Food Safety – Preventing Adulteration and Contamination that Could Lead to Unsafe Products and Costly Litigation

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Trent Taylor

McGUIREWOODS

21 U.S.C. § 342

- A food shall be deemed to be adulterated--
- (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health;
- (2) (B) if it bears or contains a pesticide chemical residue that is unsafe
- (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food;
- (4) if it has been prepared, packed, or held under insanitary conditions whereby it **may** have become contaminated with filth, or whereby it **may** have been rendered injurious to health;

Summary of FDCA

- Manufacture, distribution, and sale of food that is adulterated or misbranded are misdemeanors, if the adulteration or misbranding is unknown to the company. *See* 21 U.S.C. § 333(a)(1).
- If the adulteration or misbranding is a repeat offense, or the food in question was known to be adulterated or misbranded and manufactured, distributed, and sold nonetheless, felony charges may result. *See* 21 U.S.C. § 333(a)(2).

21 U.S.C. § 601 (m)

- The term “adulterated” shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
- (1)if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an **added substance**, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
- (2)(A)if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any **added poisonous or added deleterious substance** (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity;
- (ii) a food additive; or
- (iii) a color additive, which may, in the judgment of the Secretary, make such article unfit for human food;
- (B)if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a **pesticide chemical** which is unsafe within the meaning of section 346a of this title,
- (C)if it bears or contains any **food additive** which is unsafe within the meaning of section 348 of this title,
- (D)if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: Provided, That an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;

21 U.S.C. § 601 (m)

- (3)if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, **unhealthful, unwholesome**, or otherwise unfit for human food;
- (4)if it has been prepared, packed, or held under **insanitary conditions** whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;
- (5)if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;
- (6)if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
- (7)if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;
- (8)if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or
- (9)if it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance.

Adulterated Products

- Product composition
  - Contains or is composed of “a poisonous or deleterious substance which may render it injurious to users”
  - Consists of “any filthy, putrid, or decomposed substance”
- Conditions under which product is manufactured, shipped, or stored
  - “[P]repared, packed, or held under insanitary conditions”
  - “[M]anufacture, processing, packing, or holding do not conform with current good manufacturing practice”
- Container
  - Composed of “poisonous or deleterious substance”
- Color additive
  - Bears or contains an unsafe color additive
  - Color additive deemed “unsafe”

Recent Developments

- **Chemical Contaminants**
  - **Acrylamide:** Draft Guidance for Industry: Acrylamide in Foods[1] (November 2013)
- **Metals (Arsenic)**
  - Draft Guidance for Industry: Arsenic in Apple Juice - Action Level[7] (July 2013)
- **Natural Toxins**
  - Compliance Policy Guide Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products- Hypoglycin A Toxin (April 14, 2014)
- Food Safety Challenge (Sept. 26, 2014)

STECs Update

- Since 2012, U.S. beef producers are required to test their meats not only for the well-known pathogenic strain of *E. coli* known as 0157:H7, but also for six other strains of the bacteria known to cause illness in humans.
- These other Shiga toxin-producing *E. coli*, or STECs, which include *E. coli* 026, 011, 0103, 0121, 045, and 0145, are collectively known as “the Big Six” and are banned from meats sold in the U.S.
- As of June 2014, FSIS began analyzing for Salmonella all raw beef samples it collects for STEC analysis from 25 grams to 325 grams.

Allergens

- USDA's FSIS recently published a new guidance that stresses the importance of accounting for allergens in meat and poultry plants that make foods with multiple ingredients.
- Advises companies to pay close attention to allergen controls in HACCP plans
- Warns that allergens can be introduced at any point in the production of a food item.
- Explains that many recalls caused by undeclared allergens occurred "because of a change in product formulation by the establishment or a change in supplier's ingredient formulation that was not reflected on the labeling of the finished meat or poultry product in which the ingredient was used."
- Provides checklists for plants and inspectors to use to be aware of all stages where allergens might be introduced and steps a plant manager can take to identify all allergens.

Regulation of Allergens

Figure 1: The "Big Eight" Allergens: Tree Nuts, Peanuts, Soy, Egg, Milk, Fish, Wheat and Shellfish.

Reportable Food Registry, FDA Amendments Act of 2007, § 417

- Applies to “Responsible Parties”
  - Registered under Bioterrorism Act
  - Registered under FSMA
- Must Affirmatively Report:
  - When there is “reasonable probability that use of/or exposure to an article of food will cause serious adverse health consequences to humans or animals.”
    - Generally = Class I Recall Standard
  - Notify ASAP and within 24 hours
    - Through Electronic Portal (**http://www.safetyreportingpanel.hhs.gov/**)
    - 866-300-4374 = 24 hour “hotline”

RFR

- The Reportable Food Registry (RFR or the Registry) was established by Section 1005 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), which amended the Food, Drug, and Cosmetic Act (FD&C Act) by creating a new Section 417, Reportable Food Registry [21 U.S.C. 350f]. It required FDA to establish an electronic portal to which reports about instances of reportable food must be submitted to FDA within 24 hours by responsible parties and to which reports may be submitted by public health officials.
- A reportable food is an article of food/feed for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.
- The congressionally identified purpose of the Registry is to provide a reliable mechanism to track patterns of food and feed adulteration to support efforts by FDA to target limited inspection resources to protect the public health.

RFR

- • FDA may require a responsible party to submit to FDA consumer-oriented information regarding a reportable food. This critical information must include a description of the article of food; affected product identification codes, such as UPC, SKU, or lot or batch numbers sufficient for the consumer to identify the article of food; contact information for the responsible party; and, any other information FDA determines is necessary to enable a consumer to accurately identify whether such consumer possesses the reportable food. Fruits and vegetables that are raw agricultural commodities are exempted from this requirement.
- • FDA is required to prepare the critical information as a standardized one-page summary and publish the one-page summary on FDA.gov in a format that grocery stores can easily print for purposes for consumer notification.
- • A Grocery store that is part of a chain of establishments with 15 or more physical locations and has sold a reportable food that is the subject of a one-page critical information summary published on FDA.gov is required to notify consumers by prominently displaying the one-page summary or information from such summary within 24 hours of its FDA web posting and maintain the display for 14 days.

RFR

Table 1: Comparison of Years 1, 2, 3 and 4 RFR Total Submissions and Entries

Report Category	Year 1	Year 2	Year 3	Year 4
Total Submissions	**2600**	**1153**	**1471**	**1534**
Nonreportable submissions	(360)	(271)	(376)	(265)
Total Entries	**2240**	**882**	**1095**	**1269**
Primary (Industry and Voluntary) Entries	229	225	224	202
Subsequent Entries (Upstream and Downstream)	1872	483	609	849
Amended Entries	139	174	262	218

RFR

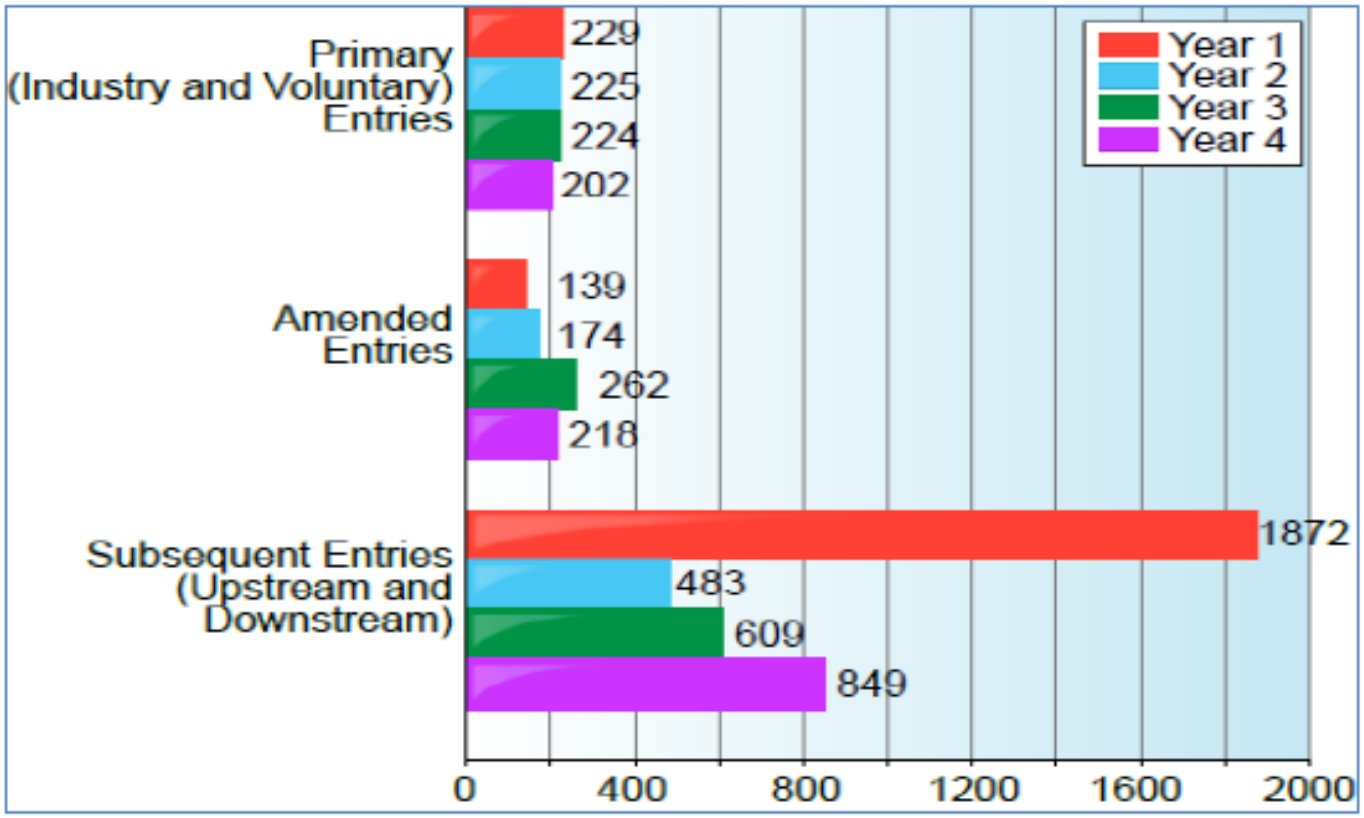
- Highlighted below are events that resulted in the submission of the greatest number of reports during Year 4:
- • *Salmonella* Bredeney in widely distributed peanut butter (related to a human illness outbreak investigation), resulting in 207 subsequent entries, i.e., reports resulting from a primary report
- • *Listeria monocytogenes* in imported smoked salmon, resulting in 80 subsequent entries
- • *E. coli* O121 in various frozen foods resulting in 69 subsequent entries (related to a human illness outbreak investigation)

RFR

- **D. COLLABORATIVE REVIEW OF RFR SUBMISSIONS AND NOTIFICATIONS**
- When a reportable food report is submitted to the Safety Reporting Portal, it is sent to the FDA Risk Control Review (RCR) team for review. The RCR team includes the following FDA organizations: the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), the Office of Emergency Operations (OEO), and the Office of Regulatory Affairs (ORA). In addition, the FDA District Office for the geographic area from which the report originated receives a copy and participates in the review. Appropriate regulatory commissioned officials in the state or states involved are automatically notified of any reportable food reports that pertain to their jurisdictions. Immediate sharing of reportable food report information allows for rapid collaboration and coordination between FDA field offices and state officials.
- Each report is reviewed by the RCR team to assess whether the subject food or feed meets the definition of a reportable food, and to identify appropriate follow-up actions. All reports are then referred to the appropriate FDA personnel for follow-up ("Risk Control Review (RCR) Process for Assessing Reportable Food Reports").
- For reports that FDA considers to meet the definition of reportable food, a District Office investigator is assigned to contact the firm or individual submitting the report to obtain additional information if necessary. The District Office investigator may visit the firm to conduct a follow-up investigation. When necessary, District Offices advise the responsible party to notify the immediate previous supplier(s) of materials and/or the immediate subsequent recipient(s) of a reportable food and provide to the supplier/recipient the initial reporter's Individual Case Safety Report (ICSR) number.
- If information submitted indicates that the subject food or feed may have been intentionally adulterated, FDA immediately sends a copy of the report to the Department of Homeland Security. If the subject food is under the exclusive jurisdiction of the USDA, a copy of the report is sent to USDA. If a submission involves a food or feed or an ingredient imported into the United States, FDA contacts the competent authority in the country of origin.

RFR

Figure1: RFR Entries by Report Type

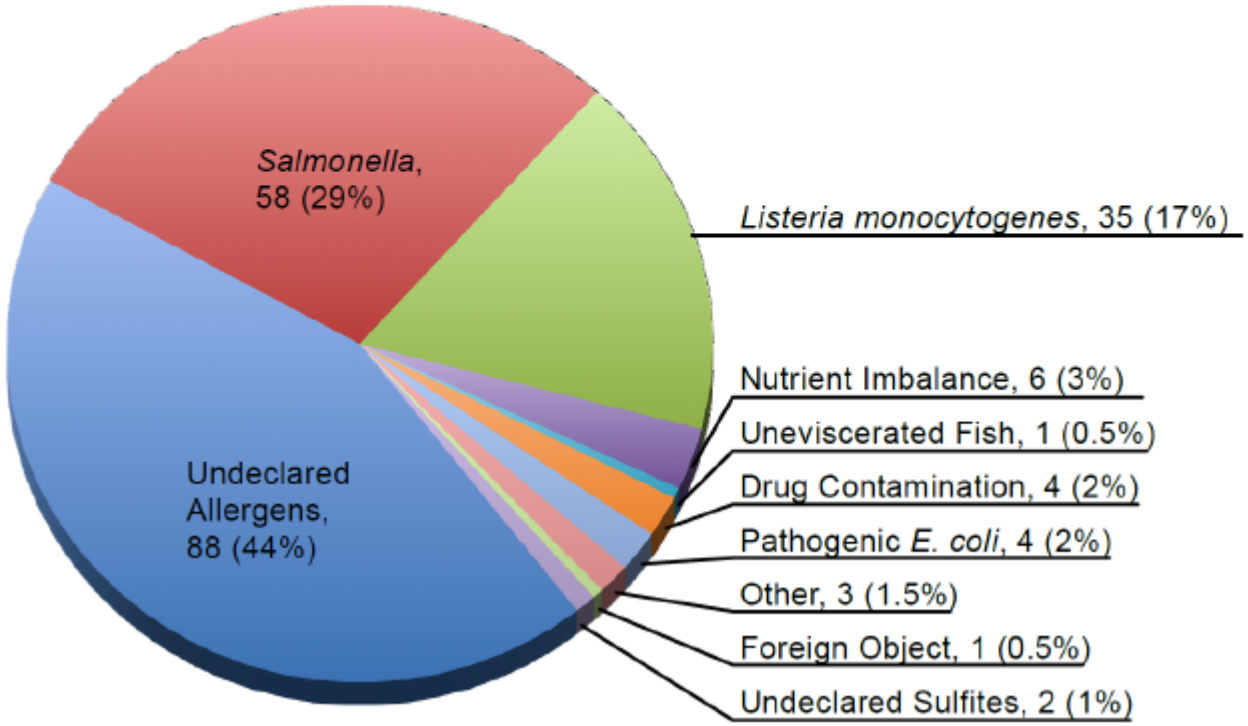


RFR

Table 6: Distribution of Primary RFR Entries by the Three Most Frequently Reported Food Safety Hazards by Year

Hazard	Year 1	Year 2	Year 3	Year 4
Salmonella	37.6%(86)	38.2%(86)	28.1%(63)	28.7%(58)
Listeria monocytogenes	14.4%(33)	17.8%(40)	21.4%(48)	17.3%(35)
Undeclared Allergens	30.1%(69)	38.3%(75)	37.9%(85)	43.6%(88)
Percentage (No. of entries)	**82.1%(188)**	**94.3%(201)**	**87.4%(196)**	**89.6%(181)**

Figure 2: Distribution of Primary RFR Entries by Food Safety Hazard, Year 4



RFR

- FDA is now seeking information from “all interested parties” to help the agency determine, among other things:
  - what information should be required in consumer notifications so that consumers can determine whether a food in their possession is a reportable food;
  - the format in which the information should be presented;
  - what types of retail establishments FDA should consider to be “grocery stores” subject to the consumer notification requirements;
  - how grocery stores should be made aware that the information has been published on FDA’s website;
  - what constitutes prominent display or sharing of the information by a grocery store with its customers;
  - the impact on grocery stores from posting the information;
  - if consumers should be notified that this type of information will not be generated for dietary supplements, infant formula, and fruits and vegetables that are raw agricultural commodities, and,
  - if FDA should require industry to submit consumer-oriented information to FDA even if the food will not be available for sale to consumers at the retail level.

Increased Enforcement Actions in the Food and Beverage Industry, Including Criminal Prosecution

Consequences

- Criminal Prosecution
- Huge Fines
- Request for a recall
- Seizure of product
- Ordering of Mandatory Recall
- Revocation of registration of an entire facility
- *See* 21 U.S.C. §§ 334(a), 350(l), 350d(c), 333(a), 21 C.F.R. § 7.46(a).

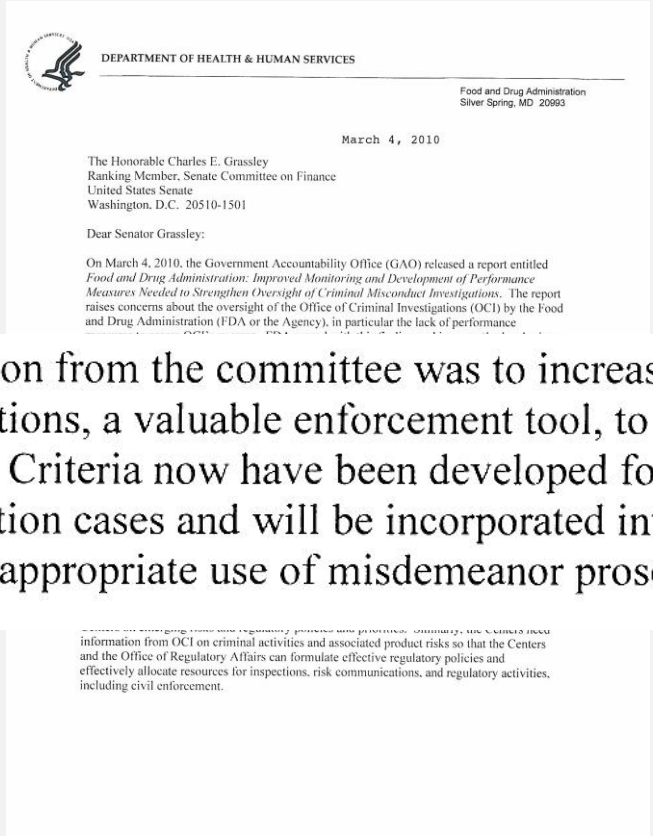
U.S. v. Park, 421 U.S. 658 (1975)

- Upheld the conviction of a food chain president for a misdemeanor violation in connection with the rat-infested condition of a company warehouse, despite no evidence that the defendant knew of the infestation.
- "The requirements of foresight and vigilance imposed on responsible corporate agents are . . . no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them."
- "[T]he public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors."

Recent Revitalization

- In 2010, a report authored by the U.S. GAO came out that criticized lax criminal enforcement of corporate officers. *See* U.S. GAO: "Food and Drug Administration – Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations" Report No. GAO-10-221; Jan. 2010, pages 13-18 and 25.
- Subsequently, the FDA announced in 2010 that it would revitalize its approach to corporate officers by increasing the use of misdemeanor prosecutions. *See* March 4, 2010, letter from Dr. Margaret Hamburg, Commissioner of Food and Drugs, to Senator Charles Grassley.

2010 Letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 4, 2010

The Honorable Charles E. Grassley
Ranking Member, Senate Committee on Finance
United States Senate
Washington, D.C. 20510-1501

Dear Senator Grassley:

On March 4, 2010, the Government Accountability Office (GAO) released a report entitled *Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal Misconduct Investigations*. The report raises concerns about the oversight of the Office of Criminal Investigations (OCI) by the Food and Drug Administration (FDA or the Agency), in particular the lack of performance

information from OCI on criminal activities and associated product risks so that the Centers and the Office of Regulatory Affairs can formulate effective regulatory policies and effectively allocate resources for inspections, risk communications, and regulatory activities, including civil enforcement.

A third recommendation from the committee was to increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable. Criteria now have been developed for consideration in selection of misdemeanor prosecution cases and will be incorporated into the revised policies and procedures that cover appropriate use of misdemeanor prosecutions.

FDA Regulatory Procedures Manual

- Soon thereafter, in January 2011, that recommendation was followed as the FDA changed its internal regulatory procedures to authorize *Park* Doctrine prosecutions against corporate executives under some circumstances. *See* U.S. Food and Drug Admin., Regulatory Procedures Manual at Section 6-5-3, available at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm.

FDA Regulatory Procedures Manual

- "When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation."
- "Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation."

FDA Regulatory Procedures Manual

"Other factors to consider include but are not limited to:

- 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."

PCA Investigation

- 2009 Salmonella Typhimurium outbreak linked to PCA
- 9 deaths, 714 ill, 166 hospitalized
- Operations in GA, VA, TX
- 90 employees;
- $25 million in sales in 2008
- FDA unaware of Blakely facility until after recall

PHOTO: JESSICA MCGOWAN/GETTY IMAGES

PCA Prosecution

- 2009, FDA announces criminal investigation claiming PCA *knowingly* sold contaminated products
- 2009, FBI joins investigation
  - Raid pursuant to warrants
- 1/2009, FDA Inspection, report reveals
  - Poor sanitation
  - Conditions that would allow salmonella to spread
  - Gap in roof
  - Roaches and rodents
- 2013, DOJ announces criminal charges
    - charged four individuals, including Parnell, in a 76-count indictment
    - an employee pled guilty to similar charges

PCA Indictment

- DOJ issues 76-count indictment, unsealed, against
  - Stewart Parnell, owner & president
  - Michael Parnell, food broker who worked on behalf of PCA
  - Samuel Lightsey, operations manager in GA
  - Mary Wilkerson, receptionist/office manager*
- Charged with:
  - Mail & wire fraud
  - Introduction of adulterated & misbranded food into interstate commerce with intent to defraud
  - Conspiracy
  - Obstruction of justice*

Outcome

- On Sept. 19, 2014, three former executives of the Peanut Corporation of America (PCA): (1) Stewart Parnell, former owner; (2) Michael Parnell, former food broker; and (3) Mary Wilkerson, former quality control manager, were convicted.
- The 12-member jury found Stewart Parnell guilty of 67 federal felony counts, including conspiracy, wire fraud and obstruction of justice, while Michael Parnell was convicted of 30 counts related to falsification of lab results but was acquitted of actually shipping salmonella-tainted food. Mary Wilkerson was convicted on one count of obstruction of justice but acquitted on another.

Jensen Farms

- In Sept. 2013, *misdemeanor* criminal charges filed against Eric and Ryan Jensen
- Faced up to 6 years in jail and a combined $1.5 million fine if found guilty
- Arrest warrants issued
- Executives were brought to their arraignments in shackles

Jensen Farms

- Pled guilty: to growing cantaloupes that led to the Listeria outbreak
- Jail time avoided
- Sentenced (Jan. 2014):
  - 6 months home detention
  - 5 years probation
  - $150,000 restitution

What to do?

Important Considerations When a Government Investigation Arises

- Responding to a government raid or search warrant?
  - Designate liaison for response and to observe search
  - Involve liaison and outside counsel
  - Verify credentials and obtain business cards
  - Limit search to areas listed in search warrant
  - Limit documents to those specifically requested by inspector
  - Request inventory and copies
  - Clearly delineate and protect privileged documents
  - Employees must be truthful in interviews

Responding to Subpoenas – Documents

- Hold notices
- Electronic backup
- Burden on client to respond and cost
- Process company intends to follow to gather
- Categories of responsive documents and other categories of likely relevant documents not covered
- Additional steps to take at this point beyond responding to subpoena

Responding to Subpoenas – Documents

- Counsel can discuss with government official
  - Find out company status – witness, subject, or target
  - Find out any additional information about investigation government may share
  - Let government know of intention to fully comply
  - Communicate information about burden and cost if appropriate
  - Ask for additional time if needed
  - Discuss categories of documents that government will be receiving in response
  - Discuss narrowing of subpoena and/or rolling production if appropriate

Responding to Subpoenas – Testimony

- Interview employee subpoenaed
- Evaluate exposure
- Representation of employee issue
- Hold notice and electronic backup
- Additional steps to take at this point beyond subpoena

Responding to Subpoenas – Testimony

- Counsel can discuss with government
  - Find out company and employee status
  - Find out what information government believes employee has
  - Evaluate exposure
  - Clarify who represent
  - Find out any additional information about investigation government may share
  - Let government know of intention to fully comply
  - Considerations for proffer or interview for grand jury preparation in advance of grand jury
  - Communicate employee concerns if appropriate

Communicating With the Government

- Early contact and establishing a cooperative relationship
  - Develop rapport
  - Communicate about experience with client
  - Obtain information about investigation that government can share – sense of timing and posture
  - Understand government focus and priorities

Communicating with Government

- Consider benefits to providing full cooperation
  - Significant factor to be considered by government in terms of whether to indict company
  - Avoid felony prosecution
  - Obtain consent decree
  - May be able to give key information to avoid company being indicted
  - Additional benefits possibly advantageous to company – better information about posture of investigation, possibly less disruption, possibly move more quickly which may be advantageous
  - In better position to help government understand hurdles that may be facing company
  - Few instances of prosecution when company has fully cooperated, unless outbreak is serious
- Potential downsides to cooperation

Communicating With the Government

- Providing information when fully cooperating
  - Importance of understanding conduct that government believes occurred
  - Attorney proffer of relevant information
  - Making relevant individuals available and providing relevant documents
- Pitching the government for a favorable resolution
  - Importance of understanding position of official/agency being pitched
    - Investigation likely initiated by FDA or USDA, but they will need to convince DOJ/US Attorney to prosecute
  - Timing of pitch
  - Understanding any office rules concerning pitch
  - Seek advice from government contact on procedurally how best to present
  - Seek advice from government contact on arguments that may best resonate
  - Appeal to DOJ/US Attorney

Avoid Trouble in the First Place

- Implement compliance programs at all levels
- Ensure food safety standards are up to date, and followed
- Keep good records
- Train employees

Questions / Comments



Thank you for your attention!