Representing, Educating and Promoting the Restaurant/Hospitality Industry

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NATIONAL RESTAURANT ASSOCIATION®

December 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Founded in 1919, the National Restaurant Association is the leading trade association for the restaurant industry. Representing more than 60,000 members and over 300,000 restaurant outlets in 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands, the National Restaurant Association has always supported government security enhancement of the nation's food supply. The restaurant industry has invested billions of dollars in the last two years to improve food security and food safety. Our efforts have clearly made a difference in protecting our nation's food supply.

We have a direct and vested interest in the final interim rules regarding the Registration of Food Facilities and Prior Notice. We fully support the need and intent of the 2002 Bioterrorism Act, and we commend the Agency for attempting the very difficult task of developing registration and prior notice guidelines for the multiple diverse food industry segments. We believe that the Agency truly attempted in the interim final rules to clarify the regulations' intent and include modifications that make the rules more user friendly without sacrificing food security.

While the interim requirements include vast improvements from the original proposals, we remain concerned with several provisions. As written, the registration rules would require "facilities who manufacture/process, pack, or hold food for consumption in the United States" to register with the FDA. The FDA has made it clear that this requirement would be imposed upon research and development facilities: "Under section 305 of the Bioterrorism Act, facilities are required to register....Therefore, R&D facilities and sample facilities that manufacture/process, pack, or hold food that is consumed in the United States, either by the facility's employees or others are required to register." In addition, foreign producers of foods used within U.S. R&D facilities would be required to register and provide prior notice of import when sending samples to companies within the U.S.

We have concerns with this interpretation and ask that the FDA fully consider the impact of this requirement upon the food industry and R&D testing in the U.S. The imposition of the new rules upon these facilities has the potential to force corporations to relocate their R&D units outside of the United States because of the challenges and higher costs associated with importing products for research or testing purposes only. The foods used within R&D facilities are not intended nor used for public consumption. As such, the

Bioterroism Rules strict application of both the registration and prior notice rules are overreaching and unnecessary. We strongly believe that the negative, unintended consequences of this requirement upon R&D facilities within the restaurant and food industry were not the intent of Congress when establishing the Bioterroism Act. We strongly request that FDA reconsider the negative impact this strict interpretation will have on U.S. R&D facilities and employees in the U.S. Due to the very limited nature of the food consumption, we believe a R&D and food testing only exemption is warranted.

We are also concerned that FDA did not incorporate into the prior notice rules a small quantity exemption. FDA is making no exceptions for even the smallest quantities of food coming across US borders via common carriers such as United Parcel Service or FEDEX for testing or otherwise. A growing number of restaurants import very small quantities for their daily specials or dining events via package delivery. The current rules make no concession for low risk status importers, small quantities or very small businesses. The burden of prior notice for respondents could be minimized if FDA reduced the information collected to only that which is absolutely necessary for tracking and exempted small quantities of food shipped on common carriers. The FDA should consider a limited blanket exemption for our largest direct trading partners in Canada and Mexico which are under similar security controls. Small quantity shipments imported from these neighboring countries via package delivery, requiring complex pre-notifications will place a large burden on small business owners nationwide who rely on Mexican and Canadian producers for their fresh catch of the day menu items.

We strongly recommend that the FDA consider incorporating into the final rules a limited exemption for very small quantities of food under 80lbs or 100 bottles of liquid or less and consider a general limited exemption to our trading partners in Canada and Mexico. Taking a large number of low risk imports out of the initial system of tracking could greatly improve the entire pre-import system and greatly reduce the economic impact and burden on small businesses.

We are hopeful that these comments will be fully considered prior to the release of the final rules. The National Restaurant Association would like to offer our assistance in helping the FDA determine the true impact of these rules and develop appropriate alternatives.

Thank you for the opportunity to submit these comments. Please feel free to call our Health and Safety Regulatory Affairs Department with any questions you may have regarding this issue, at (202) 331-5900.

Sincerely,

Steven F. Grover, R.E.H.S.
Vice President, Health and Safety Regulatory Affairs

cc: Steven C. Anderson, President and Chief Executive Officer
Lee Culpepper, Senior Vice President, Government Affairs and Public Policy