Embassy of Japan

2520 Massachusetts Avenue, NW
Washington, DC 20008
USA

August 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

Please find enclosed two copies of written comments from the Government of Japan concerning the following docket numbers:

02N-0275
02N-0276
02N-0277
02N-0278

Sincerely,

Campbell Tyler
Assistant, Economic Affairs
Embassy of Japan

02N-0276

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(別ＦＡＸ公信 1)

Initial Comments and Questions by the Government of Japan for Title III under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

1. The Government of Japan fully understands the necessity of preparedness for bioterrorism in the United States. However, measures affecting food imports, even if they are aimed at enhancing the security of the U.S. food supply against bioterrorism, should not be more trade restrictive than necessary. Such measures should not have detrimental effects on the development of both Japanese and U.S. economy as well as world economy, which is realized through trade. Such measures should not give adverse effects on the welfare of consumers as well as the interests of food producers, either.

2. From these points of views, the Government of Japan is concerned that the measures stipulated in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act") that has been enacted in the United States, such as registration of food facilities, establishment and maintenance of detailed records of manufacture and distribution of food, and prior notice of imported food shipments, are too broad and excessive. We may have to express our further concerns, depending on the application of the Act, including the contents of the regulations to be formulated. Another problem with this Act is that the cost and effectiveness / benefit of these anti-bioterrorism measures, when actually implemented, is not clear.

3. If these regulations are introduced in the United States, assertions may grow that Japan, which is the world largest net food importing country, should introduce similar measures, both from those who consider that the measures under the Act would create an undue burden on Japanese exporters, and from those who consider that such measures might be effective for preventing bioterrorism in Japan.

4. Based on the basic views stated above, our comments and questions on Title III of the Bioterrorism Act are provided in the Attachment.

<Attachment>

I General Comment

(1) Comments and questions this time should be taken very much as our initial views.
(2) We strongly request that the United States ensures that the measures that are aimed at enhancing the security of the U.S. food supply against bioterrorism are consistent with the international rules such as WTO Agreement and do not create an undue burden on trade.

II Comments for each section

1. Section 305
   (1) FDA should only require minimum information necessary for registration of food facilities, so that the requirement does not become an undue burden on private businesses.
   (2) FDA should expeditiously register facilities that have already been manufacturing food in the United States or importing food to the United States in order not to hamper their activities. For the same reason, FDA should also expeditiously process application for registration of facilities from private businesses that apply for registration in order to newly enter into the business after the regulations come into force.
   (3) In order to ensure (2) above, FDA should give appropriate guidance to the private businesses so that they can apply to FDA for registration smoothly, for example, by showing a model application sheet for registration.
   (4) Japanese facilities manufacturing low-acid foods and acidified foods have already been registered to FDA according to the requirements provided by 21 CFR Part 113 (Thermally Processed Low-acid Foods packaged in Hermetically Sealed Containers) and Part 114 (Acidified Foods). Facilities manufacturing and processing fishery products exported to the United States have also been registered under 21 CFR Part 123. FDA should approve these facilities as registered facilities under this section and should not require additional registration.
   (5) According to the arrangements of plant quarantine procedures established by plant quarantine authorities in Japan and the United States, such as working plans etc., new facilities for exporting fresh

fruits such as Unshu oranges (Satsuma mandarins), apples and pears are registered to the United States Department of Agriculture before the first shipment to the United States. Such facilities include fresh fruit selecting facilities. The registration of these facilities should be substituted for the registration under this section automatically.

(6) Concerning the registration of exporting manufacturers, FDA should approve registration by parent companies as the representative of all their branches and subsidiary companies as an alternative to the registration by each branch and subsidiary of such parent companies.

(7) FDA should take proper actions to avoid abuse of registered numbers by terrorists etc.

(8) FDA should accept electronic registration and submission of documents by organizations or agents on behalf of facilities that need to be registered in order to ensure smooth and reliable registration procedures.

(9) Since FDA will be introducing completely new regulations, unintentional errors or need for correction on application forms should not be punished too severely, such as recalling products already distributed in the market.

(10) FDA should approve the registration as valid for sufficient long time, in order to avoid undue burden on activities of private businesses by requiring frequent re-registrations.

(11) Facilities of Animal and Plant Quarantine Services of the Government of Japan should not be required to register under this section.

2. Section 306

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

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

(3) FDA should exempt companies that deal with or import food less than a certain amount of volume from the obligation of establishing and the maintaining records under this section.

(4) 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.

(5) FDA should only require that a record of major ingredients be kept as

a record of raw materials.

(6) We understand that FDA will establish "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)" at the manufacturing facilities. In this context, FDA should not require further information on business contacts of food facilities to be kept.

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

3. Section 307

(1) In order to avoid undue burden on private businesses, contents of the prior notice required should be minimal.

(2) FDA should expeditiously deal with prior notice submitted by private businesses that manufacture foods in the United States or export (or will export) foods to the United States within a certain time limit, in order not to hamper the activities of the private businesses, such as delaying of import.

(3) To ensure (2) above, FDA should provide appropriate guidance to private businesses for submitting prior notices, for example, by showing model notices.

(4) FDA should prescribe in the regulations that products with the same content whose sole difference is size, such as canned food, are required just a single notice.

(5) FDA should exempt import food products less than a certain amount of volume from the obligation of prior notice. There should be an exemption from the obligation of prior notice for import sample products of small quantity. Alternatively, there should be another simpler regulation for import of sample products.

(6) FDA should take ample security measures for electric notices.

4. Section 303

(1) 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. Especially, when FDA orders the detention of food based on this section, FDA should immediately show the reasons and the period of the detention to the stakeholders. FDA should also notify the related countries of these facts expeditiously. As soon as FDA confirms that the detained article is safe, FDA should release it immediately.

(2) In addition to (1) above, when FDA orders the detention of the products at the port of unloading, FDA should publish the fact of detention through the Import Refusal Report.
(3) When FDA gets any information relating to the detention, it should provide such information to stakeholders immediately.
(4) When a stakeholder such as an importer or an exporter, files a complaint against the detention, FDA should deal with it expeditiously within fixed date to avoid hampering the activities of private businesses.
(5) The regulation should ensure that enough compensation for the detention should be paid when the detention is found to be unjust.
(6) The regulation should ensure that when an article from a registered manufacturer is detained due to a violation on the part of the exporters or importers, any article that is directly imported to the United States by that registered manufacturer, or imported via other exporters or importers that are properly registered should not be detained.

III General questions

1. When does FDA reply to our initial comments and questions? Please explain FDA's working procedures for formulating the regulations after receiving comments and questions from stakeholders. How are our comments and questions treated in the process for formulating regulations?
2. Has FDA already conducted a cost / benefit analysis for implementation of regulations that are aimed at enhancing the security of the U.S. food supply?
3. Which article of the GATT/WTO agreements justify the strengthening of those food safety regulations?
4. Will the U.S. support Japan if Japan decides to introduce the food safety related measures that is similar to those in the Title III of the Bioterrorism Act?
5. We understand that the regulations will apply to all foods within FDA's jurisdiction. Do the regulations apply not only to processed food, but also to fresh agricultural products? Please clarify all the foods regulated by title III of the Act.
6. Is it correct to understand that foods within USDA's jurisdiction, such as meat and eggs are out of the purview of the regulations? If this is correct, please explain why such foods are exempted.

7. Japanese food manufacturers, in many cases, export and sell foods via a trading company or a shipping company, rather than export by themselves. In these cases, who (manufacturers or trading/shipping companies) must comply with obligations under the Act such as "register food facilities", "maintain records" and "notice imported food shipments"?
8. In case that trading or distributing company exports foods purchased in Japan to the United States, who must comply with obligations under the Act such as "register food facilities", "maintain records" and "notice imported food shipments"? How should these obligations be met?
9. Are manufacturing or trading companies that deal with foods manufactured, sold and consumed inside a single State within the purview of the Bioterrorism Act?
10. Are any new tasks (such as the issuance of certification, submission of the list of any exporting manufacturers, etc.) required for the government of the exporting country after the enactment of the new regulations? If yes, please explain.

IV Questions for individual provisions

1. Section 305
   (1) We understand that food facilities will be registered only by notification of the documents and there will be neither standard of registered facilities that need to be met nor a determination on whether such a standard is met by the U.S. government. Is that right?
   (2) How long will a registration be valid?
   (3) Please explain the definition of the "agent in charge of a domestic or foreign facility" in this section that needs to submit a registration to the Secretary.
   (4) Does FDA include "facilities of food additives" in the definition of "food facilities"?

2. Section 306
   (1) 21CFR113 requires automatic detention of canned foods, when deviation of thermal processing and sealing is detected because it could be a life threatening problem. Will the Bioterrorism Act also order automatic detention or inspection of records, when deviation of such critical control points is detected?
   (2) Who is required to establish and maintain the records?

"Sec.305 Registration of Food Facilities of the Bioterrorism Act"

states "Limits foreign facilities to those that manufacture, process, pack, or hold food only if food from such facility is exported to the U.S. without further processing or packaging outside the U.S." Does this mean that there is an obligation for entities that are outside the United States to establish and maintain records?

(3) When FDA accesses the records of the exporting facility relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of the food, will FDA notify the exporting country of its actions?

(4) Please clarify the scope of the record that FDA expects the manufacturers to keep. Must the manufacturers keep the record of supplier or importer of all of the ingredients, however, small the quantity may be?

3. Section 307

(1) Will FDA use prior notice in same manner to reject a shipment of foods to be exported to the United States? What circumstances will the prior notice be used to reject a shipment?

(2) Who must provide the prior notice to the FDA? Importer, exporter or both?

(3) Prior notice is an obligatory measure for import foods. Are there any equivalent measures for foods that are manufactured, distributed and consumed inside the United States?

(4) When some article is refused admission under this section, will FDA notify the government of exporting countries of that fact and immediately ask them to provide information related to the articles?

(5) Who will keep the articles that is held at the port of entry, quarantine authority of the U.S. or the U.S. importer? Who will be responsible for the maintenance of the quality of such articles?

4. Section 303

(1) Are there any reason other than no registration, no notification and inappropriate records with which the FDA will order the detention of food? If so, please identify such reasons.

(2) Please identify the measures or procedures that the importers and exporters may take to seek the repeal of an detention order by FDA.

(3) We believe that the condition for detention that "credible evidence or information indicating the article presents a threat of serious adverse health consequences or death to humans or animals" is unclear. Please provide us several examples of what would

constitute "credible evidence or information".

(4) Will FDA plan to establish a list of biological agents that are subject to intense inspection?

(5) When some food is detained under this section, will FDA notify the government of exporting country of that fact and seek necessary information?

(6) Who will keep the food that is detained under this section at the port of entry, quarantine authority of the U.S., or the U.S. importer? Who will be responsible for the maintenance of the quality of such food?

(end)

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