



Food Safety Modernization Act & the Produce Safety Rule



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Statistics

- 55 billion pounds fresh produce grown each year in US
- 26 billion pounds fresh produce imported to US each year from 58 different countries



Statistics

- 700 produce related foodborne illness outbreaks between 1990 and 2005
- Leafy vegetables account for 14% of all foodborne illnesses



Proposed Produce Safety Rule

- Under discussion and deliberation
- Current thinking
- PROPOSAL, not final regulation!



Background

- Authority under Food Drug & Cosmetic Act
 - Prepared, packed or held under unsanitary conditions ... whereby it may have been rendered injurious to health
 - If it bears or contains any poisons or deleterious substance which may render it injurious to health

Currently no implementable regulation

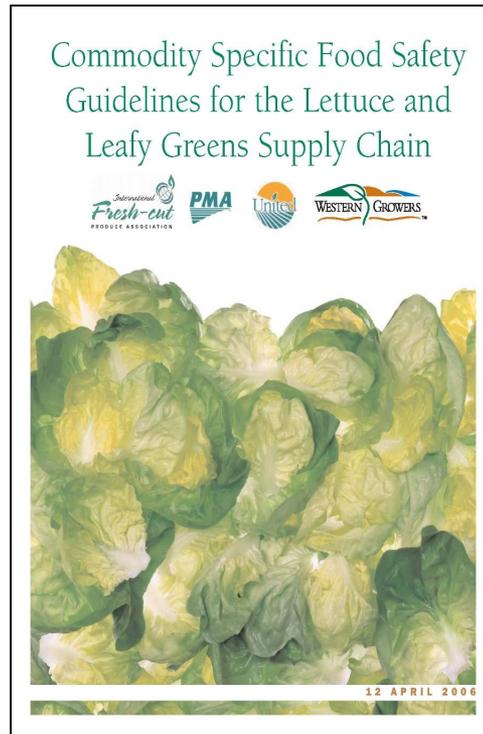
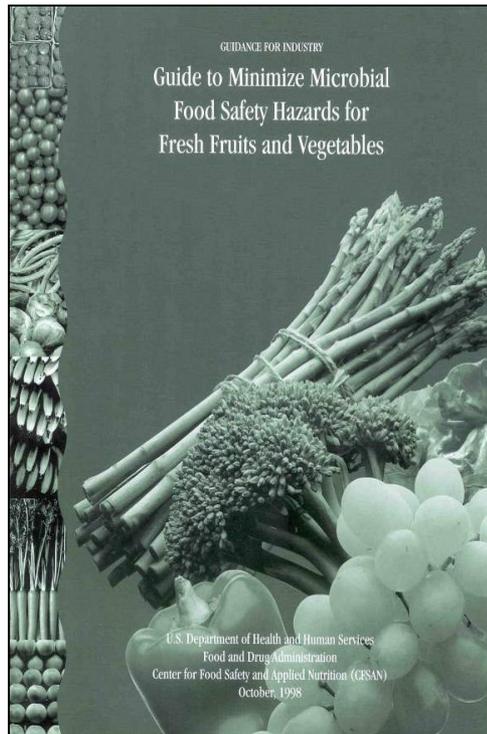


Background

- 1998 Good Agriculture Practices
- 2008 Fresh-cut guidance
- 2009 Commodity Specific Guidances



Evolving Produce Safety Best Practices





Produce Safety Rule vs. Food Preventive Controls Rule

- Produce Safety Rule
 - Growing, harvesting, postharvest handling
 - Packing of produce (where exempt from BT Act registration)
- Food Preventive Controls Rule
 - Packing of produce (where subject to BT Act registration)
 - Processing
 - _ Warehousing, shipping, receiving



Other related rules

- Foreign Supplier Verification Rule
 - Steps to assure compliance by foreign growers and shippers

Sanitary Transportation Regulation

- Shipping, transportation, receiving
- Overlap w/ Food Preventive Controls Rule
- Includes receiving by retail; shipping by farm



FSMA Directive (section 105)

- Coordinate with USDA, states, in consultation with other agencies, to...
- Establish science-based minimum standards for the safe production & harvesting of those types of fruits & vegetables where it is determined such standards minimize risk.



FSMA Directive...

- Develop regulation
- Develop guidance
- Hold public meetings



FSMA Directive...

- Content (soil amendments, hygiene, animals, water)
- Flexibility
- Appropriate to scale & diversity



Scope

In Scope:

- Fresh fruit and vegetables
- Mushrooms
- Sprouts
- Peanuts
- Tree nuts

In Scope but Exempt:

- Tester Amendment
- Normally consumed cooked (e.g., potatoes, sweet potatoes, artichokes)



Scope

- **Out of scope:**
 - Produce destined for “kill step” processing (e.g., LACF, acidified)
 - Agronomic crops (e.g., grain, canola, cocoa, cottonseed, flaxseed, rice, soybean, sugar beets)



Risk Based Approach: Practice & Commodity

Significant challenges to utilizing Commodity-only approach:

- Interplay of number, extent and severity of outbreaks
- Setting timeframes for baseline period
- Effect of exposure on illness data
- Effect of difficulty of identifying vehicle on illness data
- Availability of contamination data by commodity highly variable
- Contamination testing driven, in part, by perceived risk
- Movement of commodity to another risk category based on new data



Risk Based Approach: Practice & Commodity

- Very low risk products exempt or out of scope
 - Many very small to medium sized farms exempted (Tester)
- Extent of prescribed standards & controls varies according to the risk of the agronomic practices utilized rather than by commodity alone
 - Higher burden associated with higher risk practices
 - Agronomic practices can change over time for a given commodity and different growing regions



Flexibility

- Alternative approaches
- Variances
- Compliance dates



Traceability

- Not part of produce safety rule
 - Must still adhere to FD&C Act and BT Act (“one up and one down”)
 - IFT contracted by FDA to conduct two pilot programs, one of which involves fresh produce



Regulatory Process: Engagement with Stakeholders

- Opened a Docket
- Visited 13 states
 - Listening sessions
 - Farm & packinghouse tours



Regulatory Process: Engagement with Stakeholders

- More than 800 submissions
- Common themes:
 - One size doesn't fit all
 - Scale appropriate and not too burdensome
 - Science/risk based
 - Practical
 - Education



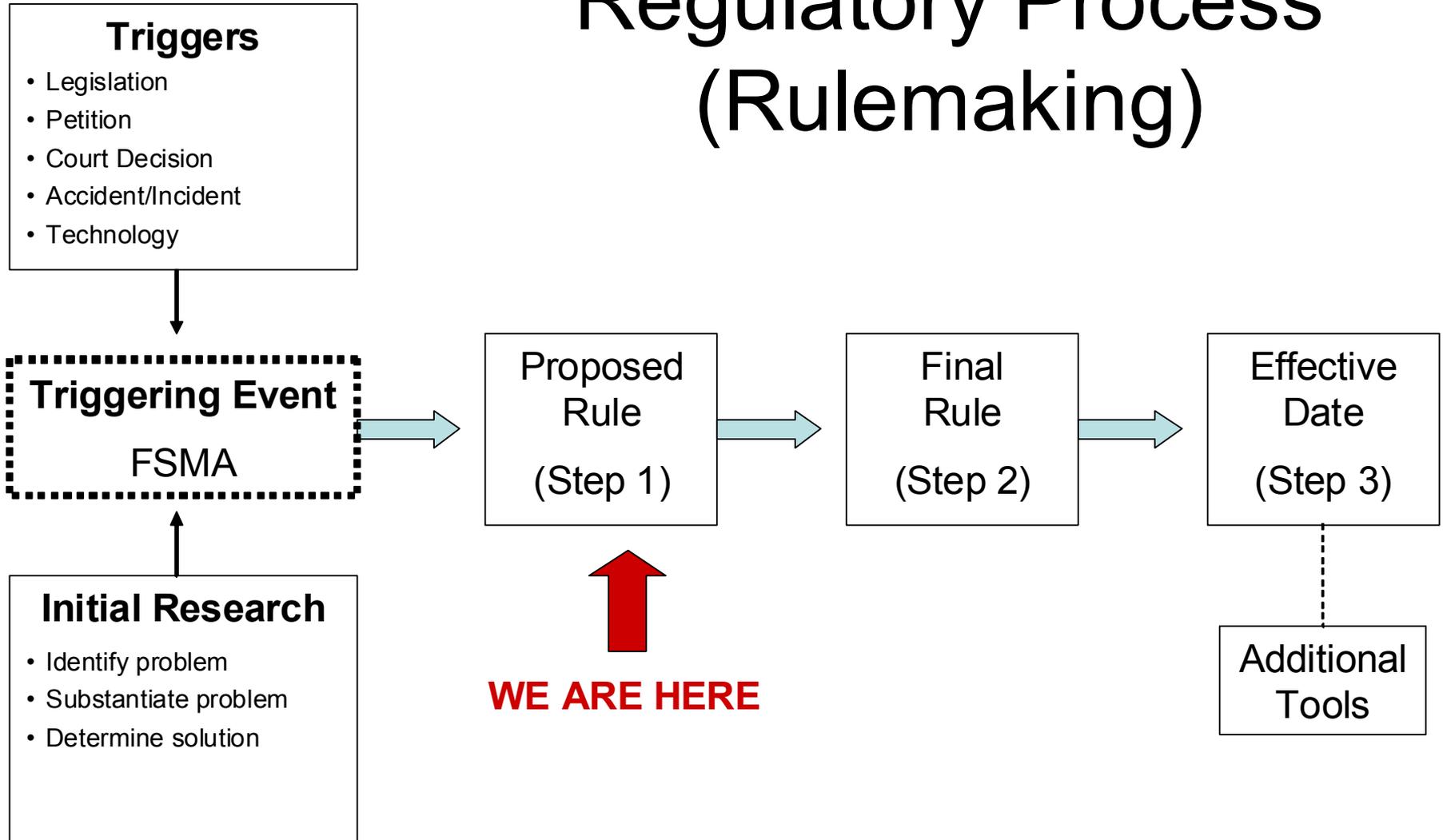
Rulemaking Process: It Doesn't Happen Overnight

1. FDA proposes rule and requests comments
2. FDA considers comments and issues final rule
3. FDA sets dates for companies to comply





Regulatory Process (Rulemaking)





Regulatory Process

- Draft regulatory & explanatory language
- Internal (FDA) legal review
- External (White House Office of Mgt & Budget) review
 - Other Federal agency review
 - Back and Forth to address comments/concerns
- Clearance
- Publish in Federal Register as **PROPOSAL**
 - Public comment period



Regulatory Process

- **PROPOSAL** Issued/published in Federal Register
 - Public comment
 - Public meetings
 - Supplemental engagements



How to Comment

Docket No. FDA-20XX-X-XXXX
assigned at publication

- Written comments:
Division of Dockets Management (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852
- Electronic submissions:
<http://www.regulations.gov>
Include Docket Number!



Regulatory Process

- Comments reviewed
- Final regulation issued



FDA is prepared; but challenges

- Experience in preventive controls
- Implementation process in place
- Work is underway
- **Enormous workload**
- **Changes take time**
- **Resources**



Implementation Timeframes

Very small farms:

- 3 years after issuance of final rule

Small farms:

- 2 years after issuance of final rule

All others:

- 1 year after issuance of final rule



Produce Safety Rule

Research

Education

&

Outreach

Implementation



Research

Consideration of alternative approaches

- Raw manure use as soil amendment.
- Water quality directly applied to edible portion of crops.

Engage

- Western Center for Food Safety (FDA Center of Excellence)
- USDA's NIFA, ARS & AMS
- Land Grant Universities & Cooperative Extension
- Industry (Center for Produce Safety, Commodity Groups, Trade Associations)

Developing Research Protocols

- Use in various agro-ecological regions



Education & Outreach

- Produce Safety Alliance
www.producesafetyalliance.cornell.edu
- Target audiences
Farmers & Regulators
Cadre of Trainers (i.e., train-the-trainer)
- **Goals**
 1. Educate & outreach for improved understanding & implementation of GAPs
 2. Develop standardized curricula and materials
 3. Provide access to training materials
- Focus
Initially - GAPs Guide
Once final - Produce Safety Regulation



Implementation & Compliance

Educate before we regulate

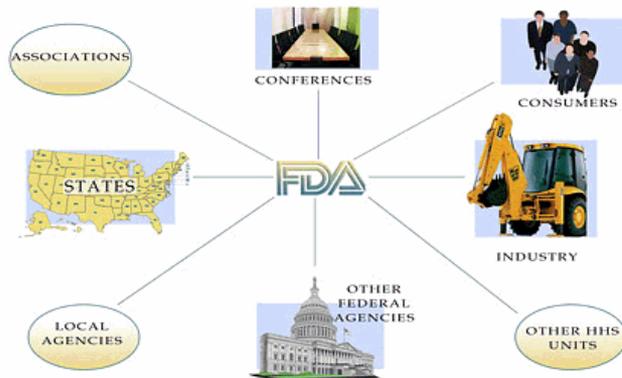
Non-traditional strategy:

- Educate & outreach to enhance compliance
 - Guidance: small entity compliance, hazards guide, Q&A
 - Updated GAPs guidance
- Utilize existing & develop new partnerships
- Consider how existing efforts & information may be used
- Develop appropriate review & oversight mechanism
- Interface with trade associations, commodity groups, farmers



Implementation & Compliance; Collaboration

- With food safety partners, industry, universities & other stakeholders
- Key to achieving the greatest progress in ensuring the safety of fresh produce





Resources

- FDA FSMA page:
<http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>
- Produce Safety Alliance:
<http://producesafetyalliance.cornell.edu/psa.html>
- FDA Produce Safety Activities:
<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/FDAProduceSafetyActivities/default.htm>



Questions?

