

Food Safety 101 for Market Managers

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Jurisdiction -- Food Safety



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- FDA -- primary agency for food safety, under FD&C Act (Center for Food Safety and Applied Nutrition) except:
 - USDA -- meat, poultry and eggs, plant "pests", testing of biopharmed crops, food animal disease control, marketing standards (e.g. "organic")
 - EPA – pesticides, drinking water

State Laws



- States have food safety laws
- State powers re inspection, seizure, court action vary; may exceed FDA's authority
- States assist federal enforcement activities, joint inspections, training
- Also local authorities (e.g., health departments)

Hierarchy - Regulatory Framework



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- Statutes (laws) – some provisions may be self-executing. No FDA discretion other than interpretation.
 - Regulations – Final rules issued by FDA after notice and comment. Force and effect of law.
 - FDA Guidance -- current interpretation of law (GAPs). Often recommendations, and alternative approach may be used to comply. But failure to follow may result in finding of adulteration.

Hierarchy – Regulatory Framework



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- Marketing Agreement/Order (state or federal). Voluntary industry initiatives adopted by vote -- with government oversight of specified issues (e.g., quality, research, marketing). Recent trend -- use for safety.
 - Model codes. Collaborative effort among government, industry, academia. May be adopted by states as regulations.
 - Voluntary industry practices/standards – enforcement through commerce.

Adulterated Food



- FD&C Act prohibits adulterated foods in interstate commerce. Broad interpretation of “interstate.”
- Adulteration – food quality is or might be impaired to level affecting public health/aesthetic sensitivities
- “Poisonous or deleterious” used in many adulteration provisions – in all but one, depends on measure of harm (quantity)

Adulterated Food



Most provisions based on condition of food

- Contains any **added** poisonous or deleterious substance -- may render injurious to health. If **naturally occurring**, adulterated only if quantity is ordinarily injurious to health
- Consists in whole or in part of any filthy, putrid or decomposed substance
- Is otherwise unfit for food

Adulterated Food



Provision based on condition of place:.

- Food **deemed to be** adulterated if prepared/packed/held under insanitary conditions – whereby **may have** become contaminated with filth, or **may have** been rendered injurious to health.
- Supreme Court upheld – conditions alone create reasonable possibility.
- Recalls/Enforcement -- Adulteration even if no illnesses/positive test results

Adulterated Food



Most produce safety issues are due to microbial contamination, usually bacteria

- E. coli 0157:H7
- Salmonella species
- Listeria monocytogenes. Zero tolerance. Industry requested tolerance 100 CFU/g in RTE foods that don't support growth
- Campylobacter
- Hepatitis A
- Norovirus

Adulterated Food



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- 1996-2006: 72 outbreaks associated with produce; 22 involving leafy greens.
- Recent produce outbreaks – greater proportion of all outbreaks than in past, larger outbreaks (# of victims).
 - Concerns – opportunities for contamination (water, workers, wildlife, soil amendments, adjacent land use), likely to be consumed raw (no kill step).

Adulterated Food



FDA action to reduce risk of contamination

- 1998 “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” -- GAPs/GMPs for growers/packers/shippers.
- 2004 Produce Safety Action Plan covers food supply chain from farm through consumer handling.
- 2006 “Draft Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables” – covers processors. Final Guide issued 2 weeks ago.

Adulterated Food



- 2006 “Leafy Greens Initiative” – assess practices at farms/facilities in CA.
- 2007 final guide for production of fresh-cut produce suggests HACCP principles.
- Hazard Analysis Critical Control Point -- prevention-based system to identify microbial/chemical/physical hazards. Plan with controls, validation, training. Includes employee health, building and equipment, production.

Adulterated Food



2005 FDA letter to CA firms that grow, pack, process, or ship fresh and fresh-cut lettuce/leafy greens --

- Ready to eat crops may be considered adulterated if contact with flood waters (insanitary conditions).
- Potential exposure to pathogens, heavy metals, sewage, animal waste. Can't recondition to provide reasonable assurance of safety.

Adulterated Food



- Increasing FDA reliance on finding of insanitary conditions to seek removal of produce from commerce.
- Practices resulting in rodents, insects, lack of adequate refrigeration, food debris on floors, improper storage of chemicals, could be found to create insanitary conditions that affect regulatory status of products at produce market.

What Now: Suggested Approaches



- FDA regulations (from farm): long-term
- CA Marketing Agreement –lettuce/leafy greens best practices (target organisms, sampling procedures and frequency, test methods, acceptance criteria)
- Possibility of Marketing Order
- Model Safety Standards – AFDO (Assoc of Food and Drug Officials) committee
- Buyers group -- only source from growers certified re same best practices as CA Marketing Agreement
- Commodity-specific, with flexibility

Recalls



- Voluntary – FDA has no statutory authority to order recalls.
- Recall –removal/correction of marketed products that violate FD&C Act (FDA would otherwise initiate legal action).
- If company-initiated, FDA requests notification, and consultation re any press release (use model language).
- Most effective means of removing widely distributed product

Recalls



What is NOT a recall?

- Stock Recovery – retrieval of violative product still within company's control
- Market Withdrawal – withdrawal of products with insignificant violations, or of nonviolative products for commercial reasons, such as quality

Recalls



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- Class I – reasonable probability that exposure to product will cause serious adverse health consequences or death
 - Class II – reasonable probability that exposure may cause temporary or medically reversible adverse health consequences, or probability of serious health effects is remote
 - Class III – exposure not likely to cause adverse health consequences

Recalls



Potential enforcement actions if no recall

- Multiple seizures
- Injunctions
- Criminal actions
- Administrative detention (Bioterrorism Act)
- Adverse publicity (public warning)
- Warning Letters

Recalls



Request based on epidemiological data

“Generally, before FDA formally requests recall action, the Agency will have evidence capable of supporting legal action, i.e. seizure. Exceptions ... a real or potential danger to health, or in emergency circumstances such as outbreak of disease involving epidemiological findings.”

FDA Regulatory Procedures Manual, March 2004

Recalls



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- If epidemiologic data developed by FDA, company making recall decision is entitled to info available from FDA through FOIA (Freedom of Information Act). If findings developed by another agency (usual scenario), request must be made to that agency.
 - If investigation is ongoing, agencies may not release data until investigation completed.
 - Data may be unavailable when recall decision is made.

Recalls



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- Initiation of FDA produce traceback investigation –
 - 1) epidemiological evidence implicates a food product **and**
 - 2) hazard analysis shows that other contributing factors were not to blame (e.g., cross-contamination, ill food workers, other on-site sources of infectious agent).
 - Need for better traceback systems; repacking an issue.

Recalls



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- Pressure for recall based on epi data
 - Paramount Farms recalled 18 million lbs raw almonds in 2004 (9 countries) after 29 illnesses in 12 states - Salmonella.
 - No link at first; later survey had 400 items.
 - Recall - > 50 customers/many brands.
 - No Salmonella ever found in product.
 - Source will probably never be known
 - Federal marketing order for almonds being revised to include mandatory pasteurization
 - Spinach recall – 1st time confirm link

Food Security Preventive Measures



FDA guidance for food service and retail

- Prepare for possibility of tampering or other criminal or terrorist acts
- Investigate suspicious activity
- Restrict access to non-public areas unless necessary for job
- Conduct background checks of all staff and provide appropriate level of supervision
- Train staff in food security procedures
- Ensure and monitor physical security of premises
- Store toxic/poisonous chemicals away from food and track quantity
- Review and verify effectiveness of security management programs

Food Safety



THANK YOU