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-2015-N-0797 : Implementation Strategy for Prevention-Oriented Food Safety Standards

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.

1. Easing up on the English translation issue:

With the Foreign Supplier Verification Program (FSVP), 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.

Otherwise, those translations should be limited to the followings:

1) the translation only for "high risk" foods as defined by FDA in the future
2) the translation only in case where a supplier has a history of regulatory compliance problems such as previously being placed on import alert
3) the translation only upon specific request of the FDA such as the Agency is planning an inspection of the suppliers

If importers require foreign suppliers such as Japanese food manufactures to submit all the 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. That is the reason why we are now suggesting the above limit on the translation.

2. Guidance which will be published by FDA in the future:

There are some existing food safety international standards (such as ISO22000, FSSC22000) which have been very much relied on by many retailers, importers and exporters. We would like to see through FDA's guidance whether international standards such as GFSI, ISO22000 meet FDA requirements. If it doesn't, it would be tremendously helpful if FDA could show where the difference is between international standards and FDA requirements.

As for guidance documentations for industries which is scheduled to be published in the future, it would be

helpful if those are issued in languages (including Japanese) than English so foreign suppliers (even if those are small medium companies) can keep themselves compliance with new FSMA requirements.

Also, commodity - specific guidance will also help suppliers get clear what is required by FDA properly so the final rule should have flexibilities as far as we know through FDA's April public meeting.

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

5/26/2015

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