



Food Safety Modernization Act- What is our response?

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Proposed Rules



Issued January 2013

- ▶ Produce Safety Rule (547 pages)
- ▶ Preventive Controls for Human Food Rule (675 pages)
- ▶ Farm: grow, harvest, pack or hold produce in raw state
- ▶ Facilities: manufacture, process, pack or hold human food

Issued July 2013

- ▶ Foreign Supplier Verification (175 pages)
- ▶ 3rd Party Auditor Certification (217 pages)
- ▶ Importer accountability and certifications

Issued October 2013

- ▶ Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (>100 pages)
- ▶ Animal Feed

Issued December 2013

- ▶ Mitigation Strategies to Protect Food Against Intentional Adulteration (>50 pages)
- ▶ Food Defense Plans/Bioterrorism

Science - based ◆ Risk - based ◆ Flexible ◆ Stakeholder Input



What's happening??

GOOD NEWS !



BAD NEWS !



Good News- FDA HEARD US!

- ▶ FDA FSMA Announcement (December 2013)
 - ▶ Significant changes needed in the rules
 1. Water quality standards and testing
 2. Standards on raw material and compost
 3. Provisions affecting mixed-farm facilities
 4. Procedures for withdrawing the qualified exemption for certain farms
 - ▶ FDA will issue a revised rule for comments (Summer 2014)
 1. Can only comment on the changed sections of the rule



“rules” must be practical to implement



Bad News- IT'S ONLY A DELAY!

▶ Rulemaking Process

1. FDA proposes the rule and requests comments
 - ▶ Open comment period
 - Produce and Preventive Controls Rules Deadline- November 15, 2013
 - Import Rule/3rd Party Certification Rule Deadline- November 26, 2013
 - Food Defense Rule Deadline – March 30, 2014
 - **Interim Produce Rule- June 2014**
2. FDA considers comments and issues a final rule
 - ▶ Published in the Federal Register (June 30, 2015 at best)
3. Compliance is based on an “Effective Date”
 - ▶ Requirements effective 60 days after final rule published
 - ▶ Business compliance dates:
 - Education/training
 - 2-4 years depending on operation size
 - No changes next growing season
4. FDA may issue additional guidance documents
 - It is an interpretation of the rule in plain language



Industry Comments to FDA

- ▶ Rules are not **“flexible”** for commodities that have never had a food safety incident
 - ▶ What about commodity specific differences?
 - **Lower-risk commodities should be handled differently**
 - Prescriptive details must have some flexibility to change based on research and not require a law
 - Water and soil amendments, in particular
 - You know your operation and through HACCP can determine your direction
 - Currently operating under GlobalGAP (GSFI benchmarked)/USDA GAP
- Why add a new standard?



◆ Risk - based

◆ Flexible

Industry Comments to FDA

- ▶ Water testing requirements are too prescriptive
 - ▶ Beginning of each growing season and every three months thereafter during the growing season (groundwater)
 - ▶ No testing if:
 - ▶ Receive water from Public Works System
 - ▶ Meets microbial standard for state
 - ▶ Demonstrate certificates of compliance
 - ▶ If untreated surface water:

If the untreated surface water is	Test
From any source where significant runoff is likely to drain into the source (river or lake)	At least every 7 days during the growing season
Underground aquifer water is transferred to surface water containment, maintained to minimize runoff to it (on-farm man-made reservoirs)	At least once each month during the growing season

◆ Science - based

◆ Risk - based

◆ Flexible

FDA Proposed Rules

- ▶ Water Standards:
 - ▶ 235 CFU generic *E. coli* standard per 100 mls
 - ▶ 0 detectable generic *E. coli* standard (highest risk uses)
- ▶ What if water is not compliant?
 - ▶ Discontinue use of water
 - ▶ Before restarting use:
 - ▶ Inspect system under grower control
 - ▶ Identify hazards/conditions that may cause the problem
 - ▶ Re-test to see if changes made are effective
 - ▶ Treat

◆ Science - based ◆ Risk - based ◆ Flexible



Industry Comments to FDA

- ▶ Prescriptive values are not reasonable and not scientifically-based
- ▶ No risk has been linked to the generic E. coli number
- ▶ Move all quantitative metrics to guidance documents
- ▶ Economic loss due to no water use has not been established
- ▶ Hardships in testing weekly
 - ▶ Staff time
 - ▶ Drive time to lab (distance)
 - ▶ Analysis cost
 - ▶ Damage to crops (heat stress) – loss up to 50%
- ▶ What are the options when water is out of compliance?
 - ▶ Crop destruct ?
 - ▶ Can't retest because you can't negate a positive result
 - ▶ No kill step for fresh produce

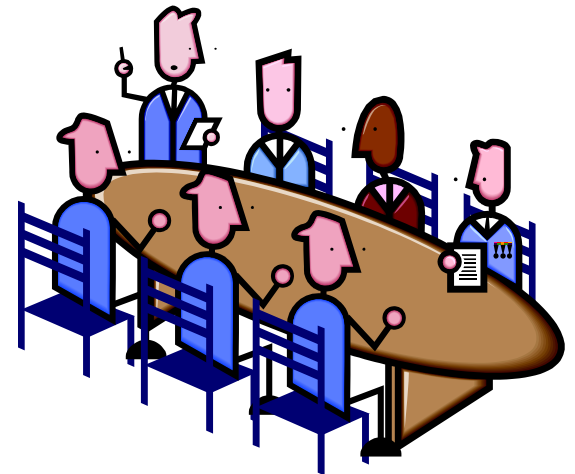


Industry Comments to FDA

- ▶ Chemical injection systems are not proven effective
(not science-based)
 - ▶ Not recommended by the FDA
 - ▶ Salesmen coming out of the woodwork - guidance on products
- ▶ Chlorine salt damage to fruit quality must be evaluated
 - ▶ 3-3.5 acre feet of irrigation water per season (7 months)
 - ▶ 6-10 hours of evaporative cooling per day
 - ▶ What is the long term impact of chemicals to the growing site?
 - ▶ Leaching into the soil, ground and surface water**(Who accepts the risk?)**
- ▶ Research is required to answer these concerns

Industry Comments to FDA

- ▶ Education and Training Programs need to be implemented
 - Smaller operations do not have dedicated food safety staff
 - Cost, time away from growing fruit
 - Concern about “ what if I don’t get it right?”



Tree Fruit Food Safety Research Update

Title	Institution	Funding Source	Completion Date	Funding Amount
<i>Validation of fresh apple packing food safety interventions</i>	WSU	WTFRC	12/31/2012	\$159,172
<i>Enhancing apple packing apple programs while ensuring fruit quality</i>	WSU	WTFRC	12/31/2014	\$72,313
<i>Apple growing and packing microbial risk factors and their potential to lead to foodborne disease outbreaks</i>	Intertox	CPS/ WTFRC	12/31/2013	\$133,613
<i>Sanitization of soft fruits with ultraviolet (UV-C) light</i>	USDA/ ARS	CPS	12/31/2012	\$78,466
<i>Assessment of sanitation techniques for tree fruit storage bins</i>	WSU	CPS/ WSDA SCBG	10/1/2013	\$171,313
<i>Investigation of overhead evaporative cooling practices for tree fruit on foodborne pathogen introduction and survival</i>	WSU/UW	WTFRC	3/31/2014	\$120,000

\$1.018 Million Research Dollars





Thank You!

Questions??

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