

FSMA Finalizes Preventive Controls Rules: What Now?

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Questions/Answers

Q: Can a state manuf. food inspection take the place of a third party inspection?

A: If the state is performing the inspection on behalf of FDA, then yes.

Q: I have worked in the food industry and in plants as well as in corporate offices for >25 years. I consult to plants. How do I get trained to train the plants or does my experience provide enough to satisfy the rule?

A: There will be a train the trainer course. For more info see
http://www.iit.edu/ifsh/alliance/upcoming_events/training.shtml

Q: Must one be trained to meet these requirements? Or, can one have enough knowledge from work and experience?

A: The FDA has provided the option for experience. Since documentation is required, more information might be needed on what they are looking for in this area.

Q: Is micro swabbing required for sanitation?

A: Environmental monitoring is one of many verification steps. It all goes back to the Hazard Analysis and the hazards that need to be controlled.

Q: Is allergen residue testing required of equipment and finished product?

A: An allergen control program is required. Depending on your circumstances, testing could be a verification step if you choose.

Q: Is environmental monitoring for Salmonella or Listeria, for example, required?

A: Environmental monitoring is a possible verification step that depends on the Hazard Analysis. For example, FDA recommends environmental monitoring when an environmental pathogen is a hazard in a RTE product that requires a preventive control.

Q: How demanding have they made the supplier management program?

A: Depends on your definition of demanding. It is more flexible than the supplemental proposed rule and is based on industry input.

Q: Is finished product testing required?

A: Depends on the Hazard Analysis. Finished product testing is a possible verification step.

Q: Is customer further defined? What about a customer such as McDonald's or Taco Bell? Are they defined as a customer even though they sell through retail establishments?

A: Customer is not defined per se. The rule states customer or other entity in the distribution chain provided they are controlling the hazard requiring the preventive control and provides written assurance they are controlling the hazard. A food service provider may qualify as "other entity" but would suggest waiting for FDA guidance to be issued or submit an inquiry on FDA's FSMA website to seek exact clarity.

Q: What are suggestions on radiological hazards?

A: This was added after the Tsunami in Japan and the radiological contamination of the food supply. My guess is if you are near a nuclear reactor and there is an incident...

Q: Compliance Dates: CGMPs and Preventive Control Dates the same?

A: Yes - September 2016 for large facilities

Q: Can you please provide some examples of Validation of Preventive Controls Ex: Pest Control, Allergen Management, GMPs?

A: Validation is not required for all preventive controls - the following do not need to be validated - food allergen, sanitation, supply chain, and recall plan.

Q: If I understood correctly you mentioned that if we currently have an accepted GFSI HACCP Food Safety Plan it will meet the requirements of the PC Rules but we should still review the plan in case it may still require some changes?

A: Response 382 in the rule states if an existing HACCP plan or GFSI-compliant food.

Q: Does the requirement to register with Homeland/FDA for facility override the new definition of Farm i.e. if you meet new definition of offsite part of farm that pack/stores/shippers RACs do you have to follow Preventive controls....food just because you are still required to register?

A: If the facility qualifies as a farm, primary or secondary, they do not have to register as a facility with FDA, they are exempt.

Q: You mentioned facility registration is due 11/16/15. We have some potential foreign suppliers that are not registered. If they do not do this by this date, what happens?

A: If foreign suppliers are required to register, they will not be able to import product.

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