Industry-Wide FSMA Concerns Arise at Food Safety Summit

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An ongoing, open dialogue between food manufacturers and the Food and Drug Administration (FDA [1]) is vital as Food Safety Modernization Act (FSMA) regulations are forged, the vice president for regulatory affairs at the International Dairy Foods Association (IDFA [2]) said at the Food Safety Summit Tuesday.

Clay Detlefsen followed FDA officials' update on FSMA in a workshop called "Doing the Right Thing — Meeting Consumer and FSMA Food Safety Expectations" at the Baltimore Convention Center. Detlefson voiced many concerns about FSMA that apply not only to the dairy industry, but to food processors on the whole. The Foreign Supplier Verification Program (FSVP), auditing and FDA access to records were also discussed.

The FSVP is an imperative focus point because, Detlefsen said, "What applies to foreign suppliers will ultimately apply to domestic suppliers."

The FSVP allows importing food manufacturers two options [3] for verifying that the food they import is safe. Option 1 is on-site auditing that puts responsibility on the foreign supplier.

However, Detlefsen said the IDFA supports FSVP Option 2, which puts responsibility on the importer rather than the foreign entity, because the flexibility it provides.

In addition, foreign facilities that are part of the same corporate ownership, for example, intra-company shipments, should not be subject to the FSVP, he said. Detlefsen recommended that the FSVP be revisited as needed, rather than triennially, as the proposed rule suggests.

The frequency and method of facility auditing [4] is also a point of discussion between manufacturers and the FDA.

The proposed frequency of mandated FDA audits of is too high, Detlefsen said. Over-auditing would present a burdensome situation that uses precious manufacturer resources, he said. Theoretically, a foreign facility that supplies 200 importers could be audited as many times. Detlefsen also suggested the FDA employ third-party auditors to alleviate that burden on the FDA and food manufacturers.

The substantial documentation required under FSMA is also on food manufacturers' minds.

FDA access to manufacturer records under FSMA is a hot topic for food manufacturers. Detlefsen said that FDA auditors should only have access to

manufacturers' records in the context of an on-site inspection. Supplier and audit reports should not be accessible to the FDA, as evidenced in the confidientiality of audit reports for infant formula and medical devices. The Freedom of Information Act should not apply to FSVP audit documentation because it's confidential business information, as noted in exemption four of FOIA.

In terms of documentation of FSVP, Detlefsen said, records should be translated to English only on an as-needed basis, because translation is costly.

Catch more of Holly's *Food Manufacturing* coverage of the Food Safety Summit at on Twitter: @foodmfged [5]

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[1] https://twitter.com/FDAfood
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[3] http://www.fda.gov/food/guidanceregulation/fsma/ucm361902.htm
[4] http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm257978.htm
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