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Hazard Analysis and Preventive Controls:
What FSMA Requires and How to Prepare

ASTA Annual Meeting; Pre-Conference Workshop

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Hazard Analysis and Preventive Controls (Food Safety Plan)

- Cornerstone of the legislation
- Major focus on prevention
- Affects day-to-day activities
- More than meets the eye
- More details will become clear when FDA issues proposed rule
- Expect to engage in discussions with FDA

Food Safety Plans

- Conduct hazard analysis of hazards of known or reasonably foreseeable hazards
- Put into place controls designed to significantly minimize or prevent those hazards
- Implement preventive controls through monitoring, corrective actions, and verification activities
- Verification activities include environmental and product testing
- Reanalysis required every 3 years
- Food safety plan and all related records available to FDA during inspection

Hazard Analysis

For hazards that may occur naturally or may be unintentionally introduced, identify and evaluate *known or reasonably foreseeable hazards* that may be associated with the facility:

- Biological
- Chemical
- Physical
- Radiological
- Natural toxins
- Pesticides
- Drug residues
- Decomposition
- Parasites
- Allergens
- Unapproved food and color additives

Preventive Controls

- Implement preventive controls, including at critical control points, to assure
  - Identified hazards (including intentional hazards involving bioterrorism) are significantly minimized or prevented
  - Food manufactured at the facility will not be adulterated or misbranded (with regard to major allergens)
- Note: Many current HACCP plans likely do not cover general adulteration

Types of Controls Defined

- Sanitation for food contact surfaces and utensils, including food contact surfaces of equipment
- Supervisor, manager, and employee training
- Environmental monitoring program
- Food allergen control program
- Recall plan
- Current Good Manufacturing Practices
- Supplier verification activities that relate to the safety of food

→ This is a “starter list” only

Food Safety Plans – Critical Control Points

- Identify and implement preventive controls at critical control points, *if any*
  - Critical Control Point: "…a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level"
- Congress envisions that some facilities might not have any critical control points
  - But you will need to justify this to FDA

Monitoring

- Monitor the effectiveness of the preventive controls
  - Remember each of the preventive controls
  - Is the monitoring clearly documented? **If it isn't documented, it didn't happen!**

Corrective Actions

- Required if the preventive controls are not properly implemented or are ineffective
  - Action is taken to reduce the likelihood of a reoccurrence
  - All affected food is evaluated for safety
  - All affected food is prevented from entering commerce if the facility cannot ensure that the food is not adulterated or does not contain an undeclared allergen
- Remember: Mistakes happen – the key is recognizing them quickly, correcting them, and documenting that correction

Verification

Operator must verify that:

- Preventive controls are adequate to address the identified hazards
- Monitoring of the controls is in place
- Appropriate decisions are being made regarding corrective actions
- Documented, periodic reanalysis of the hazard plan to ensure it is still relevant to the facility and to new and emerging threats

Verification—Testing

- 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"
- Some combination of product and environmental testing likely will be required

Product Testing

- It is widely believed that some form of product testing (ingredient and/or finished product) will be mandated and FDA will have access to those records
- Each facility needs to consider what is appropriate under its own circumstances and be prepared to justify that to the agency

Reanalysis

- At least every 3 years
- Whenever a significant change in the hazards or activities occurs
- Must either revise the Food Safety Plan OR document the basis for concluding that no change was necessary

Exemptions

- Deemed compliance for seafood HACCP, juice HACCP, and microbiological elements of Low Acid Canned Food facilities
- Limited exemption for very small businesses with sales less than $500,000 and limited distribution
- FDA has authority to modify rules or exempt
  - Warehouses for packaged food
  - Storage facilities for raw agricultural commodities
  - Animal food or feed

Food Defense

- Include intentionally introduced hazards that could be introduced by acts of bioterrorism
  - "Reasonably foreseeable standard" does NOT apply
  - Implement appropriate mitigation steps
  - FDA to issue regulations
  - This requirement likely is not included in most company's existing hazard analyses
- Must develop a written analysis of the hazards that must be made available to FDA
- Can be in "companion" section of Food Safety Plan

FDA Activities

- Public Meeting (April 20, 2011)
  - Docket for written comments (Docket No. FDA-2011-N-025)
- Meetings with Industry
- Docket for Guidance Documents (FDA-2011-N-0238)
- Proposed Rule
  - Under review at OMB
- Food Safety Preventive Controls Alliance
- Statutory effective date: July 3, 2012
  - FDA expected NOT to enforce until FINAL regulations are issued

Issues So Far

- Exemption for warehouses
  - ABA led coalition petition
- Role of testing
  - Verification vs. control
  - Frequency
  - Positive results
- Separate food defense plans
- Electronic submission/remote access to Food Safety Plans

Points to Consider

- Does each facility have a Food Safety Plan?
- When was the last time we analyzed potential hazards?
  - Has our facility undergone significant changes since then?
  - Do we anticipate significant changes in the near future?
  - Have we considered ALL the hazards listed in statute?
- What preventive controls are we using?
  - Can we match them to the list of hazards?
- Do we have critical control points?
  - If yes, have they been validated?
  - If not, can we justify that to FDA?

Points to Consider

- What monitoring activities are we performing?
  - Are these appropriately documented?
- Do we have procedures in place to determine when corrective actions are needed and what kind to take?
  - Is this documented?
  - Would those survive a careful audit?
- Have we verified these controls are effective?
  - What testing programs do we have in place?
    - Environmental?
    - Product testing?

Points to Consider

- Do we have the right personnel?
- Who is charge of our food safety plans?
  - Who will review them with inspectors?
- Where are our records?
- Do our records clearly reflect
  - The legal requirements?
  - What we are doing?
- Where is additional training needed?

FDA's Questions to Ponder

- 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
  - What is the difference between a CCP and CP?
  - Is the expectation that the same monitoring, corrective actions, verification, and validation activities can apply at places other than CCPs? Should FDA call these controls points?
  - Would it cause confusion to conduct these activities at places other than CCPs?

FDA's Questions to Ponder

- CGMPs and Sanitation
  - These programs 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?

FDA's Questions to Ponder

- Environmental Monitoring Programs
  - 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?

FDA's Questions to Ponder

- 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 a facility monitor, take corrective action and verify that training is effectively and significantly minimizing or preventing the hazard?
- Recall Plans
  - 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 activities apply to a recall plan?

FDA's Questions to Ponder

- Verification Requirements
  - What is needed to demonstrate that the preventive controls adequately control the hazard (validation)?
  - When is it appropriate to use environmental monitoring to verify that preventive controls are significantly minimizing or preventing (SMOPing) a hazard?
    - How much specificity should FDA include in the proposed rule vs. guidance?
  - When is it appropriate to use product testing to verify that preventive controls are SMOPing a hazard?
    - How much specificity should FDA include in the proposed rule vs. guidance?

Conclusion

- Section 103 is one of the most significant provisions in FSMA
- Will affect how spice manufacturers do business every day
- Documentation is critical
- Start preparing now

FDA FOOD SAFETY
MODERNIZATION ACT

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