



Proposed Preventive Controls Rule Discussion of Testing

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Requirements of FSMA

- Section 418(f)(4): verify that the preventive controls are “effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means.”



Role and Need for Testing

- Varies depending on the type of products and activities of the facility
- FDA current thinking addressed in preamble and appendix
- FDA requests comment and poses questions to help determine a risk- and science-based approach



Testing of Raw Materials/Ingredients

- Often tested as part of a supplier approval and verification program
- Verification activity when a preventive control that is adequate to significantly minimize or prevent a hazard is applied at the supplier facility and not applied at the receiving facility.



Utility and Frequency of Raw Material/Ingredient Testing

- Depends on
 - The hazard and its association with the raw material or ingredient
 - Likelihood that the consumer would become ill if the hazard were present in the raw material or ingredient
 - How that raw material or ingredient will be used by the receiving facility
 - The ability of supplier controls to significantly minimize or prevent the hazard in the raw material or ingredient



Factors to Consider for Product Testing

- Nature of hazard, evidence of adverse health consequences from that hazard in the food
- Intended consumer of the food
- Impact of the food on the contaminant
- Intended/customary use of the food
- Type of supplier controls



Factors to Consider for Product Testing

- Effect of processing on the hazard
- Whether a hazard can be reintroduced into a food that has been treated to significantly minimize the hazard,
 - through exposure to the environment or
 - by the addition of an ingredient after a treatment to significantly minimize a hazard.



Other Considerations for Testing

- Whether ingredients that may contain a hazard have been tested
- The extent of any environmental monitoring program
- Whether other programs established by the facility provide added assurance that the potential for hazards has been minimized



Finished Product Testing Questions

- Should FDA require finished product testing?
- When and how is finished product testing an appropriate means of verifying that hazards are being effectively controlled?
- Should product testing be limited to finished product testing or include raw material/ingredient testing?



Finished Product Testing Questions

- What is the appropriate level of specificity for a product testing program? Should FDA...
 - Specify particular hazards, situations or product types for which finished product testing would be required?
 - Specify the frequency of testing and, if so, whether this frequency should depend on the type of product?
 - Identify appropriate sampling plans for finished product testing?
 - Require periodic testing for trend analysis and statistical process control?



Considerations for Environmental Monitoring

- There is the potential for food to be contaminated with pathogens any time a food is exposed to the environment.
- Foods of concern: Ready-to-eat foods
- Environmental pathogens most frequently involved in the contamination of foods leading to foodborne illness: *Salmonella* spp. and *L. monocytogenes*



Environmental Pathogens

- May be introduced into a facility through raw materials or ingredients, people, or objects
- May be transient strains or resident strains
 - Resident strains become established in a “niche” or harborage site
- Growth of an environmental pathogen increases the chance that it will be transferred to other sites, including food contact surfaces and food



Purpose of Environmental Monitoring

- Verify the implementation and effectiveness of sanitation controls intended to significantly minimize or prevent the potential for an environmental pathogen to become established in the facility and contaminate RTE food



Environmental Monitoring Questions

- Should environmental testing requirements be included in the final rule?
- When and how is environmental testing an appropriate means of verifying that hazards are being effectively controlled?



Environmental Monitoring Questions

- What is the appropriate level of specificity for an environmental monitoring program? Should FDA...
 - Specify the environmental pathogen or the indicator organism for which the samples must be tested?
 - Specify the locations within the facility at which samples must be collected?
 - Specify the frequency of collection of environmental samples?
 - Specify the corrective actions that should be taken if environmental testing identifies the presence of an environmental pathogen?



Testing Example from the Produce Standards Rule

Sprouts



Proposed Testing for Sprouts

- Test the growing, harvesting, packing and holding environment for *Listeria* spp. or *Lm* AND
- Test spent sprout irrigation water from each production batch for *E. coli* O157:H7 and *Salmonella* spp. OR
- When testing spent irrigation water is not practical, test each production batch of soil-grown sprouts at the in-process stage for *E. coli* O157:H7 and *Salmonella* spp.



Proposed Requirements for Environmental Testing for Sprouts

- Written environmental monitoring plan that is designed to identify *L. monocytogenes* if present in the environment
- Sampling plan must specify
 - Test organism
 - Frequency of sampling (no less than monthly)
 - Sample collection sites must include food contact surfaces and non-FCSs



Proposed Actions for a *Listeria*-Positive

- Conduct additional testing of surfaces and areas surrounding the area where *Listeria* spp. or *L. monocytogenes* was detected
- Clean and sanitize the affected surfaces and surrounding areas
- Conduct additional microbial sampling and testing to determine whether the *Listeria* spp. or *L. monocytogenes* has been eliminated
- Conduct finished product testing when appropriate
- Perform any other actions necessary to prevent reoccurrence of the contamination



Proposed Requirements for Testing Water or Sprouts

- Written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts
- Test the collected samples for *E. coli* O157:H7 and *Salmonella* spp. using a validated method