FSMA Finalizes FSVP & 3rd Party Accreditation

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Questions/Answers

Q: Can the industry expect further clarification of Importer from the FDA? How might this term be further defined otherwise?

A: The FDA has been asked through the rulemaking process to clarify the definition of an importer. The final rule contains the definition (also in the slides). Guidance documents might provide interpretations and then we will have to see how others interpret the definition.

Q: Does FSVP apply to imported articles of food that will be further processed by the domestic importer (raw materials & ingredients), or are these covered through the PC Rule?

A: RACs are covered by the FSVP rule. See the preamble of the rule on page 74254 7. Raw Agricultural Commodities (comment 86), also comment 176 on page 74282.

Q: I understand food packaging is also covered under the rule. Does this apply to all food contact materials as well?

A: Yes, they appear to be included in the definition of "food" in FSVP but not in the PC rule. See Comment 5 on page 74233 of the FSVP final rule

Q: I am a direct importer of produce, warehouse- no transformation of the RACs, what do I need to implement? Other than FSVP?

A: You will need a FSVP program as an importer. You will need to comply with the FSVP rule and verify that the products you are importing are grown under the same standards as the produce safety rule. Once the products are in the US, you will need to continue to operate under the produce rule or the Preventive Controls rule, depending on the type of operation you are. As a wholesaler, you are likely under the Preventive Controls rule as a holding facility.

Q: Can you elaborate on VQIP?

A: The Voluntary Qualified Importer Program is an optional program for frequent importers. It is like a pre-check program for importers. The FDA released a draft guidance document last summer but has not finalized the program. More information is on the FDA website: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm448728.htm

Q: I am buying a material from a distributor that importing the food from a foreign manufacturer. The distributor sells to many different US manufacturer and acknowledges responsibility as the importer for the foreign supplier verification program. What type of document / certification do I need to show the FDA that the distributor is complying with the foreign supplier verification program? Is a certification from the distributor stating that they are the importer and responsible for FSVP sufficient?

A: As a manufacturer in the US, purchasing from a US based distributor, you would need to have a supply

chain program in your Preventive Control plan. The distributor is the importer and responsible for the foreign supplier verification. You determine your own supply chain program and it is based on the hazard analysis.

Q: Is FDA going to train people for become FSMA auditors? What is the eligibility to become one?
A: FDA mentions training in the preamble and acknowledges the need for information. Annual food safety training is required for all auditors in §1.650 (a)(3) in the Final Rule. The final rule also goes into detail on the process for accredited third party certification.

Q: Our raw material supplier is primarily responsible for the verification of imports unless we are the first tier importer, correct? Is there a list of these high risk imports?
A: Correct. The preventive controls rule does have a requirement for a supply chain program so some documentation might still be necessary. The FDA published a draft methodology to determine high risk foods but has not developed a list of foods yet. This will be very controversial when it happens because no one wants to be on the list.

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