Preventive Controls and Hazard Analysis

A Deeper Dive into what the FSMA Proposed Rule Means to the Industry

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Or, given we have yet to publish a proposed rule, maybe we just go wading.
First, to set the stage:

What Congress told us to require
FSMA Requirement for Preventive Controls

• Under FSMA Section 103 (Section 418 of the Federal Food, Drug, and Cosmetic Act) facilities are required to conduct a hazard analysis and implement preventive controls for identified hazards.

• Applies to businesses that are required to register under the Bioterrorism Act of 2002.
  – FSMA has provided several exemptions, e.g., those subject to seafood and juice HACCP regulations
FSMA Definition of Preventive Controls

- *Preventive controls*: risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified in the hazard analysis…and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.
FSMA Preventive Controls

- Sanitation procedures for food-contact surfaces and utensils and food-contact surfaces of equipment;
- Supervisor, manager and employee hygiene training;
- An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment;
- A food allergen control program;
- A recall plan;
- Current Good Manufacturing Practices under 21CFR 110;
- Supplier verification activities that relate to the safety of food.
Hazard Analysis

• Identify and evaluate known or reasonably foreseeable hazards
  – Biological, chemical, physical and radiological (natural toxins, pesticides, drug residues, decomposition, parasites, allergens, unapproved food and color additives)
  – Hazards that occur naturally or may be unintentionally introduced
Preventive Controls

• Identify and implement preventive controls, including at critical control points, if any, to significantly minimize or prevent the hazards identified in the hazard analysis
Monitoring and Corrective Actions

- Monitor the performance of the preventive controls
- Establish corrective action procedures for improper implementation of preventive controls
Verification

• The preventive controls are adequate to control the hazards
• Monitoring is being conducted and appropriate decisions are made about corrective actions
• The preventive controls are effectively and significantly minimizing or preventing the occurrence of the identified hazards
  – Including through use of environmental and product testing programs
• Reanalysis of the plan (no less frequently than every 3 years)
Recordkeeping

Written plan and documentation of

- Monitoring of preventive controls
- Instances of nonconformance material to food safety
- Results of testing and other verification activities
- Instances when corrective actions were implemented
- Efficacy of preventive controls and corrective actions

Available to authorized representative of FDA on request
Exemptions

• Facilities required to comply with
  – Seafood HACCP regulation
  – Juice HACCP regulation
  – Low-acid canned foods regulation (for microbiological hazards only)
  – Dietary supplement GMPs

• Alcoholic beverages

• A “qualified facility” (very small business or one with limited annual sales (< $500K) selling directly to consumers or to restaurants/ retail food establishments in same state or within 275 miles)
HACCP but not HACCP

• The law looks a lot like HACCP but is different in many aspects
  – FSMA included identification and evaluation of intentionally introduced hazards
  – Preventive controls are not restricted to implementation at CCPs
HACCP but not HACCP

• The law looks a lot like HACCP but is different in many aspects (cont.)
  – Preventive controls (procedures, practices, and processes) include
    • CGMPs/sanitation
    • Environmental monitoring
    • Training
    • Recall plan
Intentionally Introduced Hazards

• How would a facility determine what these hazards are, since they are generally not “known or reasonably foreseeable”?
• (Or are they, in some circumstances?)
Preventive Controls & CCPs

• As with HACCP, preventive controls require monitoring, corrective actions, verification (including validation)
• Is the expectation that these same activities can apply at places other than CCPs? Do we call these controls points?
• Would it cause confusion to conduct these activities at places other than CCPs? (What is the difference between a CCP and CP?)
CGMPs/Sanitation

- Generally have been considered as Prerequisite Programs or SSOPs
- If implemented as preventive controls, should they be required to have monitoring, corrective actions and verification, as with HACCP CCPs?
- Are these always preventive controls or only where they address “known or reasonably foreseeable hazards”? What hazards?
Environmental Monitoring Program

• Preventive control? Or verification activity?
• If implemented as a preventive control, what are the specific monitoring, corrective actions and verification activities?
• If implemented as a verification activity, what is the preventive control being verified and what is the hazard being controlled?
Training

- Training has been considered a prerequisite program. Can it be applied as a preventive control?
- What are the hazards that would be prevented?
- How would we monitor, take corrective action and verify that training is effectively and significantly minimizing or preventing the hazard?
Recall Plan

• Recalls happen when a hazard has not been “prevented” – how does the recall plan work as a preventive control?

• If preventive controls require monitoring, corrective actions and verification, how would these be applied to a recall plan?
Verification Requirements

• Preventive controls are adequate to control the hazard (validation)
  – What is needed to demonstrate that the preventive controls adequately control the hazard?
• This requirement is likely to mean that industry will have to put more focus on validation, and not just of CCPs.
Verification Requirements

• Verification that preventive controls are significantly minimizing or preventing (SMOPing) the occurrence of identified hazards
  – Environmental testing programs
  – Product testing programs

• This requirement is likely to mean that industry will have to put more focus on these activities.
Environmental Monitoring Verification

• When is it appropriate to use environmental monitoring to verify that preventive controls are SMOPing a hazard?
• How much specificity should we include in the proposed rule vs. guidance?
Product Testing Verification

• When is it appropriate to use product testing to verify that preventive controls are SMOPing a hazard?
• How much specificity should we include in the proposed rule vs. guidance?
So, what does this approach mean for industry?

- Does the use of the term “preventive controls” provide industry more flexibility than if FSMA had used “HACCP”?
- Or will this be more confusing for industry?
So, what does this approach mean for industry?

- Will requiring all (or almost all) facilities to conduct a hazard analysis and implement preventive controls
  - Provide a level playing field?
  - Provide facilities with greater assurance that their suppliers are controlling hazards at their facility?
  - Provide facilities with a means to demonstrate to customers that they are producing safe products?
FSMA Provides Industry with Opportunities

• Develop risk-based, prevention-oriented procedures for manufacturing/processing/packing/holding food
• Disseminate industry best practices for food safety – “Food safety is not a competitive issue.”
• “Raise the bar” for food safety
Thank you!