

June 3, 2005

**Comments by the Government of Japan on the United States' Compliance Policy Guide
regarding Prior Notice of Imported Food Under the Public Health Security and
Bioterrorism Preparedness and Response Act of 2002
(Docket No. 2003-D0554)**

The Government of Japan has filed comments on three occasions on the United States' interim Final Rule of "Prior Notice (PN) of Imported Food" (hereinafter referred to as "the Rule") under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The requests made to the U.S. Government in the comments have also been reiterated in the series of discussions between the two Governments under the "Japan-U.S. Regulatory Reform and Competition Policy Initiative."

While the comment period for the interim Final Rule is already over, the Government of Japan, by filing comments to the Compliance Policy Guide, hereby recapitulates and submits the concerns and requests it has made so far, in order to make a constructive input to the Food and Drug Administration's (FDA) work in finalizing the Rule and its future implementation. The Government of Japan strongly wishes the following points to be ensured to the maximum in the Final Rule. If it is truly difficult for the U.S. Government to incorporate them into the Final Rule for the time being, the Government of Japan requests the U.S. Government to implement them at least operationally and lower the level of burden on food senders complying the rule in foreign countries.

Mail users are requested to submit a Prior Notice to FDA through FDA's PN System Interface. This system allows only those who can readily use the Internet and can understand English well to send foods to the U.S. by mail, and leaves out others to suffer unreasonable inconvenience and receive unequal treatment. Based on this recognition, the Government of Japan requests the U.S Government to:

- (1) Ensure not obliging non-commercial senders of food for non-commercial purposes to be subject to the Prior Notice requirement, not only as an implementing interpretation of the Rule under the "Compliance Policy Guide," but also as an explicit provision in the forthcoming Final Rule;
- (2) Explicitly stipulate in the forthcoming Final Rule to exempt food shipped by retail store or other commercial shippers on behalf of non-commercial individuals from the Prior Notice requirement, if the non-commercial nature of the shipped food is clearly declared on the parcel;
- (3) Establish an interface system of the FDA's Prior Notice System that will accept completion of the Prior Notice procedure in major languages including Japanese;
- (4) Put in place necessary arrangements for delivering food-containing mail items to the address following FDA or U.S. Customs inspection even if a Prior Notice number does not properly accompany the items;

- (5) Ensure the full implementation of the above points at United States Customs to prevent refusal of food importation through the discretionary decision of customs inspectors (While the majority of non-commercial users of express delivery service understand that Prior Notice is not required in shipping food for non-commercial purposes, some containers including food without Prior Notice number have been actually suspended at U.S. Customs, for which the deliverer was obliged to compensate the senders.); and
- (6) Establish a contact point at the United States establishments in Japan at which Japanese nationals could inquire in Japanese about compliance matters with the Prior Notice rule, and inform food processors, the Japan Post, commercial transport service providers and Japanese nationals of the latest status of the Rule without delay through appropriate means including the website of the United States Embassy in Japan.

In filing these comments, the Government of Japan expresses its confidence that it is in the interests of both Governments to ensure both the security and the efficiency of physical distribution.