



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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The Honorable Charles W. "Chip" Pickering
House of Representatives
Washington, D.C. 20515-2403

AUG 20 2003

Dear Mr. Pickering:

Thank you for your letter of June 26, 2003, regarding a proposed rule published by the Food and Drug Administration (FDA or the Agency). As you know, the proposed rule is necessary to implement Section 307, Prior Notice of Imported Food Shipments, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). You expressed concern that the proposed rule applies to food shipments that are in transit and are not intended for domestic markets. Your letter indicates that the World Shipping Council has asserted that this is inappropriate.

FDA appreciates your comments regarding the proposed rule. Similar concerns were raised during the public comment period. We will carefully consider this issue as we develop the final regulation.

The prior notice provision of the Bioterrorism Act expressly applies to "an article of food that is being imported or offered for import into the United States." In our proposed rule, we stated that this means it applies to all food that is brought across the U.S. border except food carried in a traveler's personal baggage for personal use. We further stated that "FDA believes that food that is brought into the United States to be put into foreign trade zones, or for transshipment or reexport immediate or otherwise, is 'imported or offered for import' and thus must comply with the prior notice requirements."

The comment period on this proposed rule closed on April 4, 2003. FDA conducted extensive outreach, both domestically and abroad, during the public comment period to ensure that affected parties were aware of the proposed requirements and could provide meaningful comment to the Agency for us to consider. The Agency has received numerous comments on this proposal and is considering them as we develop the final regulation to implement this provision of the Bioterrorism Act. We have forwarded your correspondence to our Dockets Management Branch for inclusion in the docket for this matter.

02N-0278

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Thank you again for your letter. We appreciate your interest in FDA's food safety and security activities. If you may be of further assistance, please let us know.

Sincerely,


 Amit K. Sachdev
Associate Commissioner
for Legislation

cc: Dockets Management Branch (HFA-305)
Docket No.: 02N-0278