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# MEMORANDUM

**From**: Joseph A. Levitt
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**Date**: February 28, 2017

**Re**: **FDA Holds Public Hearing on Food Safety Import Strategy Under FSMA**

Earlier this month, the Food and Drug Administration (FDA) held a two-day public hearing that addressed the agency's plans to engage in strategic partnerships to enhance the safety of imported foods. FDA used the hearing as an opportunity to ask questions of and learn from private entities and food safety authorities in other countries. The key topics discussed were the use of third-party certification bodies in regulatory decision-making, systems recognition, international capacity building, and commodity-specific exports and programs. Below we summarize some of the highlights from the hearing that may be of particular interest to food manufacturers and their trade associations. FDA has opened a docket for comments on the issues discussed at the hearing, which is open through May 16, 2017. 1/

- **FDA nearly has completed a systems recognition agreement with Australia.** Currently FDA has systems recognition agreements with New Zealand and Canada. These agreements recognize that the United States and the partner country have food safety systems and regulatory programs that yield similar food safety outcomes, which results in modified requirements for importers of certain finished foods under the Foreign Supplier Verifications Program (FSVP) regulation. FDA has assessed Australia and is nearing the end of signing a systems recognition agreement.

- **New Zealand's systems recognition agreement will undergo review this year.** New Zealand piloted the systems recognition program in 2012. Per the agreement, both countries must reassess how their food safety systems align with each other at least every five years. As a result, FDA soon will reassess its systems recognition agreement with New Zealand. In addition to the reassessment of systems recognition agreements, FDA recognizes that it needs to create a monitoring program to measure the agreements' performance.

- **FDA is still considering how to approach systems recognition with the European Union (EU).** FDA currently is in the process of evaluating EU-wide food safety standards. However, FDA has not made any final determinations as to how it would approach designing a systems recognition agreement with the EU. For example, FDA still is deciding whether such an agreement would include some or all EU member states. Several questions of

1/ The docket is available on www.regulations.gov at Docket No. FDA-2016-N-4662.

foreign governments at the hearing focused on how other countries handle similar agreements with the EU.

- **The forthcoming FSVP draft guidance will include more information about systems recognition for importers.** For modified FSVP requirements to apply, an importer must document that the foreign supplier is in good compliance standing with the food safety system officially recognized as comparable or equivalent to that of the United States (i.e., that a systems recognition agreement exists). FDA stated that the forthcoming FSVP guidance will address how to determine if a supplier is in good compliance standing.

- **FDA gave no indication as to when it will publish the FSVP draft guidance.** Susan Mayne, Director of FDA's Center for Food Safety and Applied Nutrition, said that the FSVP compliance dates—beginning on May 30, 2017 for certain importers—would not be postponed even though the draft guidance has not yet been issued. (Note that several trade associations have requested that FDA extend the Preventive Controls supplier verification and FSVP compliance dates in light of the lack of guidance.)

- **FDA is at the initial stages of thinking about how to use third-party certifications as a part of its regulatory program.** Although FDA has begun to start a dialogue with private certification entities such as the Global Food Safety Initiative (GFSI), the agency stressed that this dialogue is at the initial stages. Regarding the Produce Safety rule, the agency recently announced that it "contemplates leveraging third-party audits as part of its overall compliance strategy . . . by building on current private audit activity and by working with the produce industry and other government and private partners to strengthen the rigor and reliability of private audits." 2/

- **FDA is interested in how foreign food safety authorities use information from third-party certification schemes.** FDA used the public hearing to inquire about how foreign food safety agencies incorporate information from third-party certification schemes into their oversight activities. Representatives from the food safety agencies of Canada, Belgium, and the United Kingdom discussed how they evaluate private schemes, the transparency of audit processes, and related challenges. For example, a representative from the Canadian Food Inspection Agency (CFIA) described how CFIA developed its Private Certification Policy following a pilot with GFSI. 3/ Under the policy, CFIA considers the results of third-party audits when evaluating the risk posed by a food facility, which informs inspection strategy. The policy reduces the type, frequency, and duration of future inspections if a facility has passed audits from particular private certification schemes. Although the Private Certification Policy formally took effect in September 2015, its implementation is occurring gradually in concert with the implementation of the Safe Food for Canadians Act.

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We will continue to monitor FDA's food import programs and strategy. Should you have any questions, or wish to discuss these issues further, please contact us.

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2/ FDA, *Third-Party Audits and FSMA* (Feb. 27, 2017), https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm543296.htm.

3/ Canadian Food Inspection Agency, *Private Certification Policy (Food Safety)* (Jan. 14, 2016), http://www.inspection.gc.ca/about-the-cfia/accountability/consultations-and-engagement/regulatory-risk-based-oversight/private-certification-policy/eng/1452808755126/1452808821799?chap=0.