
Webinar: Complying with FSMA's Preventive Control Rule as a Small Business

November 10, 2017 | Shawn K. Stevens, Food Safety Consultant and Lawyer
Questions/Answers

Q: What is the most prevalent pathogen in a food facility that causes food borne illness /outbreak?

A: While it varies based upon the products at issue, the two pathogens most frequently responsible for environmental contamination of food products are *Listeria monocytogenes* and *Salmonella*. To a lesser extent, *E. coli* O157:H7 has also been responsible for foodborne illness outbreaks.

Q: If you are a brand and only use co-packers to make your items, would the hazard analysis be at the co-packer level and your food safety plan be mostly a supply chain program?

A: If you own the brand, but co-packers manufacture the product on your behalf, then in most cases, yes, the onus to develop and implement a written food safety plan will be on the co-packer actually manufacturing and packaging the product.

Q: How is FDA inspecting foreign small businesses?

A: As of October 11, 2017, FDA has conducted 383 foreign inspections this year. FDA will typically prioritize inspections based upon risk associated with the product and size of supplier.

Q: Do you have a webinar scheduled for FSVP and importer requirements and Transportation requirements?

A: Not currently, but would be happy to schedule one.

Q: How is FDA inspecting foreign small businesses that export to the US?

A: As of October 11, 2017, FDA has conducted 383 foreign inspections this year. FDA will typically prioritize inspections based upon risk associated with the product and size of supplier.

Q: How would you address owner's concern of putting on paper company proprietary information that other's may see, when normally it was "guarded" by close employees/owners etc . "the small business dilemma" of protecting the knowledge of the business

A: Trigger the government's obligation to protect the confidentiality of any information you provide from public or other disclosures, I recommend that clients insert the following language into the footer of their operational and food safety programs:

"THIS DOCUMENT AND THE INFORMATION CONTAINED HEREIN CONSTITUTES TRADE SECRET, CONFIDENTIAL AND PROPRIETARY COMMERCIAL INFORMATION PURSUANT TO 5 U.S.C. 552(b)(4), AND SHALL BE STRICTLY PROTECTED AS SUCH FROM ANY DISSEMINATION AND/OR DISCLOSURE."

Q: As Seafood has some exemptions in FSMA would Seafood HACCP Training and Certification be equal to the required PCQI Training?

A: There is a strong argument that a person trained in Seafood HACCP has received training in the “development and application of risk-based preventative controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply an effective food safety system.” With that said, there are differences in HACCP and the preventive control requirements and, to be safe, I would nevertheless recommend obtaining the PCQI training offered by FSPCA.