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**Comments by the Government of Japan on the United States' Interim Final Rule "Prior Notice of Imported Food Shipments" Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
(DOCKET No. 2002N-0278)**

The Government of Japan appreciates the opportunity to provide comments as follows on the United States' Interim Final Rule of "Prior Notice of Imported Food Shipments" (hereinafter referred to as "the Rule") under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereinafter referred to as "the Act"), published in the United States' Federal Register October 10, 2003 and notified to the WTO dated October 16, 2003 (G/SPS/N/USA/690/Add.2).

1. The Prior Notice (PN) based on the Rule must be applied on an item-by-item basis for exporting products. If a lot for one export is large, application on hundreds or thousands of items needs to be made respectively at one time. Therefore, however simplified the application procedure may become, it is apparent that, in the beginning phase of implementation, food exporters will be obliged to take a considerable length of time to properly understand the procedure that are different from the previous one as well as to write and review a massive amount of documents concerned. Nonetheless, as the PN system will not work until the actual start of implementation, it will be very difficult for parties concerned in Japan to fully conform to the Rule. So as to avoid such a situation, the Government of Japan request the U.S. Government to provide sufficient period of time for parties concerned to prepare for further changes of the Rule, if any in future.
2. After the Rule was publicized, it does not seem that the U.S. Government has made sufficient explanation of the Rule to individuals who intend to send food products as international packages or bring them into the U.S. by themselves. The Government of Japan urges the U.S. Government to start informing them immediately of the details of the Rule for their better understanding.
3. The Government of Japan requests the U.S. Government to issue brochures explaining procedures on the Rule in Japanese and to establish contact points for consultation in Japan so that Japanese people can make inquiries about the Rule in Japanese, and to continue to hold seminars to promote their comprehension of the Rule. It will facilitate the U.S. Government in implementing the Act and applying its Rule smoothly to Japanese food manufacturers, which include many small and medium-sized enterprises.

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4. As to containers, customs clearance agents or transporters transmit a PN through the existing Automatic Broker Interface operated by the U.S. Customs and Border Protection Bureau (CBP-ABI/ACS). Mail users are, on the other hand, required to file a PN by themselves to the FDA through FDA's PN system Interface and to state the PN number on customs notice forms. This means that only those who can access to the Internet and can understand English may be able to send foods to the U.S. by mail. The Government of Japan recognizes that, due to this restriction, a number of mail users (especially Japanese users) will suffer exorbitant and unnecessarily complicated burden and responsibilities in sending foods under the Act.

Moreover, mail items containing food without a PN Confirmation Number will be detained at the port of entry into the U.S. for 72 hours, and then be destroyed or returned to the sender under the Act. However, food products contained in mail items without PN Confirmation Numbers do not necessarily fall under the classification of "articles of which the importation or uttering is prohibited" in the U.S. Rather, prior notices have been merely neglected in such cases. As postal services are globally recognized to be handiest means of delivery that should be secured as a minimum social infrastructure, the Government of Japan believes that such a requirement under the Rule is extremely stringent.

The Government of Japan therefore strongly requests that the U.S. Government take the following measures:

- (1) Simplify the PN requirements through FDA's PN System Interface for mail users;
- (2) Deliver mail items containing food, even if the contents are not accompanied by PN Confirmation Numbers, to the addressees as long as the U.S. authorities find no problem with the contents at border inspection; and
- (3) Accept PN by fax and mail other than the Internet.

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米国におけるバイオテロ対策のための食品安全規制の強化に係る日本政府のコメント
—輸入食品発送の事前通知—
(DOCKET No. 2002N-0278)

米国の「公衆の健康安全保障及びバイオテロへの準備及び対策法（2002年6月成立）」に基づき、最終規則案の一つである「輸入食品発送の事前通知」に関し、日本政府は、10月10日付で米国官報に掲載され、10月16日付でWTO・SPS通報（G/SPS/N/USA/690/Add.2）された当該施行規則案（輸入食品発送の事前通知）に対し、コメントを行う機会が提供されたことに感謝する。以下は、日本政府のコメントである。

1. 事前通知は輸出品のアイテムごとに申請しなければならないため、輸出ロットの規模が大きい場合には数百～千単位のアイテムを同時に申請しなければならない。したがって、いかに簡素化された申請手続きになったとしても、規則施行時には、従来とは異なった手続き方法を理解し、膨大な関係書類を作成・見直すために相応の日数を要することは明らかである。にもかかわらず、事前通知システムは、最終規則の施行直前まで稼働しないため、我が国の関係者は本規則への対応を困難としている。今後、そのような状況を回避するため、規則変更が生じた場合には、十分な準備期間が設定される必要がある。
2. 最終規則案が公表された後、米国政府からは、食品を発送あるいは持ち込もうとする個人への本規則の十分な説明がなされてきたとは思えない。そのような個人の本規則への理解を促進するため、早急に個人向け周知を開始するよう要望する。
3. 米国政府が、我が国に関し、円滑に本法を執行するとともに本規則を運用していくために、手続を説明する和文パンフレットの発行及び日本国内において日本語で問い合わせできる相談窓口の設置を強く要望する。また、引き続き理解促進のためのセミナーを開催することを要望する。
4. 貨物については、通関代行業者、輸送業者等が、既存の通関方法である税関国境保護局の自動ブローカー・インターフェース（CBP ABI/ACS）により事前通知を行うものであるのに対し、郵便物については、郵便利用者自身が、FDAのPNシステム・インターフェースにより事前通知を行い、税関告知書にPN番号を記載しなければならない。これはインターネットに接続できる環境を有し、英語を理解する者でなければ米国あてに食品を郵送することができないことを意味しており、郵便の利用者は余計な煩雑さを伴う多大な負荷・負担を強いられるものと認識している。

