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## FDA likely to include supplier verification in preventive controls rule

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By Amber Healy

The need to verify supplier controls as part of the rules implementing the Food Safety Modernization Act (FSMA) is so important that FDA is likely to require U.S. companies to adopt the same supplier verification controls as will be mandated of foreign food companies.

That's the prediction made by Marc Sanchez, founder and senior counsel with Contract In-House Counsel and Consultants, LLC, a law firm based in Atlanta, in a webinar Wednesday afternoon sponsored by TraceGains Inc.

That prediction is likely to come true. FDA Deputy Commissioner for Foods and Veterinary Medicine Mike Taylor announced publicly Sept. 19 that the agency would require supplier verification in the preventive controls rule.

Sanchez reiterated the components of FSVP and the third-party certification rule, both published by the agency in late July (see *FCN* Aug. 2, 2013, Page 1), including the two options the agency is considering for when hazards must be addressed: Either by focusing on annual on-site audits, in which a foreign supplier must identify hazards likely to occur with the product being shipped into the United States; or by instead choosing among different ways to verify that the hazards have been addressed.

Verification that systems are in place to control for contamination or other safety concerns, whether by annual audits, random sampling or other methods, is so crucial to FDA's efforts to be proactive and prevent problems that the agency has left open the door for adding some of the activities to the preventive controls rule, Sanchez told the more than 100 participants in the webinar.

"Here we're basically saying that supplier verification of foreign products must occur, but we didn't see that in the preventive controls rule for domestic products." He pointed out that the White House Office of Management and Budget, when reviewing the preventive control rule removed the supplier verification requirement, something FDA had mandated as a best practice (see *FCN* March 22, 2013, Page 1).

FDA is taking comment on whether "verification activities should come back into the preventive control rule," Sanchez said. "My hunch is that it's going to happen."

Verifying domestic products in addition to those sourced internationally will ensure that FDA treats all food products the same and does not give domestic products preferential treatment under the rule, he said.

Sanchez pointed to a legal case over a USDA regulation that could be an indicator of what might happen if foreign suppliers feel their products are facing additional hurdles when coming into the United States.

Currently, a number of meat and poultry groups in the U.S., Mexico and Canada are trying to get a rule thrown out or revised that identifies the country of origin of meat products, in particular products like ground beef that contain animals raised in the those three countries. The District Court for the District of Columbia recently threw out the meat groups' request to




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declare the rule unconstitutional on First Amendment grounds, but the groups have filed an appeal because they feel mandatory country-of-origin labeling discourages importation of beef cattle from Canada and Mexico into the U.S. (see *FCN* Sept. 27, 2013, Page 19).

There's another warning to be heeded in that case, Sanchez said. The judge, in her ruling, told the meat organizations that they had not commented on USDA's proposed rule when they had the chance to raise their concerns about possible product discrimination, and as a result they lost some of their legal standing to contest the final rule.

FDA already has extended the comment period for the first two FSMA rules, published in January, and likely will extend the comment period for the FSVP and third-party certification rules as well, but "if you don't comment on the proposed rules, you might waive your right to challenge" what's in the final regulation, he said.

Additionally, Sanchez said he believes FDA has "tipped its hand" in the FSVP proposal on its preference for electronic recordkeeping systems, as all documents linked with imported products and any steps taken to address all possible hazards must be available upon request. FDA probably won't want to wait for an importer to dig up a paper document during an on-site audit, and the agency wants as much information as possible when conducting port-of-entry re-inspections, he said. The best way to accomplish those goals and not slow the processing of imported goods is to have all documentation available electronically, he said.



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