Inspection and Enforcement Authority

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Agenda

- Inspections
- Enforcement Tools
- State Law and Relationship to Federal Law

Inspections - FDA

- FDA has general authority to inspect
  - any “factory, warehouse, or establishment” where food is manufactured, processed, packed, or held for or after introduction into interstate commerce
  - Any vehicle used to transport food in interstate commerce
- FDA can delegate inspections to state officials

FDA Inspection Frequency

- "High Risk" domestic facilities
  - Once within 5 years of FSMA enactment
  - Then once every 3 years
- Other domestic facilities
  - Once within 7 years of FSMA enactment
  - Then once every 5 years
- Foreign facilities
  - 600 facilities in first year of FSMA, twice as many each year for the next five years

FFDCA § 704

Inspections - FDA

- Must be
  - At reasonable times
  - Within reasonable limits
  - In a reasonable manner
- Investigator has to present
  - Written notice of inspection (FDA Form 482)
  - Credentials
- No warrant required unless inspection refused

What Can FDA Inspect?

- Records
  - "All pertinent equipment, finished and unfinished materials, containers, and labeling" (FFDCA § 704)
  - Shipping records (FFDCA § 703)
    - FDA may obtain records of interstate shipment from carriers or persons receiving goods after shipment
    - Must be provided if FDA makes a written request, but in that case they cannot be used against the providing party in a criminal prosecution
  - FDA not entitled (by statute) to: (FFDCA § 704)
    - Financial data, sales data, pricing data
    - Personnel data (other than qualifications)
    - R&D data

What Can FDA Inspect?

- Records
  - Broader access in emergency situations:
    - When FDA has “reasonable belief” that an article food is adulterated and presents a threat of serious adverse health consequence or death to humans or animals (SAHCODHA)
    - Can access all records relating to that food or to a food FDA believes is reasonably likely to be affected in a similar manner
    - Requires written notice

What Can FDA Inspect?

- Samples
  - FDA may collect samples during an inspection
  - FDA to provide a receipt for the samples
  - Upon request, FDA must provide part of the sample to facility
  - FDA to pay “fair value” for samples taken
  - Inspections increasingly sample intensive – “swabathons”

What Can FDA Inspect?

- Photographs
  - No express authority in FFDCA for photographs
  - FDA investigators are trained to take photographs when appropriate without asking permission
  - If the company objects, investigators are told to assert that the right exists based on two court cases
    - Court cases are distinguishable – one involves photographs the company consented to; the other involves aerial photography (i.e., plain view)
  - If the company continues to object, investigators are to obtain contact information the company's legal counsel
    - Investigators are to report the situation to the District Office
    - FDA Office of Chief Counsel may contact the company's legal counsel to discuss the authority to take photographs
  - However, FDA states in Draft Guidance it considers refusal to allow photographs by foreign facility to constitute a refusal of inspection

Foreign Facilities

- FDA has authority to inspect foreign facilities that import food into the U.S.
- Foreign inspections are more resource-intensive than domestic inspections, so FDA conducts fewer of them
- FSMA charged FDA with conducting more inspections of foreign facilities
- Foreign inspections are usually announced in advance for logistical reasons

FDA Inspection Process

- Investigator arrives and presents Form 482
- Introductory conference
  - Companies often show investigator to a conference room and assemble a team to participate in the inspection
  - Identify who is available to answer questions
  - Assign a company employee to accompany the investigator
- Inspections can last multiple days (or weeks)
- Close-out meeting
- Possible FDA Form 483
- Establishment Inspection Report (EIR)

FDA Inspection Process

- Close-out meeting
  - Held at the end of the inspection
  - If a Form 483 is issued, investigator will review it with the company
  - Review any corrective actions already completed
  - FDA may also raise “discussion points”
- Form 483
  - If issued, should respond within 15 business days
  - Identify corrective actions (with timeframes for future actions) and provide documentation when appropriate
  - If 483 response is late, FDA does not have to consider it before issuing a Warning Letter
- Establishment Inspection Reports (EIRs)

FDA Inspection Process

- Signing documents
  - Investigator might present affidavits or forms for company representatives to sign voluntarily at the close-out meeting or during the inspection
  - There is no requirement to sign any documents
  - There is no requirement to admit anything
  - Any signed documents will be made part of the record
- Reinspection Fees
  - Under FSMA, FDA is authorized to collect fees when conducting an inspection to verify compliance with earlier food safety related observations

Classification of Inspections

- Indicates what if any action FDA expects following an inspection
- NAI – “No Action Indicated”
- VAI – “Voluntary Action Indicated”
- OAI – “Official Action Indicated”
  - OAI signals pending enforcement action

COVID-19 Effect on Inspections

- FDA paused all but the most critical inspections when COVID began
- FDA has been conducting “mission critical” inspections since March 2020
- Mission critical:
  - foodborne outbreak
  - follow-up to recall
  - root cause investigation for consumer complaints where there are serious injuries

COVID-19 Effect on Inspections

- FDA announced that domestic inspections would resume July 20, 2020
- Not “business-as-usual”
- Will use COVID advisory tool to prioritize inspections and assess regional safety
  - The “phase of the State”
  - Statistics measured at the county level to gauge the current trend
  - Statistics measured at the county level to gauge intensity of infection
- There is no international COVID advisory tool like for domestic inspections.
- FDA is monitoring the Department of State travel warnings and advisories to determine when can resume routine foreign inspections
- FDA plans to continue pre-announcing all inspections using a standard script to gauge the status of the facility

Remote Regulatory Assessments

- Remote Regulatory Assessment ("RRA") is a review of records and information provided by the firm showing the status of portions of its manufacturing processes
- FDA is performing a "study" of RRAs
- Contacting ~30 human food facilities where:
  - There is an ongoing compliance dialogue; and
  - Corrective actions after the last inspection may be verified through records review (e.g., update an SOP or Food Safety Plan)
- Participation is voluntary

Remote Regulatory Assessments

- FDA will contact the facility to request the RRA
- Facility is expected to reply to FDA whether or not they choose to participate
  - No penalty for not participating
- RRA limited to information that can be easily provided securely and electronically (e.g., via email)
  - FDA open to firms sharing and explaining the documentation via videoconference
- Following the RRA, discussion of findings with management officials
- No regulatory action expected as a result of RRA
  - If significant deficiencies, FDA may begin regulatory inspection
  - No Form 482 or Form 483
  - Will document review in a memo or in the case file

FSIS Inspection Authority

- Unlike FDA, which relies on spot inspections, FSIS uses a "continuous inspection" program
  - FSIS inspector usually must be present for an official establishment to operate
  - Sometimes will involve multiple inspectors
  - For slaughter operations, combination of "online" and "offline" inspection
- FSIS inspectors have significant in-plant authority, including the ability to stop the production line or stop product shipments

FSIS Inspection Authority

- FSIS inspection authority
  - FMIA allows for “inspection of all meat products” prepared at official establishments
  - “Inspectors shall have access at all times, by day or night . . . to every part of said establishment”
- Product produced without inspection is not eligible for the USDA mark of inspection and is considered adulterated
- FSIS reinspects product offered for import

FSIS Records Access

- FSIS has broad records access
  - Establishments must “keep such records as will fully and correctly disclose all transactions involved in their businesses”
  - Establishments “shall, at all reasonable times upon notice . . . afford . . . access to their places of business and opportunity to examine the facilities, inventory, and records thereof”

FSIS Inspection

- FSIS's inspection authority extends to retail establishments and warehouses
  - Retail establishments and warehouses are not "official establishments" and don't require continuous inspection
  - But FSIS inspectors may conduct spot inspections
  - Inspections can include facilities (e.g., deli, butcher counter, receiving, warehouse space) and records

COVID-19 Effect on Inspections

- Because FSIS uses a continuous inspection program for establishments, COVID-19 has not been as disruptive for FSIS as for FDA
- Inspections continue with social distancing protocols in place

FFDCA "Prohibited Acts"

- FFDCA defines a number of "prohibited acts," including:
  - Introducing into interstate commerce adulterated or misbranded food
  - Adulterating or misbranding food in interstate commerce
  - Refusal to permit inspection or copying or records to which FDA has access

FFDCA § 301

FDA Enforcement

- Key FDA enforcement tools:
  - Form 483s
  - Regulatory Meeting
  - Warning Letters
  - Recalls
  - Administrative Detention
  - Seizures
  - Suspension of Registration
  - Import Alerts
  - Court Actions – Civil and Criminal

Regulatory Meetings

- Requested by FDA to inform responsible individuals or firms about how one or more products, practices, processes, or other activities are considered to be in violation of the law
- May follow issuance of a Warning Letter or be called to discuss documented violations that did not warrant issuance of a Warning Letter
- Expect commitment by the responsible individuals to correct the conditions or practices
- Commitments verified through evaluation of subsequent communications and documentation and/or a follow-up inspection

Warning Letters

- Letter detailing alleged violations
  - Requests written response from the company
- Usually follows a “bad” inspection
  - But not always; other factors can trigger them (e.g., labeling violations)
- FDA seeking to drive voluntary compliance
- FDA can escalate action if issue not resolved

Recalls

- Recall: Removal or correction of marketed product FDA believes to be in violation and against which FDA would initiate enforcement action (e.g., seizure)
- FDA expects companies to voluntarily recall products presenting a food safety risk
- FDA has mandatory recall authority in limited situations

Classes of Recalls

- Class I
  - Reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death
  - E.g., a pathogen in RTE product
- Class II
  - May cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote
  - E.g., foreign objects (usually)
- Class III
  - Use of or exposure to a violative product is not likely to cause adverse health consequences
  - E.g., aesthetic defect; undeclared non-allergenic ingredient

FDA Recall Authority

- Under FSMA, FDA can mandate a recall in a Class I situation
- Must first request voluntary recall
- If company refuses, FDA can issue order mandating the company cease distribution and notify its customers
- There is an expedited hearing process available
- Company can face civil penalties for mandatory recall

Administrative Detention

- Allows FDA to detain a food without obtaining a court order
- FDA may detain any food if there is “reason to believe” it is adulterated or misbranded
- Detention is temporary and is designed to give FDA time to get a court order for a seizure

Seizures

- Food is seized in the marketplace and placed under government control
- FDA may request a seizure of any adulterated or misbranded food
- Requires a court order
  - Structured as a legal proceeding against the product
- Relatively uncommon

Suspension of Registration

- FDA may suspend a facility's registration in serious situations
  - Reasonable probability that exposure to food will cause serious adverse health consequences or death to humans or animals
  - Can suspend registration of facility that created the reasonable probability, or
  - That knew of or had reason to know of the reasonable probability **and** packed, received, or held the food
- Effectively shuts down facility

FFDCA § 415

Imports

- FDA has significant authority to police and detain imported food at the border
  - Can refuse entry if food "appears" to be
    - Produced under insanitary conditions
    - Forbidden from sale in the originating country
    - Adulterated or misbranded
    - In violation of certain FSMA recordkeeping requirements
  - FDA does not have to prove an actual violation

Import Alerts

- Administrative instruction to FDA border investigators to detain all shipments of an identified food
- “Detention without physical examination”
- Used when FDA believes there is a systemic problem with a food, company, or region

FFDCA Civil & Criminal Liability

- FFDCA imposes civil and criminal liability for any prohibited act
  - First violation technically is a federal misdemeanor
  - Second violation technically is a federal felony
  - Violation with intent to deceive is a felony
- FDA Office of Criminal Investigations (OCI) conducts criminal investigations and brings them before Department of Justice (DOJ)
- DOJ must initiate civil or criminal proceeding
- FDA and DOJ have broad enforcement discretion

FFDCA § 303

FFDCA Civil & Criminal Liability

- FFDCA is construed as a strict liability statute
  - Do not need to show intent
- *Park* Doctrine
  - *U.S. v. Park* (1975 S. Ct. Case)
  - Corporate officials can be held criminally liable for violations of the FFDCA in areas of the company under the official's control

FFDCA Civil & Criminal Liability

- *United States v. Park*
  - FDA brought criminal charges against CEO of Acme Markets for violations of FFDCA
  - SCOTUS noted that as CEO, Park was responsible for overseeing sanitation and ensuring compliance with the FFDCA
  - Court held Park could be liable because he had final responsibility for ensuring compliance and failed to do so
  - *Park* affirmed that strict liability applies to corporate officials whose failure to exercise authority leads to a violation of the FFDCA
- Corporate officials can be held criminally liable for violations of the FFDCA in areas of the company under the official's control

FFDCA Civil & Criminal Liability

- Yates Memo (2015)
  - Instructs federal prosecutors to prioritize holding corporate executives responsible for criminal acts of a company
    - "One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing."
    - "Absent extraordinary circumstances or approved departmental policy, the DOJ will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation"
- Latter policy relaxed in 2018, and DOJ's civil attorneys have discretion to negotiate individual releases in civil cases where additional investigation of those individuals is not warranted with "written supervisory approval"

FFDCA Civil & Criminal Liability

- Civil Penalties
  - Consent decrees / Injunctions
    - Court ordered
    - Usually requires corrective actions and FDA approval to resume operations
    - Can be challenging to operate under
    - Violators can be held in contempt of court
  - Monetary penalties in specific situations
    - *E.g.*, foods with unapproved pesticide residues
    - Rare for foods; not typically included in consent decrees

FSIS Enforcement Authority

- Noncompliance Records (NRs)
- Heightened inspection activities
  - e.g., Food Safety Assessments, Public Health Risk Evaluations
- In-plant or in-commerce control actions
  - “tagging” product, stopping or slowing a production line
- Notice of Warning
- Voluntary Recalls
- Withholding or Withdrawal of Inspection
- Referral for criminal prosecution

State Enforcement

- State food and drug acts
  - "mini FFDCAs"
  - Often reference or incorporate federal standards
  - Many states have "stop-sale" authority
- States conduct a significant portion of food inspections
- State attorneys general enforce consumer protection laws

California Proposition 65

- Requires warnings before exposing consumers to carcinogens or reproductive toxicants
- Not limited to food, but includes substances sometimes found in food (e.g., acrylamide, lead)
- Private right of action to enforce the law

State Slack-Fill Laws

- Many states have their own laws or regulations concerning non-functional “slack fill”
- Often coupled with a private right of action to enforce violations
- Lawsuits particularly common where companies reduce the amount of food but maintain the same package size

Questions and Discussion

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