

PETE SESSIONS
32ND DISTRICT, TEXAS

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December 16, 2003

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

Dear Sir or Madam:

As you know, Congress charged the Food and Drug Administration (FDA) with implementing The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The Act). Today, I understand that the FDA is proposing final regulations implementing two sections in Title III of the Act regarding Registration of Food Facilities, and Prior Notice of Imported Food shipments. I am writing today to state for the public record that the present FDA interim requirements implementing these two sections of The Act could adversely and directly affect employment in my congressional district.

While the interim requirements implementing these two sections in Title III of the Act include vast improvements from the original proposals, I 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 as follows: "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, it is my understanding that 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.

I 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. before making these interim regulations permanent. 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 Bioterrorism Rules strict application of both the registration and prior notice rules are overreaching and unnecessary. I 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 Bioterrorism Act.

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Therefore, I strongly request that the 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, I believe an "R&D and food testing only exemption" is warranted. I recommend that this "R&D and food testing only exemption" apply to the importation of small quantities of food (200 pounds or less) used for testing.

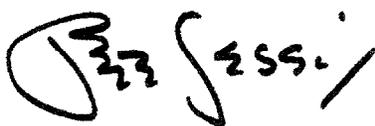
I am also concerned that FDA did not incorporate into the prior notice rules a "small quantity exemption". FDA is making no exceptions for even the smallest quantities of food coming across US borders via common carriers such as United Parcel Service or FEDEX for testing or otherwise. As you may or may not know, 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.

Therefore, I 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.

I expect these comments will be fully considered prior to the release of the final rules. I look forward to working with you on these difficult yet important issues. You may either contact me directly with any questions you may have concerning my positions outlined in this letter, or, on the staff level, please contact Tucker Anderson, my Legislative Director at 202.226.8429.

Sincerely,

A handwritten signature in black ink, appearing to read "Pete Sessions". The signature is stylized and includes a large loop at the beginning and a long horizontal stroke at the end.

Pete Sessions (R-Dallas)
Member of Congress