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

Comments by Japan External Trade Organization on
Docket No. FDA–2011–N–0143 (RIN 0910-AG64): Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
and Docket No. FDA-2011-N-0146 (RIN 0910-AG66): Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

I appreciate that you give us an opportunity to comment on your important draft regulation of Food Safety Modernization Act (FSMA). The Japanese food industries always have a sincere interest in enhancing food safety for the consumers of Japan and of the United States.

This will present comments of Japan External Trade Organization (JETRO), which is Japan government related organization to enhance mutual trade relationship between Japan and other countries including USA, on the above proposed rules.

【The matter of language】

1. Translation of regulations and guidance documents:

Proper respect for good relations between the food safety authority within Japan and that of the U.S. would be aided by having the FDA Office of International Affairs provide a Japanese-language translation of the new rules, as well as all of of the guidance documents for FSMA sections 301 and 307. We know FDA has issued three Bioterrorism Act (BTA) guidance documents written in Japanese to date. More should follow, to aid full compliance.

2. Records:

With the Foreign Supplier Verification Program, FDA should limit the documents which must be written in English to those submission documents which are made by importers and originally written in English. The reason is as follows.

First, some importers possibly monitor and audit foreign suppliers in other language. So, these documents related with monitoring and audit (such as communication records between importers and foreign suppliers) should be allowed to be written in other language.

Second, documents made by foreign suppliers should be excluded from documents which FDA thinks should be written in English. If importers require foreign suppliers such as Japanese food manufactures to submit documents written in English, it can be the heavy waste of cost, time and productivity through duplication of paperwork for Japanese food manufactures which are making and retaining documents in

Japanese to be used daily by Japanese workers. We expect to be able to share above the concern about increasing costs due to the difference of used languages with you.

In addition, regarding the English-language records requirement in proposed § 1.658, it is too short for the auditor/certification body to prepare for the English translation of its records in 2 business days. They may need at least 5 business days or more.

(*) We would like to reiterate this matter of language. It is a critical issue for Japanese manufactures which hope to continue imports to USA whether they can make documents and keep records of imports in Japanese and how they can receive a food safety audit in Japanese from third party auditors including accredited institutions. It is because most of Japanese food manufacturers are small and medium-sized enterprises which cannot deal with English, although requirements for their food safety are sufficiently met.

【The overall】

3. Proportionality:

Many of the proposed requirements for importers are contrary to the principle of proportionality which means higher standards are required for higher risk food while lower standards for lower risk food.

Concretely speaking, standards which are required importers of relatively lower risk food to meet are possibly more demanding and stricter than those for importers of relatively high risk food such as seafood and juice. The proposed rule does not explain why the foreign supplier verification requirements in the proposed rule should be more demanding than those in FDA's existing seafood and juice HACCP regulations. The fact that Congress exempted imported seafood and juice products from the new foreign supplier verification requirements strongly suggests that Congress considered the verification requirements to be adequate. We think there is nothing stricter than the seafood and juice HACCP rules.

Hence, we request that wider discretion should be given to importers while FDA examines the importers' status of compliance with this regulation only by monitoring procedures.

4. Safer and less demanding option (Oppose Option1):

Surely, we understand the importance of the food safety for residents in USA.

In that sense, Option 1 seems to be effective to ensure the food safety, but we perceive the big problem which this too strict and rigid option holds, and clearly oppose option1.This problem is as follows.

Option 1 requires importers as well as foreign suppliers to focus their energies on audits and paper work, and as a result of that, the inability for them to exclusively concentrate on the essential and primary works to supply "safe foods" can actually deprive American people of an opportunity to access various foreign foods and can hamper highly diverse food culture in USA.

Furthermore, these imposed heavy burdens on importers and suppliers due to too strict and too rigid regulation can head toward rapid shrinks of food imports market in USA and can threaten food stable security in USA, because many importers/suppliers which have no sufficient resources to do paper works possibly give up imports/exports to USA.

Thus, we support Option 2 (,if possible, the free choice (Option 1 or Option2) by importers) to eliminate above negative impact as much as possible, while enhancing the feasibility and efficiency to appropriately control an array of various hazards by giving wider discretion to importers.

We'd like to take this opportunity to confirm your statement (in section 404) that the provisions of the act and any amendments to the FD&C Act should not be construed in a way that is inconsistent with the agreement establishing the World Trade Organization (WTO) or any other treaty or international agreement.

5. Equivalence Principle (as necessary):

Regarding proposed 1.513 ["What FSVP may I have if I am importing a food from a country with an officially recognized or equivalent food safety system?"], we understand FDA is developing an approach for "system recognition" and that FDA has concluded a systems recognition agreement with New Zealand. We hope that FDA will give positive and timely due consideration to other countries, whose food safety systems are also comparable to the United States if these countries are actually found to hope this approach.

In considering about that, the fact that there are "potentially (*)" so many food safety regulations equivalent to the American food safety regulation around the world should be remembered.

(*) For example, Japanese food products which are produced under Japanese "Food Sanitation Act" are safe, and the relatively very small number of food-poisoning deaths in Japan each year (only 11 deaths in 2012 total) underscores the high level of Japanese products' safety. In addition, we have heard from Japanese importers based in USA that there have been no reported serious food illnesses or injuries stemming from food imports from Japan suppliers over the last several decades.

6. Need for additional FDA guidance:

This proposed regulation (Section 301) includes several ambiguous descriptions such as "Hazards reasonably likely to occur." We hope that FDA will provide guidance as to how the agency will interpret this term. The supervisory guideline which demonstrates the regulatory interpretation and procedures of inspection should be formulated and published, so as to enhance the predictability and transparency of administrative action for importers and to lessen burdens of compliance. This guideline should explain how FDA intends to monitor importers, how to examine importers' compliance with regulations, and specifically what types of documents are required for importers.

This supervisory guideline should identify what types of hazards are considered to be SAHCODHA (Serious Adverse Health Consequences or Death to Humans or Animals) hazards. And all necessary onsite auditing should be limited to hazards shown by this guideline.)

【The definition】

7. Annual Sales Threshold for "very small foreign suppler":

The definitions at 21 CFR 1.500 should define "very small foreign supplier" as "a business that has less than $1,000,000" in annual food sales to the United States. In Japan, the average company only requires a 3-5 employees (*) to support the sales of $1,000,000, which is the minimum number to have the guidance of a HACCP team in that company.

In addition to increasing the dollar threshold, the definition should be based on a foreign suppler's food sales to the US market only. Many Japanese companies export only a small amount of their annual food production to the U.S. Such limited distribution of a small number of products poses an extremely low risk to the US food system and US consumers. Importers of such foods should be subject to the modified verification requirements for importers of foods from "very small foreign suppliers."

(*) According to the report issued by the Japanese government called "Food Industry Financial Situation Survey," which was published in March 2012, the average per employee sales of a typical food manufacturing company in 2010 was 73,784,000 Yen. And the average per employee sales of food manufacturing company with capital of lesser than 10,000,000 yen was 37,585,000 yen.

8. Exemption:

FDA has requested comments on whether importers should be exempt or subject to reduced verification requirements when importing food from a foreign supplier that is part of the same corporate structure. We support such an exemption.

When both importer and foreign supplier are part of the same corporate family and same supply chain management system, the importer and foreign supplier will adhere to the same food safety standards and practices, so foreign supplier verification is unnecessary.

【Other issue】

9. International Standards:

A proper harmonization with international standards is needed. FDA should harmonize the FSMA requirements for the food safety plan with international and domestic HACCP programs. If there is anything different from these programs in the final rule, FDA should explain what is different from the existing HACCP programs.

FDA should provide food exporters and importers with background information and specific examples of differences, including how firms are directed to set their CCPs and critical limits.

We understand using an accreditation body's status as a signatory to an IAF MLA as the one of the criterion for recognition or as a factor weighing in favor of an application for recognition under the accredited third-party audits and certification program. So we support your tentative conclusion which says documented conformance to ISO/IEC 17011:2004 would be relevant in demonstrating that an accreditation body is qualified for recognition.

There are some existing food safety international standards (such as ISO22000, FSSC22000, etc.). FDA should consider such international standards can provide assurance that products meet U.S. requirements.

10. Import alert search system on the FDA website:

With the current website of FDA, it is hard and tough task for importers to search for the import alert. So, to lessen the burden on the importers to search as much as possible, the developed system will enable us to easily and systemically search for the import alerts should be prepared.

If you have any questions about our comments, please do not hesitate to contact us.
Sincerely,

12/13/2013

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