
FSMA Ready? Here's Your List of To-dos

March 14, 2016 | Hilary Thesmar, PhD, RD, CFS, VP Food Safety Programs, FMI
Questions/Answers

Q: It seems the vast majority of the training sessions from FSPCA are geared to processors. Any specific training targeted to warehouses/distribution centers?

A: Warehouses and distribution centers are required to follow the Preventive Controls Rule and can take the training from the FSPCA. The examples used in the training are mostly manufacturing examples but the concepts still apply.

Q: Are Packaging Supplies covered under the Foreign Supplier Verification?

A: Food packaging materials are considered to be food contact surfaces and subject to cGMP requirements in the Preventive Controls Rule. Packaging is considered to be "manufacturing/processing" in the Preventive Controls rule preamble.

Q: If my supplier imports from China, do I have to request verification from my supplier located here in USA?

A: It depends on the hazard analysis of the ingredients and who is controlling the hazard.

Q: How does packaging materials affected with FSMA?

A: Food packaging materials are considered to be food contact surfaces and subject to cGMP requirements in the Preventive Controls Rule. Packaging is considered to be "manufacturing/processing" in the Preventive Controls rule preamble.

Q: All products manufactured in our facility contain no allergens. However, we act as a DC for other finished goods that do contain some of the big 8 allergens. Should we had any special steps for allergen control for these sealed finished goods with allergens?

A: The DC should include an allergen control program as part of the food safety plan. If the allergens are all in packaged products the hazards might only occur if there is a spill.

Q: We are not a farm but a manufacturing facility. We receive fresh fruit for one of our products that we manufacture at our facility. Does the Produce Safety rule apply to us?

A: No - in your case, fruit is an ingredient in your process.

Q: What about sites which have FSSC 22000 certification? What would be the suggested to-do list?

A: Facilities complying with GFSI benchmarked programs need to do a GAP analysis to determine compliance with FSMA. Since FSMA is a regulatory requirement, it is possible that there might be slight differences or modifications in how information is collected and maintained. Having a GFSI program in place will very likely make FSMA compliance a simpler process.

Q: Do central kitchens that do not ship into interstate commerce have to follow preventive control rules?

A: It depends. In general, yes. However, there are exemptions for small businesses and for companies that sell directly to "qualified facilities." Facility registration is still required and some documentation regarding exemption status is required in the rule.

Q: Would a school kitchen that supplies food to another school come under preventive control rule or a retailer that supplies food to another store?

A: No - these would be under the retail exemption and not required to comply with FSMA. If the food is prepared at a central kitchen or commissary that is not attached to a school or retail store, then it would be required to register and comply with FSMA.

Q: If a manufacturer sells a non RTE product to a consumer does the manufacturer have to have a food safety plan as the manufacturer is not mitigating the hazard?

A: The requirement to comply with the Preventive Controls is dependent on the type of facility and the facility registration requirements. A hazard analysis is required and the food safety plan will be based on the hazard analysis. All facilities required to comply with the Preventive Controls rule have to complete a hazard analysis and have a food safety plan in place.

Q: Would Sanitary Transportation apply to Wholesale Distributors that run their own delivery trucks? I don't want to assume anything.

A: In the proposed rule, yes. We will need to see the final rule to know if there are any changes.

Q: If a site is already GFSI certified how much of a gap do you think there will be in order to fully comply?

A: The FDA is recommending that each company do a GAP analysis to determine what they need to do to comply with FSMA. Since FSMA is a regulatory requirement, it is possible that there might be slight differences or modifications in how information is collected and maintained.

Q: Any idea when the Guidance for Preventive Controls will be available?

A: FDA is working on a Hazards Guide and also an Allergen Guide. They are stating 2016 for the timing but we do not know for sure when the documents will be released.

Q: What is equivalent to FSPCA training on FSMA?

A: Right now, I am only aware of FSPCA. Other programs might be available in the future.

Q: If we import raw materials for processing or import packaging materials. Do we apply to rules on Foreign Supplier Verifications?

A: Yes, if you own products at the time of import, you will need to comply with the Foreign Supplier Verification Rule.

Q: Can an architect or engineer who works for the food industry take the FSPCA training to better understand all the requirements and how they may affect facility design?

A: The training is open to anyone and is focused on the requirements in the regulation and how to develop a food safety plan.

Q: Could some facilities need a Food Safety Plan for different processes/products or does the plan have to be a single plan?

A: The food safety plan can be product or process based if the hazards are the same.

Q: Do the "preventive controls" requirements apply to the distributors storing unexposed packaged food that doesn't require time/temperature control?

A: Modified requirements apply to these facilities. See Subpart D of the Preventive Controls Final Rule, and in particular 117.206.

Q: What is phase in date for the companies that are not Large (Human Food)?

A: For the Preventive Controls rule it depends on the activity and the size of the company. For details see http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm#Compliance_Dates

Q: FSMA enforcement date mentions number of employees. Our facility includes retail locations. Should the total number of employees include retail employees, or just manufacturing, distribution and admin support?

A: In the Preventive Controls rule preamble, the FDA states that they use full time equivalent employees and bases the determination of the size of the company on the same definition used by the U.S. Small Business Administration (SBA) under 13 CFR part 121.

Q: Our sister company is a transportation company. It operates as its own entity. Does it have to be registered with FDA separate from our manufacturing company?

A: Registration is facility based. If the transportation company owns a warehouse or manufacturing facility, then it would need to register that facility with the FDA.

Q: Are training programs for PCQI available via web-based training? Any examples, if so?

A: There are computer based training programs being developed for PCQI. I am not aware of any available yet.

Q: For the Supply Chain Program, my company blends ingredients together and provides bulk powders to customers. In our case would our Suppliers be responsible for supplying the documentation?

A: The need for a supply chain program depends on the hazard analysis and the need for a supply chain preventive control. The documentation is part of your food safety plan.

Q: We are exporters to the US. Do our suppliers in turn need to have HARPC or be FMSA compliant?

A: You need to meet the equivalent requirements of the Preventive Controls or Produce safety rules. The US owner of the product at the time of import will complete the Foreign Supplier Verification.

Q: Most of our suppliers are already approved through BRC or IFS or SQF or FSSC22000?

A: The certification and audit for the GFSI program can serve as the documentation for FSVP.

Q: We have BRC and HACCP and radiological hazards does not apply for us. Do we need to add radiological hazards still?

A: Radiological hazards will need to be considered in your hazard analysis. Most likely radiological hazards are not known or reasonably foreseeable.

Q: What if the US Company does not have a US citizen owner?

A: Does not need to be a US Citizen - just a US owner or consignee. The US Company is the FSVP.

Q: What is the best website to find the FSMA rules?

A: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/>

Q: Does FSMA apply to dietary supplements?

A: Dietary supplements are exempt from FSMA. However, dietary ingredients used in foods are subject to cGMPs. This is a very complex regulatory area and I recommend that you review the regulation or seek the advice of someone knowledgeable about dietary supplement regulations.

Q: Supply chain program question. If receiving spices to be used in a RTE product and the spices may have a bacteria count, does this require a supply chain program from the spice supplier?

A: It all depends on the hazard analysis. If you determine that bacteria are a hazard requiring a preventive control, and your spice supplier is controlling the hazard, then a supply chain control program is appropriate.

Q: Are sprout growers then exempt from Preventive Controls, Sanitary Transportation and Food Defense?

A: Sprout growers are required to comply with produce safety. Depending on what the facility does, there might be other regulatory requirements.

Q: How does preventative controls or FSVP apply to food contact packaging purchased/produced overseas?

A: Food packaging materials are considered food contact surfaces. If there is a possibility of contamination then it must be addressed in the hazard analysis.

Q: What is the difference between "document your PC qualified individual " and "train all qualified individuals"? Thanks in advance.

A: Training is required for Preventive Controls Qualified Individuals and Qualified Individuals and training records are required for both.

Q: How is Sanitary Transportation apply when using FedEx?

A: We will learn more when the final rule published next month. The scope of the proposed rule covered rail and road transportation. As part of the food safety plan, it would be important to maintain temperature control and avoid contamination during transportation of any kind.

Q: Does the manufacturer/processor need to make sure the transportation is done properly - ie how is this different from the STF regs?

A: We will learn more when the final rule publishes next month. It is important that contamination of the product is prevented at all times. If temperature control is part of the food safety plan, then the temperature control should be maintained throughout the product life cycle.

Q: Please explain the exemptions (if any) for a Pilot Plant. Thank you.

A: It depends on the facility registration requirement. Additionally, there is an exemption from the supply chain control program and the Foreign Supplier Verification Program for pilot plants since they are not "receiving facilities." In the Preventive Controls final rule see § 117.405(a)(3))

Q: Can you expand on supply chain preventive controls? Specifically Records and Continuing guarantee?

A: A supply chain control program is specified in subpart G. Receiving facilities (pilot plants are not receiving facilities) are required to implement supply chain controls for hazards requiring a supply chain preventive control. If the hazard is controls by the supplier, then this applies.

Q: We are a Canadian co-manufacturer who exports to US direct to the retail chain. We are FDA registered/federally registered (CFIA) and SQF certified. Is it safe to say that we must comply with all under the manufacturer umbrella although we are the exporter?

A: Yes, you will need to meet the same requirements as specified in the Preventive Controls rule. The FSVP importer is the US owner or US agent. They will be the ones to verify that you meet those requirements and your SQF program and audit can be the basis of that verification.

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