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FDA's Criminal Enforcement Powers and What They Mean to the Spice Industry

2015 ASTA Regulatory Workshop

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Agenda

- Legal Framework
- FDA Enforcement Powers
- *Park* Doctrine
- Recent Enforcement Actions
- FSMA Considerations

Legal Framework

- The Federal Food, Drug, and Cosmetic Act (FFDCA) focuses on adulteration and misbranding
- Prohibited Acts
  - Introducing or delivering any food that is adulterated or misbranded into interstate commerce
  - The adulteration or misbranding of any food
  - The receipt in interstate commerce of any food that is adulterated or misbranded
  - The manufacture of any food that is adulterated or misbranded
    - (FFDCA § 301; 21 U.S.C. § 331)

Legal Framework

- A food is adulterated if:
  - It “bears or contains any poisonous or deleterious substance which may render it injurious to health”;
  - It contains a “filthy, putrid, or decomposed substance”;
  - It is “unfit for food”;
  - It contains an unapproved food additive;
  - It has been held or prepared under “insanitary conditions” whereby it may have become contaminated with filth; or
  - If a valuable component has been substituted or omitted.
    - (FFDCA § 402; 21 U.S.C. § 342)

Legal Framework

- A food is “misbranded” for reasons that include:
  - Its label or labeling is “false or misleading in any particular” (FFDCA § 403(a)(1); 21 U.S.C. § 343(a)(1))
  - It contains any undeclared major food allergens (FFDCA § 403(w); 21 U.S.C. § 343(w))
- FDA has established very detailed labeling requirements for food labels and labeling
  - Mandatory content (e.g., Nutrition Labeling)
  - Voluntary content (e.g., nutrition-related claims)
- “Labeling” interpreted broadly: books, brochures, websites, social media content, internet search terms

Legal Framework

- Penalties
  - Misdemeanor Violation
    - Subject to one year in jail and/or
      - For violations that result in death:
        - Individuals may be subject to fines of up to $250,000
        - Organizations may be fined up to $500,000
      - For other misdemeanors:
        - Individuals may be subject to fines up to $100,000
        - Companies may be subject to fines up to $200,0000

  - Felony Violations
    - If the party has previously been convicted under the act, or committed the prohibited act with the intent to defraud or mislead, the party may be:
    - Subject to three years in jail and/or
      - For individuals, a fine of up to $250,000
      - For companies, a fine of up to $500,000
  - If party derived pecuniary gain from the offense or caused pecuniary loss to another, the fine may double the gross gain/loss
    - 21 U.S.C. § 303(a); 18 U.S.C. §§ 3359, 3571

FDA Enforcement Powers

- Advisory
  - Untitled Letters
    - For violations less serious than Warning Letters
    - Unlike Warning Letters, Untitled Letters do not include statement that failure to correct the violation promptly will lead to enforcement action
  - Warning Letters
    - Put a company on notice that FDA considers it to be violating the law
    - Provides company an opportunity to correct violation before agency takes formal enforcement action

FDA Enforcement Powers

- Administrative Powers
  - Administrative Detention (domestic or imports)
    - Before passage of FDA Food Safety Modernization Act (FSMA), FDA could detain any article of food found to present a threat of serious adverse health consequences or death
    - Now, FDA can detain food if it has “reason to believe” that the food is adulterated or misbranded

FDA Enforcement Powers

- Administrative Powers
  - Mandatory Recalls
    - If food is adulterated or misbranded, FDA expects a recall
    - FSMA granted FDA the authority to mandate a recall if a firm refuses to recall product voluntarily and the food may cause serious adverse health consequences or death
    - There must be a “reasonable probability” that the food is adulterated or contains undeclared allergens
  - Suspension of Registration
    - FSMA granted FDA the authority to suspend a facility’s registration if FDA determines that there is a “reasonable probability” that food from the facility will cause serious adverse health consequences or death

FDA Enforcement Powers

- Judicial
  - Seizures
    - Court-ordered seizure of product by a Federal Marshall
  - Injunctions
    - Court order to cease conduct causing violation
  - Debarments
    - Prohibits future participation in the industry
  - Criminal Prosecutions
    - FFDCA is a strict-liability statute

Park Doctrine

- Named for Supreme Court case *United States v. Park*, 421 U.S. 658 (1975)
  - Stemmed from earlier case, which upheld the conviction of the president of a company repackaging misbranded drugs
- *Park* reaffirmed that strict liability applies to corporate officials whose failure to exercise authority leads to a violation of the FFDCA
  - Government prosecuted Acme Markets and its CEO, Park, for violating FFDCA by allowing food to be stored in rodent-infested warehouse
  - Park claimed he relied on subordinate to remedy problem
  - SCOTUS said Park could be liable because he had final responsibility for ensuring compliance and failed to do so

Park Doctrine

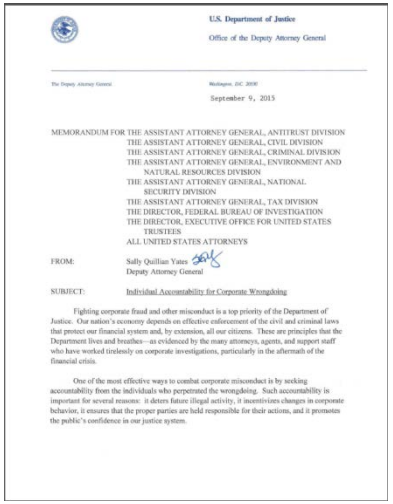
- Corporate officials can be held criminally liable for violations of the FFDCA in areas of the company under the official's control
  - Strict liability: intent or awareness, or even negligence, are not required
  - Corporate official does not need have any actual knowledge of, or participation in, the specific offense

Park Doctrine

- Factors that influence initiation of prosecution:
  - Corporate official's position and relationship to the violation;
  - Whether the official had authority to correct or prevent the violation;
  - Official's knowledge of and actual participation in the violation;
  - 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;
  - Seriousness of the violation;
  - Quality of legal and factual support for the proposed prosecution; and
  - Whether the proposed prosecution is a prudent use of agency resources
    - Source: *FDA Regulatory Procedures Manual*

Yates Memorandum

- September 2015 Department of Justice (DOJ) policy memo directs the government to pursue individual prosecutions in corporate investigations
  - Issued by Deputy Attorney General Sally Quillian Yates (Yates Memorandum)
- DOJ determined corporate fines and penalties are insufficient to deter criminal conduct
- As part of corporate investigations, DOJ will investigate and prosecute culpable executives and employees, who may potentially serve significant jail time
- Consistent with shifting trends in federal prosecutions



U.S. Department of Justice

Office of the Deputy Attorney General

September 9, 2015

MEMORANDUM FOR THE ASSISTANT ATTORNEY GENERAL, ANTITRUST DIVISION
THE ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION
THE ASSISTANT ATTORNEY GENERAL, CRIMINAL DIVISION
THE ASSISTANT ATTORNEY GENERAL, ENVIRONMENT AND NATURAL RESOURCES DIVISION
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FROM: Sally Quillian Yates
Deputy Attorney General

SUBJECT: Individual Accountability for Corporate Wrongdoing

Fighting corporate fraud and other misconduct is a top priority of the Department of Justice. Our nation's economy depends on effective enforcement of the civil and criminal laws that protect our financial system and, by extension, all our citizens. These are principles that the Department lives and breathes—as evidenced by the many attorneys, agents, and support staff who have worked tirelessly on corporate investigations, particularly in the aftermath of the financial crisis.

One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing. Such accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system.

Recent Enforcement Actions

Recent Enforcement Actions

- Mandatory Recall
- Suspension of Registration
- Consent Decree
- Misdemeanor Prosecution
- Felony Prosecution

Mandatory Recalls

- Kasel Associates Industry
  - FDA for-cause inspection in 2012 found finished pet treat products and 48 of 87 environmental samples testing positive for Salmonella
    - More than 10 species found, indicating multiple sources of contamination
  - Company voluntarily recalled some product, but not others
  - FDA sent company a “Notification of Opportunity to Initiate a Voluntary Recall” letter
    - Provided company with two days to conduct a voluntary recall
    - Company complied
- USPlabs
  - Manufacturer of dietary supplements linked to outbreak of non-viral hepatitis in 2013
  - FDA a issued Warning Letter in October 2013 stating that products were adulterated because they contained a new dietary ingredient that was not the subject of a required notification to FDA
    - Products then linked to cluster of liver illnesses in several states
  - FDA sent company a “Notification of Opportunity to Initiate a Voluntary Recall” letter
    - Company then issued a recall voluntarily

Suspension of Registration

- Sunland, Inc.
  - Company's peanut butter was linked to outbreak of *Salmonella* in 2012
    - Company also had "history of violations"
  - FDA suspended the company's registration in November 2012
    - FDA noted company's testing records showed multiple positive results from both environmental testing and in finished products, as well as unsanitary conditions in facility
    - Company distributed lots even after testing identified *Salmonella* in the lots
  - Effectively shut down the facility because it was prohibited from introducing food into commerce, or importing or exporting food, while registration was suspended
  - In January 2013, FDA vacated the suspension order and entered into a consent decree of permanent injunction

Consent Decrees

- Wholesome Soy Products
  - FDA routine inspection in 2014 identified multiple findings of contaminated food and environmental samples
    - Both product and environmental samples tested positive for *Listeria monocytogenes* (*Lm*)
  - Company recalled product and sanitized facility, then resumed operations
  - After resuming operations, an outbreak was linked to the *Lm* strain found in previous samples
    - FDA follow-up inspection found nine samples testing positive for *Lm*
    - Based on the findings, FDA concluded that sprouts could not safely be manufactured by the company in that environment
  - Company entered into a consent decree of permanent injunction with FDA in April 2015
    - Decree prohibits company from receiving, processing, manufacturing, preparing, packing, holding, and distributing ready-to-eat mung bean and soybean sprouts

Misdemeanor Prosecutions

- ConAgra Grocery Products
  - Peanut butter contaminated with *Salmonella* led to more than 700 illnesses
  - Company pleaded guilty to a single misdemeanor violation of unknowingly introducing private label peanut butter contaminated with *Salmonella* into interstate commerce
  - Under a plea agreement reached in 2015, company will pay a criminal fine of $8,011,000 and forfeit assets of $3,200,000
    - Largest criminal fine ever paid in food safety case
  - Company also will continue to follow food safety and quality policies and confirm adherence to the policies for two years

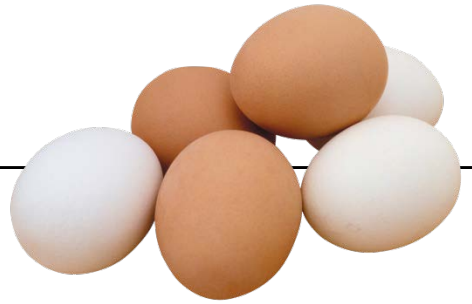
Misdemeanor Prosecutions

- Jensen Farms
  - 147 ill in 28 states, 33 deaths resulting from cantaloupe contaminated with *Lm*
  - Two primary principles, Eric and Ryan Jensen, charged September 2013; sentenced January 2014
  - Pleaded guilty to unknowingly introducing adulterated food into commerce
  - Sentenced to 5 years probation, 6 months home detention, $150,000 restitution (each); 100 hours community service

Misdemeanor Prosecutions

- Orchid Island Juice Co.
  - Unpasteurized juice associated with outbreak of *Salmonella Typhimurium* in 2005
  - Company and two corporate officers charged with introducing adulterated juice that was manufactured under insanitary conditions and with introducing unpasteurized juice that contained a poisonous and deleterious substance
    - Pleaded guilty to misdemeanor charges
  - Company was fined $200,000 and given three years of probation in 2010
  - One individual fined $100,000 and the other $25,000
    - Both received three years of probation

Misdemeanor/Felony Prosecutions



- Quality Egg LLC
  - *Salmonella* outbreak caused by eggs led to more than 1,900 illnesses, recall of 550 million eggs
  - Company and owners Austin “Jack” DeCoster and his son, Peter DeCoster, charged in June 2014; sentenced April 2015
    - Company pleaded guilty to felony violations: bribing USDA inspector, introducing adulterated and misbranded food into interstate commerce
    - Owners pleaded guilty to misdemeanor violations of introducing adulterated food into interstate commerce
  - Sentenced to $6.8 million fine (for the company), $100,000 (for each individual), 3 months in jail
    - Sentence currently being appealed

Felony Prosecution

- Peanut Corporation of America (PCA)
  - *Salmonella* outbreak in 2009 led to more than 700 illnesses, 9 deaths
  - PCA officials charged with 76-count indictment
    - introduction of adulterated and misbranded food into interstate commerce with the intent to defraud and mislead
    - conspiracy, fraud, wire fraud, obstruction of justice
  - Felony charges brought against company owner, Stuart Parnell, and peanut broker, Michael Parnell, for introducing adulterated food into interstate commerce "with the intent to defraud or mislead"
  - Jury found all three individuals guilty in September 2014; sentenced to jail time in September 2015:
    - Stuart Parnell (President): 28 years
    - Michael Parnell (VP Sales): 20 years
    - Mary Wilkerson (QA Manager): 5 years
    - Daniel Kilgore (Operations Manager): 6 years
    - Samuel Lightsey (Operations Manager): 3 years

FSMA Considerations

New FDA Culture

- FSMA implementation is occurring just as FDA culture has changed
- FDA is:
  - More inspection-oriented
    - Conducting more domestic inspections (with the states)
    - Expanding definition of “high risk”
    - Testing more, especially environmental testing
  - More enforcement-minded
    - FDA is more critical and more inclined to identify issues
    - Increase in Warning Letters for food adulteration based on food inspections/GMP violations
    - Increase in court injunctions

What Does This Mean?

- FDA's expectations are changing
- Inspections are changing
- Testing has increased
- Crackdowns will increase in frequency

Increased Records Access Authority

- FSMA provides FDA with greatly expanded access to records during routine inspections

Essential Records Under FSMA	
Food Safety Plan	- Corrective Action Procedures and Records
- Hazard Analysis (and re-analysis)	- Verification Procedures and Records
- Sanitation Controls	-- Environmental and Product Testing Procedures and Records
- Allergen Controls	- Supplier Verification Plan and Implementation Activities
- Process Controls	- Recall Plan
- Monitoring Procedures and Records	Food Defense Plan and Implementation Activities
- Validation Data for Process Controls	Sanitary Transportation Procedures

Implications of Records Access

- This new authority facilitates a “systems-based inspection” approach
  - Lets FDA know how a company is operating when inspectors aren’t present
  - FDA will know what happened not just today, but last week, last month, and last year!
- Records review will be a central component of FDA inspections
  - Inspections will become more like an IRS audit
  - But GMP-focused inspections aren’t going away
- **Companies’ decisions will be become much more exposed to scrutiny by inspectors**

Conclusion

- FFDCA is a strict-liability statute
- FDA increasingly using misdemeanor prosecutions as an enforcement tool
- Increasing push for corporate-level prosecutions
- FDA's enforcement powers expanded under FSMA
- Increase in records access and enforcement tools under FSMA will create a new inspection paradigm and increased potential for liability

Questions?

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