American Bakers Association

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July 8, 2003

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

Re: Docket No. 02N-0275; Administrative Detention of Food for Human Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
68 Federal Register 25241 (May 9, 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 concerns regarding the agency's proposed rule regarding administrative detention of food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

ABA appreciates the efforts FDA has put forth in trying to develop a comprehensive, streamlined approach for expedited procedures for detained perishable and non-perishable foods, as well as, the related appeal process. Since FDA already has the statutory authority to detain foods, ABA agrees that there should be clear and straightforward procedures for both detention and appeal that can be easily utilized by government and industry. Based on this objective, ABA will set forth in its comments recommendations to FDA that we believe will make the system more rational and workable for all parties involved.

FDA's top priority must be to insure proper focus on food security so that consumers can be assured of a wholesome and safe food supply. ABA is hopeful that it's comments addressing issues of workability and rationale for detention will assist the agency as it moves forward to finalize this important policy.

02N-0275

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Workability Issues

Definition of Perishable

ABA strongly believes that for the definition FDA uses in its detention proposal for "perishable" is not reasonable or workable. For this reason, ABA proposes the currently existing NIST Handbook 130 Regulations for Uniform Open Dating Definition for Perishable; Semi-Perishable and Long Term Shelf Life be applied this as the final rule is formulated. These definitions have a history of use and acceptance by industry and government alike. These definitions are:

- "Perishable Food means any food for which a significant risk of spoilage, loss of value, or loss of palatability within 60 days of the date of packaging"
- "Semi-Perishable means any food for which a significant risk for spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 minimum of 60 days, but within 6 months, after the date of packaging"
- "Long Shelf-Life means any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than six months after the date of packaging , including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container"

Expedited Appeal Process

Based on ABA's recommendation to use the NIST Handbook 130 Regulations for Uniform Open Dating Definition for Perishable; Semi-Perishable and Long Term Shelf Life, ABA appreciates FDA's attempt in timing for an expedited appeal process for both perishable and long term shelf life foods. Since ABA recommends a three tier approach adding the semi-perishable food category, the baking industry believes it would be appropriate to treat those foods in the same manner as perishable for appeal purposes.

At the same time, ABA questions the need for this additional rulemaking since it appears that FDA considers the threshold for detention to be equivalent to the standard for initiating a Class I recall. ABA notes that the proposed language is identical to the regulatory standard for such recalls, and the agency explained in its economic impact analysis of the proposal that without administrative detention, FDA would have likely initiated a Class I recall for such serious threats.

Authority to Detain

Based on the serious nature of administrative detention, ABA strongly believes that such decisions should be made by official at the regional FDA director level or higher. ABA is concerned that FDA intends to allow judgment of credible threats on a case-by-case- judgment creating an un-level field of authority. Additionally, based on this fact, ABA does not think that state officials should have the right to detain products unless it is approved by the respective regional FDA directors or more senior level FDA officials because of the cost implications and serious business impact such action would cause. FDA should realize that it would be very unfair for industry to bear the cost of product lost due to unjustified or unnecessary retention of product.

Economic Impact

Since bakery products generally have a very short shelf life, ABA is concerned that even a short detention, such as the one FDA proposes for perishable foods, is likely to have serious economic impact on business and in all likelihood, will render detained bakery product unmarketable.

Communications to Industry

ABA is very concerned that FDA has not devised a way to communicate with key industry officials regarding essential information in the event of a food security event that in some cases could be sensitive and/or classified. If information is classified, how will FDA clearly communicate the cause for detention? To effectively respond to FDA's concerns of a serious threat, companies and FDA will benefit from having specific details regarding such situations. Industry is highly motivated to cooperate with FDA to protect consumers and maintain national security interests in the event of a real threat. For this reason, it will be imperative that FDA and industry work together as a team to quickly address such occurrences. Therefore, ABA strongly recommends that FDA devise a clear communications strategy and that the agency should test such plans to make sure that they will work seamlessly.

Establishing Standards and Procedures to Ensure Constitutional Rights Implicated by the Bioterrorism Act are Fully Respected and Enforceable in Actual Practice.

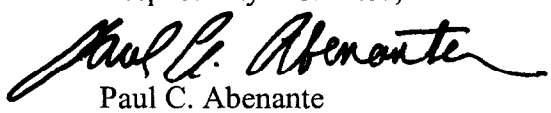
In the ABA comments filed on the FDA proposal concerning the establishment and maintenance of records [Docket No. 02N-0277] as well as here, ABA urges the agency to establish evidentiary standards and procedural safeguards through rulemaking to ensure that the constitutional rights of the regulated industry are respected and enforceable as a matter of actual practice. During the implementation of the Nutrition Labeling and Education Act of 1990 (NLEA), ABA urged FDA to take seriously its obligations under the First Amendment and implement the NLEA in a manner that respected the constitutionally protected freedom of speech of the public and the regulated industry. Despite the strong body of Supreme Court case law supporting these comments, the agency implemented the NLEA in a manner that ignored the

First Amendment, and justified its approach by arguing that the unique public health issues presented by health claims made the First Amendment standards advocated by the food industry inapplicable to the rulemaking process. After years of intractable NLEA policies that infringe the free speech rights of the industry and public, FDA now is engaged in the remedial steps required to begin to reform its policies to conform with First Amendment standards.

ABA urges FDA to take seriously its obligations to abide by the constitution and integrate the evidentiary standards and procedural safeguards into the regulations implementing the Bioterrorism Act from the beginning, including with respect to administrative detention. ABA urges FDA to take a holistic approach which examines together the new inspection and enforcement authorities established under the Bioterrorism Act, including records access and administrative detention authorities. As discussed in our comments on the FDA proposal concerning the establishment and maintenance of records, there are critically important Fourth and Fifth Amendment standards which are implicated in defining the circumstances in which the government is authorized to conduct a search of business records, and the scope of records that can be lawfully be examined by the government in responding to the public health need presented. Since administrative detention authority also is triggered in the context of FDA inspection and sampling authorities, ABA urges the agency to ensure that the evidentiary standards and procedures adopted satisfy applicable Fourth Amendment and other constitutional requirements. In particular, ABA urges the agency to examine the "credible evidence" standard with reference to Fourth Amendment and related evidentiary standards developed in case law, and not to rely on a superficial reading of the statute or a plain language interpretation drawn from Webster's Dictionary. The "public health triggers" defining FDA authority under the Bioterrorism Act are critically important jurisdictional provisions with authorize extraordinary intrusions and control over private commercial property, including product subject to administrative detention. ABA urges the agency to place the highest priority possible on the establishment of clear evidentiary standards and procedures to ensure that the constitutional rights of the regulated industry are respected and can be enforced in the ordinary course of business.

ABA appreciates this opportunity to comment on FDA's administrative detention proposal. The Association is hopeful that our detailed concerns 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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