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Legal Realities of Food Safety

Produce Marketing Association -- Webinar

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Disclaimer

This presentation is a summary and should not be relied upon as a substitute for legal advice that applies the regulatory requirements to specific operations.

Types of Inspections

- Comprehensive (routine/generally scheduled)
  - Domestic facilities
    - "High risk" – all within 5 years, then once every 3 years
    - Others – all within 7 years, then once every 5 years
  - Foreign facilities
    - At least 600 within 1 year, and double the number of inspections every year for the next 5 years
- Directed
  - "For cause"
  - Follow-up to previous inspection
  - Recall effectiveness check
  - Consumer complaint
  - Criminal

Inspector Requirements

- Inspector must present:
  - Written notice of inspection (Form FDA 482)
  - Appropriate credentials
- FDA must conduct inspections
  - “At reasonable times”
  - “Within reasonable limits”
  - “In a reasonable manner”

Inspections – FDA Jurisdiction

- FDA may obtain records of interstate shipment
- Must be provided if FDA gives “written request”
  - In such case, records cannot be used in criminal prosecution against party supplying records
  - Generally, FDA will decline to make request in writing

Inspections -- Data

- By statute, FDA is NOT entitled to –
  - Financial data
  - Sales data (other than shipment records)
  - Pricing data
  - Personnel data (other than personnel qualifications)
  - Research data

Inspections -- Samples

- FDA may collect samples of product or labeling
  - Upon request, FDA to provide part of official sample to facility owner (companies usually take their own, too)
  - Receipt to be provided for collected samples
- Upon request, FDA to provide copy of analytical results of samples

Inspections -- Photographs

- FDA training: take photographs if potentially useful; do not ask company's permission
- If company objects, inspectors assert that FDA's right has been established, citing two court cases
- If continued objection, inspector obtains name/contact information of company's legal counsel or senior management
  - Reports information to FDA District Office
  - FDA Office of Chief Counsel (OCC) may contact company's legal counsel to discuss photo authority

Inspections -- Records Access

- FSMA -- broader FDA records access during inspections when “reasonable probability” of serious adverse health consequences or death from food
  - Prior authority: Access records for food at issue
  - Current authority: Expands access to records of related products if reasonable belief that they are likely to be affected in similar manner
- Written notice (Form FDA 482c)

Inspections

- "Close out conference" with inspector and team
  - May be presentation of Form FDA-483 (Inspectional Observations)
  - Ask questions if any alleged violations need clarification
  - Discuss any remedial action already implemented
  - Respectfully correct any misperception
- Company should respond to 483 within 15 business days
  - Discuss any corrective action taken and timeframe for completing other actions
  - Address systemic causes, if appropriate
  - Respectfully disagree with alleged violations if there is justification for your position
  - FDA will review a response to a 483 before deciding whether to issue a Warning Letter

Warning Letters

- FDA may address “minor violations” through “suitable written notice or warning”
- Warning letters are “informal and advisory,” not a conclusion of a violation, and not “final agency action”
- A response must be submitted within 15 working days unless an extension is granted

Final Report

- Establishment Inspection Report (EIR), filed by the inspector, details the observations made during the inspection and will include the results of any tests
- In the EIR, inspector may have noted areas of concern which will be the subject of the next inspection
- In general, FDA policy is to provide company with copy of EIR when inspection is closed
- All documents prepared by FDA in connection with an inspection (except confidential information) are available publicly through the Freedom of Information Act (FOIA) unless FDA is considering/has initiated enforcement action
- FDA makes final “confidentiality” determination

Inspection Do's and Don'ts

- Pre-inspection: Do's
  - Have a company Inspection Manual
  - Have a trained Inspection Team
  - Identify what FDA (or the state) may inspect
  - Be familiar with relevant sections of FDA's Investigations Operations Manual
  - Include policies on:
    - Photographs
    - FDA record review
    - Complaint file review
    - Providing shipping records
    - Procedures boundaries (areas and interviews of employees)
    - Being accompanied
  - Conduct mock inspections periodically
  - Review prior inspection reports and check status of any promised corrective action

Inspection Do's and Don'ts

- During the Inspection: Do's
  - Be courteous, professional and firm
  - Document identification
  - Review FDA 482 - Notice of Inspection
  - Hold opening conference/present inspection policies
  - Protect trade secrets
  - Repeat policies, if necessary
  - Use designated company spokesperson(s)
  - Use company "reporter" to take notes during the inspection
  - Collect duplicate samples

Inspection Do's and Don'ts

- During the Inspection: Don'ts
  - Keep inspectors waiting
  - Sign any documents
  - Volunteer information
  - Be untruthful or deceptive
  - Be intimidated
  - Admit any wrongdoing
  - Allow inspector to go anywhere unaccompanied

Noncompliance -- FSMA

- Violation of law
- Compliance helps determine whether food adulterated under
  - 402(a)(3) -- manufactured in way that is unfit for food
  - 402(a)(4) -- prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health
- Could be enforcement action
- Could be criminal implications depending on the facts
- Facility suspension (SAHCODHA risk); facilities must know or have reason to know of such reasonable probability
- Fees – facility reinspection (due to violations materially related to food safety requirement) or failure to comply with a recall order
- If product liability action -- violation could be considered negligence per se if related to food safety
- If recall -- may be evidence of causation

FSMA Whistleblower Protection

- Prohibits retaliation against employees who:
  - Provided information to officials,
  - Testified in violation proceedings, or
  - Refused to participate in work-related activities due to food safety concerns
- If employer violation -- reinstatement, compensatory damages, costs reasonably incurred by whistleblower
- Company policy and compliance plan are important

Criminal Liability

- "Responsible corporate officer doctrine"/ Park Doctrine
  - U.S. Supreme Court case (1975) -- United States v. Park
  - Strict criminal liability theory
- Misdemeanor conviction, under public welfare laws, based on:
  - FD&C Act violations
  - Corporate officer -- authority to prevent/correct violation
  - No knowledge/intent/participation necessary
  - Objective impossibility defense?
- Used in Jensen Farms

Criminal Liability

- Factors that FDA will consider re prosecution:
  - Whether the violation involves actual or potential harm to the public;
  - Whether the violation is obvious;
  - Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
  - Whether the violation is widespread;
  - Whether the violation is serious;
  - The quality of the legal and factual support for the proposed prosecution; and
  - Whether the proposed prosecution is a prudent use of agency resources.

Recalls

- Recall
  - Removal/correction of marketed product FDA believed to be in violation and against which FDA "would initiate enforcement action (*e.g.*, seizure)"
- Market withdrawal
  - May involve product in commerce with only minor violation that would not be subject to legal action or a quality issue that is not a safety risk
- Stock recovery
  - Product has not been marketed or has not left firm's direct control

Recalls

- Class I -- “reasonable probability” that product will cause “serious adverse health consequences or death to humans or animals” (“SAHCODHA” risk)
- Class II -- product may cause “temporary or medically reversible adverse health consequences” or where probability of severe adverse consequences is “remote”
- Class III -- product “not likely to cause adverse health consequences”
- Reportable Food Registry -- food is “reportable” only if there is a Class I level of risk

Recalls

- Voluntary
  - Company Initiated Recall
  - FDA Requested Recall
- Mandatory (FSMA)
  - Class I level risk
  - Civil Penalties
    - Up to $50,000 for an individual and $250,000 for any other entity that violates recall order
    - Capped at $500,000 for all violations adjudicated in a single proceeding

Challenges -- Illness Outbreaks

- Preliminary epidemiological evidence links foodborne illness outbreak to product
  - Suspected food source may change (2008 *Salmonella* Saintpaul outbreak; from tomatoes to jalapeno and serrano peppers)
  - May not be a positive test result for pathogen in product
  - May not be a validated methodology at time a recall decision must be made
  - Other potential sources may not investigated thoroughly
- FDA -- will request a voluntary recall when
  - CDC establishes a statistical food/illness association through epi data, and
  - FDA identifies a source through traceback
- Accuracy should be as important as speed –at what point is the information sufficiently strong to justify a recall

Challenges -- Pathogen Tests

- Pathogen detected in random product sample
  - Positive test result for product with multiple ingredients; no positives when test ingredients
  - Evaluate need for recall if product is past shelf life
  - Difficulty confirming sampling/testing details
  - Concerns re methodology used
  - Risk of false positive

THANK YOU

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