

July 7, 2003

**Questions and Comments by the Government of Japan on the United States' Proposed Regulation "Establishment and Maintenance of Records (Article 306)" Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (DOCKET No. 02N-0277)**

The Government of Japan appreciates the opportunity to provide comments on the United States' proposed regulation of "Establishment and Maintenance of Records" under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, published in the United States' Federal Register May 9, 2003 and notified to the WTO Members on May 15, 2003 (G/SPS/N/USA/703). The followings are our questions and comments.

**1. Questions**

**(1) Please clarify the definition and content of "packing."**

Before going through the customs clearance, packed freights will be further fortified, for instance, by hard cartons or wooden frames, in order to strengthen resistance to frictions and strikes during exporting process. In this case, are hard cartons and wooden frames that never contact food, as they merely fortify the "packed" freights, also included in "packing?"

**(2) Please clarify the definition and content of "holding."**

In Japan, in order to go through the customs clearance for the exports to the U.S., freights must be transferred into bonded warehouses or bonded area and be left there until acquiring the permission of export. Is the restoration only for receiving the permission of export also included in "holding?"

**(3) 21CFR113 requires automatic detention of canned foods when deviation of thermal processing or sealing is detected, because the deviation could be life-threatening. Will the Bioterrorism Act also order the automatic detention or inspection of records, when deviation in such critical control points is detected?**

**(4) Would the FDA directly request for records or directly inspect the records of firms that are located outside the U.S.? If not, how would the FDA go about obtaining such records or making such inspections?**

**(5) Will the FDA accept information by facsimile or e-mail written in Japanese?**

**(6) Some products are forwarded from the original factory to the last shipment via several distribution bases. Do all of these records have to be maintained? (In relation to Section 305, is registration required for these relay facilities?)**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 1 and 11**

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**[Docket No. 02N-0277]**

RIN 0910-AC39

**Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice of proposed rulemaking.

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**SUMMARY:** The Food and Drug Administration (FDA) is proposing regulations that would require the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States. In addition, these requirements apply to certain foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. The proposed regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and are necessary to properly address credible threats of serious adverse health consequences or death to humans and animals. FDA expects that the requirements the agency is proposing in these regulations, if finalized as proposed, would result in a significant improvement in FDA's ability to respond to and help contain threats of serious adverse health

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**(7) Will the records be published?**

**(8) When the FDA requests the access to the records, how will the time difference between foreign countries and the U.S. be dealt with when considering the time frame required by the regulation?**

**(9) This Article 306 stipulates that a foreign facility which holds food to be consumed in the U.S. must establish and maintain records at the place of the facility. In this case, we presume that such a foreign facility is equal to the one which is required to be registered in Article 305, according to the explanation by FDA in relation to this regulation draft, "Proposed Rules" page 25191.**

In Japan, however, a warehouse company is in a position only to hold goods deposited by the owner of the goods, and it is not necessarily in a position to obtain information of the goods with regard to exports, such as whether they are destined to the U.S. or not. Therefore, we are of the view that an owner of goods, an exporter in Japan or an importer in the U.S. should be defined as "register facilities" under Article 305.

Further, it is also our view that, as in the case of Article 305, an owner of goods, an exporter in Japan or an importer in the U.S. not a warehouse company, which hold information about export of foods, should be required to establish and maintain records at the place of a foreign facility. Please clarify if this understanding is correct or not.

**(10) According to Sec. 1. 363, failure to establish and maintain records will be "prohibited acts." Will there be any criminal charges filed in administrative sanctions imposed against those who committed "prohibited acts" even if they do not reside in the U.S.?**

## **2. Comments**

**(1) We request that the FDA ensure the proposed regulation to be consistent with the WTO agreement and not to create an undue burden on trade.**

**(2) The WTO Member countries have to apply measures only to the extent necessary to protect human, animal or plant life or health, based on sufficient and scientific grounds under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). In light of the obligation, please clarify the scientific grounds the FDA takes into account in introducing this proposed regulation, and whether the FDA applies the proposed regulation only to the extent necessary to accomplish its objectives.**

**(3) We request that for those who need to ask about "Establishment and Maintenance of Records" under this proposed regulation, the FDA establish consultation service staffed with Japanese speakers at the U.S. embassy and**

consulates in Japan.

(4) The FDA should only require minimum information necessary to be kept as record, so as not to create an undue burden on private businesses.

(5) The FDA should give appropriate guidance to private businesses in establishing and maintaining the records smoothly, for example, by showing a model of how records should be kept.

(6) The scope of the contents of the record required by the Bioterrorism Act should be within those required by current 21 CFR113, 21CFR114, and 21CFR123 for the seafood HACCP regulations.

(7) In requiring a record of raw material of a product, the FDA should limit its requirement to that of major ingredients of the product.

(8) With regard to the requirements for the creation and the maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food (i.e., one up, one down) for "persons other than transporters," the FDA should not require any further information not directly linked to the objectives of the regulation, such as business situation or conditions of the "source" and "recipients."

(9) The FDA should not require manufacturing and processing records of fresh agricultural products that are sold as such on the market.

(10) Under the article, it is required to maintain the records containing ingredients used in a food product. Though the quantitative formula is excluded, we suppose it will result in a part of trade secrets being recorded in terms of e.g. the combination of spices. Therefore, we regard it sufficient to maintain the records on Nutrition Facts, (Supplement Facts, or its equivalents indicated on final products).

(11) In other regulations concerning public health security and bioterrorism such as Article 307, foreign facilities will not be subject to criminal charges in administrative sanctions. It would therefore be appropriate in this regulation (Article 306) to take the same approach not to impose any criminal charges in administrative measures to foreign facilities.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 1 and 11**

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consequences or death to humans or animals from accidental or deliberate contamination of food.

**DATES:** Submit written or electronic comments by [*insert date 60 days after date of publication in the Federal Register*]. Written comments on the information collection provisions should be submitted by [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to [sshapiro@omb.eop.gov](mailto:sshapiro@omb.eop.gov) or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Nega Beru, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1400.

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