Morgan Lewis

FSMA – Proposed Rules and the New Risk Environment

presented by Robert G. Hibbert
and Anthony T. Pavel
Morgan, Lewis & Bockius LLP

Morgan Lewis Webinar
February 27, 2013
12:00-1:00 pm ET

Introduction and Overview

- Identify key elements of the pending preventive controls and produce safety proposals
- Place proposals in broader FSMA context
- Discuss issues, questions, and concerns raised by the current proposals
- Assess the current dynamics of the risk environment, both regulatory and beyond
- Suggest potential strategies for managing risk in FSMA-driven environment

Some Overarching Issues

- FDA puts strong emphasis on “Industry’s primary role on food safety”
- “Risk-based” approach to proposals, as well as implementation
- Resources and cost–FDA did not get additional funding to implement and enforce; cost to industry looms
- Impact on supply chain–particularly non-U.S. sourced supplies

Proposed Rules in Context

- Other major proposed rules pending, including:
  - Foreign Supplier Verification Program
  - Preventive Controls for Animal Food
  - Accredited Third Party Certification
- Immediate enforcement enhancements
  - Suspension
  - Recordkeeping
- Goal is to establish a food safety system ranging from farm to fork on a global scale
- Science and risk based
- Fully and reliably documented
- Fully traceable and accountable

Preventive Controls

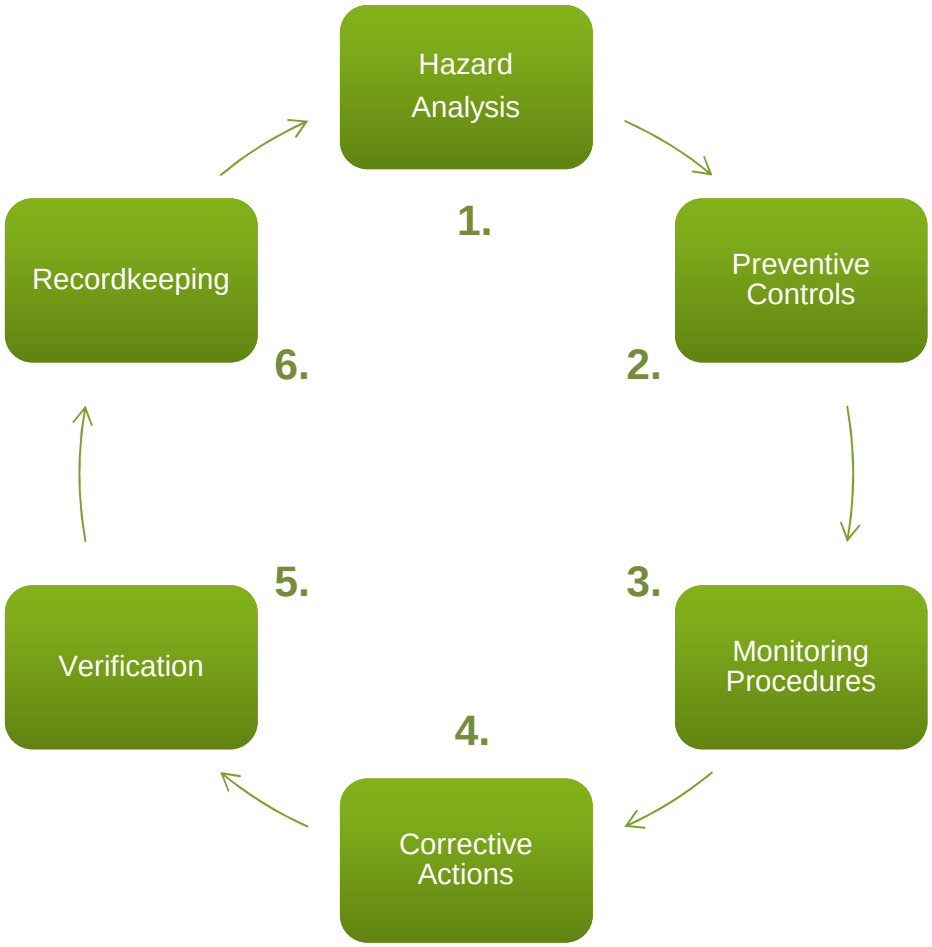
- Hazard analysis and risk-based preventive controls
- Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
- Updated Good Manufacturing Practices

Preventive Controls

Who Is Covered?

- Facilities that manufacture, process, pack, or hold human food
- In general, facilities required to register with FDA under section 415 of the FD&C Act
- Applies to domestic and imported food
  - *Agency has asked for comments re: definition of a "very small business" for implementation and exemptions*

Hazard Analysis and Risk-Based Preventive Controls



Preventive Controls

- Process controls
- Food allergen controls
  - Protection against cross-contact; labeling
- Sanitation controls
  - Cleanliness of food contact surfaces; prevention of cross-contact and cross-contamination
- Recall plan
- Also
  - Supplier approval and verification, interplay with pending foreign supplier verification proposals

Preventive Controls

Verification–Validation

- Collecting and evaluating scientific and technical information (or conducting studies) to demonstrate that the preventive controls are effective in controlling the hazards
- Must be performed prior to implementation or within six weeks of production
  - *Questions remain regarding finished product testing, environmental testing*

Preventive Controls

Qualified Individual

Must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system.

Preventive Controls

Responsibilities of a Qualified Individual

- Preparation of the food safety plan
- Validation of the preventive controls
- Review of records
- Reanalysis of the food safety plan

Preventive Controls

Recordkeeping

- Written food safety plan
- Monitoring of preventive controls
- Corrective actions
- Verification activities
- Training for qualified individuals
- Review of records and audits of food safety plans

Preventive Controls for Human Food

- Exemptions and Modified Requirements
  - Foods subject to low-acid canned food regulations
  - Foods subject to HACCP (seafood/juice)
  - Dietary supplements
  - Alcoholic beverages
  - Facilities (e.g., warehouses) that store only packaged foods and are not exposed to environment
    - *Refrigerated foods must have temperature, monitoring, verification, and records controls*

Preventive Controls for Human Food

- Effective and compliance dates
  - Effective date: 60 days after final rule published
  - Compliance dates:
    - *Small businesses (fewer than 500 employees)–two years after publication*
    - *Very small businesses (less than $250,000 (or, alternatively, $500,00 or $1,000,000) in annual sales)–three years*
      - Very small businesses considered “qualified” facilities subject to modified requirements
    - *Other Businesses–one year after final rule publication*

Proposed Rule on Produce Safety

- Who is covered?
  - Farms that grow/harvest/pack or hold most produce in raw/natural state ("raw agricultural commodities")
  - Farms/farm portions of mixed facilities
  - Domestic and imported produce
  - Proposed limitations on coverage
- "Produce" = fruits and vegetables
  - Includes mushrooms, sprouts, herbs, and tree nuts, but **not** grains

Proposed Rule on Produce Safety

- The proposed rule would apply to **almost all produce**
- Exemptions:
  - Specific commodities rarely consumed raw
    - *Proposal includes an "exhaustive" list of exempted produce*
      - includes asparagus, kidney beans, and potatoes …
  - Produce subject to a kill step through commercial processing, so long as documentation is kept (e.g., oranges for juice)
- Produce that is not a raw agricultural commodity
  - Subject to preventive controls

Proposed Rule on Produce Safety

- Would set standards to control for five specific hazards
  - Worker training and health and hygiene
  - Agricultural water
  - Biological soil amendments
  - Domesticated and wild animals
  - Equipment, tools, and buildings
- Sprouts addressed in detail; long history of issues
- Resembles cGMPs more than HACCP

Proposed Rule on Produce Safety

- Recordkeeping will be new to some/many producers; no need to create duplicative records
- Qualitative assessment of risk helps to inform proposed rule
  - Scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce
  - Available for public comment as part of proposed rule

Proposed Rule on Produce Safety

- Compliance dates staggered
  - Very small farms ($25,000–$250,000): four years after effective date (six years for some water requirements)
  - Small farms ($250,001–$500,000): three years after effective date (five years for some water requirements)
  - Other covered farms: two years after effective date (four years for some water requirements)

Big Picture and Points of Controversy/Concern

- Proposals must be considered in light of pending/forthcoming proposals for imports, testing, transport
- Implementation time frame–USDA FSIS “Mega-Reg” as point of reference
- Practical considerations–formal enforcement several years out; however, proposals clearly represent FDA’s current thinking. *See,* e.g., FDA Warning Letter issued to Chamberlain Farms - December 14, 2012

Big Picture and Points of Controversy/Concern

- Allergens–*significant focus*
  - e.g., roles of cross-contamination versus allergen control/sanitation
- Environmental testing/finished product testing
  - Relegated to appendices of proposal
  - What will expectations be in light of traditional HACCP principals?
- Qualified individual
  - Expectations while model curriculum is pending
  - Effect on academic credentials, assessment of experience

Sunland, Inc. Action

- Suspension of registration 11/26/12–first time under FSMA
- Consequences of suspension
- Allegations:
  - Evidence of outbreak
  - Sole source of implicated product
  - Records of violative test results
  - Shipments of implicated product
- Consent Decree issued 12/21/12

Non-Regulatory Risk

- Proposals–opportunity for comment, modification and time line
- Establishment of current standard of care
- Benefits and burdens of flexibility
- Customer and consumer expectations
- Liability risks

Steps to Consider Now

- Establishment/clarification of food safety term
- Evaluation of current program based upon
  - Current regulatory requirements
  - Those anticipated by proposals
  - Overall food safety trends
  - Expectations of consumers, customers, and other stakeholders
- Establish action plan with timetables
- Rebut presumption in proposal when appropriate and properly document
- Evaluate risk throughout entire supply chain
- Prioritize, minimize, and protect against risk

Litigation Issues

- Things to be thinking of from a litigation perspective while evaluating and evolving regulatory expectations
- While FD&C Act does not have private right of action, proposed rules will be used as benchmarks in state-law-based claims
  - Evaluate risk throughout entire supply chain
    - *Potential liability–suppliers, customers, consumers*
    - *Impact proposed rules have upon existing agreements*
    - *Overall reassessment of guarantees, specifications, and other elements of contracts and supply agreements*
  - Prioritize, minimize, and protect against risk
    - *Insurance coverage*

Insurance Coverage Issues

- Consult coverage counsel
- Portfolio counseling
- Issue-spotting; policy negotiation
- Recall insurance issues, affect on current recall policies

Conclusions

- FSMA-proposed rules have immediate relevance by:
  - Raising issues for comment and revision
  - Functioning as comprehensive guidance documents
  - Influencing current standards and expectations
  - Providing broader window into FDA's approach to FSMA
- Intelligent response should involve:
  - Systematic evaluation of proposed rules contents and potential impacts
  - Development of action plan
  - Broad-based risk-management program