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Food and Drug Administration
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RE: Docket Nos. 02N-0278 -- Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The Customs and International Trade Bar Association (CITBA) welcomes the opportunity to comment on the Food and Drug Administration's (FDA) proposed rules to implement the prior notice of imported food provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). CITBA is a bar association consisting of attorneys practicing primarily in the area of customs and international trade law.

CITBA strongly supports national efforts to reduce the risks of bioterrorism. However, we would like to emphasize the need for the rules governing importation of food to be clear, consistent, and well coordinated with the various other regulatory regimes that already exist. The security and protection that is achieved by the Bioterrorism Act will be maximized only if the system takes into account the realities of commercial operations, and is understandable and logical to the thousands of affected importers. Furthermore, Congress was clear in passing the Bioterrorism Act that an appropriate balance must be achieved between the need for additional security and the needs of industry in facilitating legitimate trade. Without such a balance, the proposed rule has the potential not only to increase import costs significantly and unnecessarily but also to delay and impede the import of products that are regulated by the rule.

As a general matter CITBA is concerned about the numerous inconsistencies between the requirements proposed by the FDA's notice and the existing Bureau of Customs and Border Protection (CBP) definitions and practices. These differences in treatment are likely to lead to widespread confusion and compliance problems, and undermine the

security improvements made in recent CBP initiatives. For this reason, CITBA strongly supports the initiative announced by FDA and CBP to explore ways to improve coordination between the two agencies.

In particular, CITBA urges the two agencies to permit importers who are participants in the Customs Trade Partnership Against Terrorism (C-TPAT) and Free and Secure Trade (FAST) programs to comply with their prior notice obligations in a manner that does not undermine the benefits of participation in these programs. C-TPAT and FAST improve U.S. security on a number of levels, including the risk of bioterrorism, and help focus limited border resources on higher risk cargo. FDA and CBP should therefore be careful not to remove incentives for participation in these programs by making importations of food items more cumbersome than other types of entries. The companies participating in these programs have made a substantial commitment to improving security by putting in place appropriate security systems, and submitting to periodic review of those systems by CBP. We believe this would also assist the FDA in prioritizing shipments for scrutiny and in delegating resources to those shipments where increased scrutiny is merited and/or the shippers and carriers are not known. Coordination in risk analysis should be further explored; for example, FDA might follow the CBP model wherein C-TPAT membership is a positive factor in risk assessment for specific shipments.

CBP has recognized the superiority of an account-based approach to commercial compliance as well as security. Account-based approaches are superior because they focus limited resources on higher risk areas. A shipment-by-shipment approach to security risk analysis imposes tremendous burdens on traders and regulators, and does not permit a meaningful assessment of security risks given the high volume of expected shipments. For these reasons, CITBA urges the FDA to continue discussions with CBP in regards to the security systems they already have in place.

CITBA is grateful for the efforts that the FDA has made so far to create a workable Prior Notice system that balances food security with the realities of the import trade. Thank you in advance for your attention to the issues raised in this letter.

Respectfully submitted,

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