early and three hours late) is extreme and unmanageable, creating a great resource burden for staff and generating an immense amount of additional paperwork for both FDA and industry. Moreover, the limited time scheme that FDA proposes will drastically slow or even stop the smooth flow of commerce over the borders without providing any real benefit for security. ABA recommends that the three hour late provision be dropped as it is unreasonable and over burdensome and proposes that late arrivals not exceed a 5 day window to stay within the statute.

Following the requirements of the statute, ABA recommends that FDA allow an eight hour minimum notice prior to shipment arrival at the port of entry. FDA's proposal of notice by noon the day prior for shipment arrival in actuality is a twelve to thirty-six hour time frame that is unworkable, especially for perishable and just-in-time shipments which are currently common practice for baking industry flow of ingredients and products.

Clearly, FDA has given little thought to the impact of its proposal on perishable products such as bakery products. With the anticipated dramatic slow down of trade and flow of products

and ingredients across U.S. borders, there will be a great impact on freshly baked products and "just in time" deliveries of vital ingredients that are currently a standard industry practice to assure timely product delivery. It will be imperative for the FDA border inspectors to expand their current work schedule of Monday through Friday; under the new scheme, FDA boarder inspectors will be needed seven days per week, 24 hours per day.

Canadian export statistics to the United States in 2002 indicate that overall imports into the U.S. were \$410 billion (Canadian) and agricultural imports were \$30 billion (Canadian). This is just one country's statistics illustrating the overwhelming amount of import business that is conducted annually. FDA's suggestion that each shipment be timed within a four-hour scheduling period for transporters to arrive at the boarder, is overwhelmingly unreasonable and would prove to slow or even stop the normal flow of trade.

Existing International Trade Regulations

ABA is very concerned that FDA's new proposal is redundant based on existing U.S. Customs requirements. Since coordination of the two systems will not be available until at least 2005, that guarantees double reporting work for industry and government reviewers.

ABA is very concerned that FDA's proposed rule for prior notice of imported foods appears to ignore the difference between sea/air ports and land border points. While it takes longer amounts of time for goods to be shipped great distances, it takes very little time for food to be shipped from Canada or Mexico into the United States. Creating an immense, slow moving border between Canada/Mexico and the United States equates with creating borders between two states where commerce has been seamless in the past. Businesses are fully integrated on both sides of the border after many years of successful and cooperative development, supported by such government initiatives as the North American Free Trade Agreement.

The proposed rule could result in a barrier being erected at land borders that will cause severe damage to food businesses on both sides of the border. ABA recommends that FDA study the details of the actual situation at the land borders so that its proposed rule allows an uninterrupted, efficient flow of perishable goods to continue.

Further, it appears that FDA has given no consideration to reviewing international trade security developments. For instance, there are indications that the European community is beginning to develop food security traceability policy. ABA strongly encourages FDA to work together with other trading partners to ensure that a fair and equitable food security system that supports international trade be developed among the nations. To not proceed in this fashion, could well raise questions of infringements/violations of existing bilateral customs agreements.

Consideration of Safe History

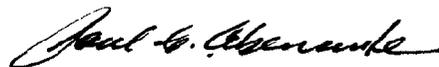
While ABA understands the importance of reviewing questionable shipments that are not well-documented, we believe that credit should be given to historically responsible importers who have demonstrated effective and successful systems of secure transport; their methods for an effective and safe routine should be studied and put into practice by others. Many ABA members ship product and ingredients across the U.S. border daily in a responsible manner, and have done so for years. FDA's final rule should recognize these efforts and include a provision that could serve as an incentive to importers who have proven themselves.

ABA notes that current U.S. Customs programs including the Customs Trade Partnership Against Terrorism (C-TPAT) and the newly created Free and Secure Trade Program (FAST) are successful government-industry partnerships. The FAST program includes an expedited release for qualifying commercial shipments. ABA believes that this successful approach is one that FDA should consider as it progresses towards developing a final policy that can effectively and efficiently move products into the United States.

In closing, ABA notes that FDA can 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 proposal. 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,



Paul C. Abenante
President & CEO
American Bakers Association