



Industry's response to FDA's proposed food safety rules

Food Safety Working Group
Florida Citrus Packers
Indian River Citrus League



Proposed Rules

- [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#)
- [Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food](#)
- Foreign Supplier Verification Program
- Accreditation of Third-party auditors/certification bodies




Produce Safety Rule Highlights

- Focus on microbiological hazards related to growing, harvesting, packing and holding
- Five major pathways: Water, Soil Amend (waste), Animals, worker hygiene, Equipment/buildings.
- Exempts produce that receives commercial processing – e.g. “kill step”
- Agricultural Water: intended to, or likely to, contact harvestable portion
 - Must be safe and sanitary quality for its intended use.
 - Surface waters greatest potential for contamination




Highlights (2)

- Know or have reason to believe that Ag Water is not of adequate quality: Treat, Not use
- Record Keeping: inspections, science, monitoring, testing results,
- Reasonable steps to minimize animal intrusions.
- Variance vs Alternative
- Risk Based rather than commodity specific
 - Don't argue based on outbreak data



Highlights (3)

- Ask the question whether citrus should be covered: no outbreaks, few routes of contam.
- Does not address terrorism
- Recommend do assessment and food safety plan
- Product testing is impractical
- Generic E. coli is the indicator organism of choice



Water Systems

- If under your control
 - Adequately maintained
 - Inspect and properly store all equipment in system
 - Inspect system and keep free of trash, contam
- Direct Contact: 235 CFU or MPN generic E. coli per 100 ml single sample or rolling geometric mean of more than 126 CFU (or MPN) per 100 ml
 - Test every 7 days during growing season.
- Float Tanks – Considering mandating that water be at least 10 degrees warmer than core of fruit. (hour by hour monitoring)

Focus of Comments

- We are bound to the use of FL Class IV Water (Ag), as part of Clean Water Act
- World Health Organization (WHO) is currently, and should remain the appropriate INTL std. for water used in citrus production.
- Explain our product and process in detail (assume nothing). Step by step risk reduction.
- Develop Risk Model for fresh FL citrus
- Further explore die-off and intervals
- Alternative: still subject to testing requirements?

Comments (2)

- Testing every 7 days is not practical or necessary. Should be dictated by historic data
- Dunk Tank – internalization is not a factor for citrus.
- FDA understand – that on East Coast – there are not alternative water sources. Not justifiable to force treatment of spray water.
- Continue to emphasize that citrus should not be covered. Low Risk. Few Routes.



Preventive Controls

- Require covered facilities to maintain a food safety plan, institute preventive controls to mitigate hazards, monitor and verify controls, corrective actions and records.
- Applies to all facilities that are required to register with FDA under FDA's current food facility registration regulations (section 415 FD&C Act), unless exempt (does not include farms).
- Includes manufacturing/processing: includes waxing and cooling.

Who is Exempt?

- Sales < \$500k, more than half sales to consumers and local retail/restaurant within state or 275 miles
- Very Small Business
- Farms: pack or hold food, provided that all food used is grown, raised or consumed on that farm or another farm under same ownership.

Focus of Comments:

- Operations that handle just intact produce should be regulated by the Produce Safety rule, regardless of size, type of produce handled, who grew it, how far from where it was grown or how many steps in the supply chain the produce had gone through since it left the farm.

Focus of Comments (2)

- The Produce Safety rule, as proposed, already has sufficient requirements to cover the most likely potential sources of contamination in a post-harvest handling operation, and the added requirements in the proposed Preventive Controls rule would be overkill for many such operations.
- Waxing, cooling, fumigation, sprout inhibition, ripening and other such treatments that intact produce may experience during farm handling should also be considered "farming" regardless of the size operation, and should not be a reason to relegate an operation to Preventive Controls

