(別ＦＡＸ公信１)
July 7, 2003

Questions and Comments by the Government of Japan on the United States' Proposed Regulation "Administrative Detention of Food for Human or Animal Consumption (Article 303)" Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (DOCKET No. 02N-0275)

The Government of Japan appreciates the opportunity to provide comments on the United States' proposed regulation of "Administrative Detention of Food for Human or Animal Consumption" 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 14, 2003 (G/SPS/N/USA/704). The followings are our questions and comments.

1. Questions

(1) We regard the condition for detention, "credible evidence or information... indicating the article presents a threat of serious adverse health consequences or death to humans or animals," as unclear. Please provide us with several examples constituting "credible evidence or information."

(2) Specifically, for what purpose and how is an inspection carried out? While it would naturally take several days for the inspection on certain items to yield results, would the freight have to be kept detained until the results of the inspection is obtained?

(3) Under the proposed regulation, would the FDA send the Detention Order directly to the owner, operator, or agent in charge of the place where the article of food is located even in cases where the owner, operator, or agent does 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

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regulation, and whether the FDA applies the proposed regulation only to the extent necessary to accomplish its objectives.

(3) We request that for those exporters who need to ask about "Administrative Detention of Food for Human or Animal Consumption" 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 ensure transparent implementation of this section in order to prevent this section from becoming unnecessary trade barrier or restrictions on the activities of private businesses.

(5) In addition to (4) above, when the FDA orders the detention of the products at the port for unloading, the FDA should publish the fact of detention through the Import Refusal Report.

(6) When the FDA gets any information relating to the detention, it should provide such information to the parties concerned and their countries immediately.

(7) The regulation should stipulate that sufficient compensation for the detention should be provided when the detention is found unjust.

(8) In a case where a foreign manufacturer makes proper registration for its export to the U.S. while the manufacturer's importer/exporter makes incomplete registration and the export is detained for inspection, the regulation should stipulate that the detention should not affect the export of the manufacturer itself or via an importer/exporter other than the importer/exporter which made the incomplete registration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Parts 1 and 16

[Docket No. 02N–0275]

RIN 0910–AC38

Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation that provides procedures for the detention of an article of food, if an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals (''administrative detention''). The proposed regulation implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which authorizes the use of administrative detentions and requires regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order.

DATES: Submit written or electronic comments by [*insert date 60 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, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Marquita Steadman, Center for Food Safety and Applied Nutrition (HFS–007), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–827–6733.

SUPPLEMENTARY INFORMATION:

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