

## Guidance or Regulations?

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## Current Regulation

Primary Regulation:

- Food Drug and Cosmetic Act
- RSMo 196 – Mo. Law Governing Inspection and Manufacture of Food
  - \*No allowance for adulterated Food
  - \*Pathogens such as E. coli and Salmonella are adulterants

## Field Sanitation

- Current OSHA Regulation: 29CFR 1928.110(a) applies to agricultural establishment where:
  - eleven (11) or more employees are engaged on any given day in hand-labor operations in the field.
    - One toilet and one handwash station for every 20 workers not more than ¼ mile from work station
- Does not apply to shifts of three hours or less

## The FDA View

- 'We are now putting the emphasis on guidance and understanding the science and regulatory strategies. At any point, 'something could change. But it takes years to write regulations.'
  - Statement by David Acheson FDA Commissioner of Food Safety at FDA Public Hearing, April 2007.

## The FDA View

- Identify vulnerable points within the production process and develop testing or policies to prevent them.
- Rely on growers implementing voluntary standards – Good agricultural practices
- No Pre-Market Authority for enforcement action

## Association of Food and Drug Officials

- Professional association of state and local regulatory officials
- In favor of national regulation
- Oppose voluntary program
- Gave testimony at hearing on produce

## Agricultural Marketing Service (AMS)

- Advanced notice of proposed rulemaking
- Handling Regulations for Leafy Greens
- Published in Federal Register 10/04/07. Comment period closed 12/03/07.
- Goal is to reduce risk of pathogenic contamination during production and handling

## AMS – Notice of Proposed Rule

- Handlers enter into a voluntary agreement, but then compliance is mandatory with the agreement's regulations.
- Agreement specifies "Best Practices" for minimizing risk of contamination.
- Agreement guidelines could be commodity-specific & based on FDA's *Guide to Minimize Microbial Food Safety Hazards in Fresh Fruits and Vegetables*.

## AMS – Notice of Proposed Rulemaking

- Features of the marketing agreement may include:
  - Compliance certification
  - Verification audits
  - Includes production, shipping, packing, processing
  - Handlers meeting requirements may be authorized to use an official certification mark
  - Verification audits conducted by Federal or Federal-State Inspection Programs.

## AMS – Notice of Proposed Rulemaking

"Market Order".

- "Once established, compliance with order regulations are mandatory for all handlers of the affected commodity within the production area"
- In a marketing agreement, growers, handlers, and processors voluntarily sign the agreement and then are bound to comply

## Notice of Proposed Rulemaking

- AMS issued the notice in the wake of the E. coli outbreaks of September, 2006.
- AMS issues agreements or orders after public notice and hearings at the request of industry
- Members of the leafy greens industry expressed need for national standards – but not a formal request
- AMS expressed belief that a marketing agreement is more likely to meet the needs of the industry

## The Canadian View

- Test your way to Safety
- 1000 Samples of produce tested annually
  - 500 leafy green samples tested for E. coli
  - 500 tomato samples tested annually
- Will only accept California product from producer who is part of Leafy Greens Marketing Agreement

## Mexico

- Has only recently begun purchasing spinach from California (Dec. 2007)
- Will only purchase California spinach from member of Calif. Leafy Greens Marketing Agreement

## California

### California Leafy Greens Marketing Agreement

- California's **voluntary** program developed and operated by producers (farmers, shippers, processors)
- Sets some standards for growers (I.e. setback distances from crops and untreated manure defined).

## California

- Mark of inspection given to those producers operating under the Marketing Agreement
- After signing the marketing agreement, mandatory compliance as determined by government inspectors
- After signing, handlers may only purchase from farmers who are participating in the marketing agreement

## Arizona

- Adopted the Arizona Leafy Greens Marketing Agreement – 10/07
- Modeled after California's marketing agreement

## Current Steps

- FDA provided Guidance Document for processor cut produce
- Grant money provided by government and industry for research into causes of produce contamination and mechanisms for contamination
- Voluntary Guidelines for growers implemented in western states
- Third Party audits conducted by large processors and by some chains ("big box stores")

## Beyond the Guidelines.....

- Where one large processor "sets the bar":
  - Won't accept produce grown within one mile of a cattle feedlot or dairy operation
  - Within 150 yards of a river or wildlife habitat
  - Animal tracks in a field – field unacceptable for harvest – any animal – "frogs to dogs".
- Companies are battling for market share and food safety is a marketing tool – "they are all asking for a different level of compliance" – Bob Martin California grower.

## What Needs to Be Done

- Realization: Food grown in the ground will never be 100% Risk Free
- Make the Farm the First Line of Defense
  - Follow Good Agricultural Practices
- Processors Must follow Good Manufacturing Practices
- Consumer must follow safe food handling practices at home

## Research

- Actual mechanism as to how pathogens (E. coli and salmonella) become internalized in plant tissue
- Which animals are actually a risk in the field?
- Are insects a vector of disease on produce?
- How long will pathogens survive in the soil?