Food Safety and FSMA: Nothing New to the Almond Industry

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Food Safety and FSMA: Leveraging Our Almond Industry Practices

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Five FSMA Proposed Rules

- **Produce Safety Standards**
  - Published Jan. 16, 2013; Comments by Nov. 22

- **Preventive Controls for Human Food**
  - Published Jan. 16, 2013; Comments by Nov. 22

- **Foreign Supplier Verification Program**
  - Published July 29, 2013; Comments by Jan. 27, 2014

- **Accredited Third Party Certification**
  - Published July 29, 2013; Comments by Jan. 27, 2014

- **Preventive Controls for Animal Feed**
  - Published Oct. 29, 2013; Comments by Feb. 26, 2014

- **And more to come...**
Proposed Produce Safety and Preventive Controls Rules

- 12 web/face-to-face meetings with United Fresh leaders, representing widest spectrum of commodities and the supply chain (including almonds)
- Examined every line of the proposed rules, and some that were omitted...
What did we hear?

FDA did pretty well,
- 5 most likely risks
- Animal monitoring
- Worker hygiene, food contact surfaces
- Mandatory records

but...
- “Farm” definition
- Water (and all the other metrics)
- Exemptions
- Alternatives/Variances
- And several details...
What did we hear?

Water is the biggest issue

• Recreational water standards for *E. coli* in direct contact water used pre-harvest (irrigation, plant protection sprays)

• Testing
  – Wells: Every 3 months throughout growing season
  – Protected Surface Water: Monthly
  – Surface Water subject to runoff: Weekly
Why is water an issue?

- Some water sources are outside a grower’s control (rivers, canals...)
- Weekly testing is going to get expensive
- Tests for potential contamination; ignores persistence to the consumer
- And scientists agree: *E. coli* is a poor indicator of water safety
- Proposed rule does not allow for “alternatives” to *E. coli* testing or testing frequencies
- Environmental impact? FDA needs to know
What else did we hear?

- Blanket exclusions, carved in stone
  - Rarely Consumed Raw
  - Commercially Processed
  - Very small (<$25,000) and “Tester” Operations
- Practices, Dietary Preferences and Risks change
- Modified requirements, or guidance for how to account for lower risks due to consumer, commercial handling
  - More on this later
What else did we hear?

• For those not excluded, it’s one size fits all
  – We like no mention of “high risk” commodities
  – We agree that some practices are a greater risk than others (raw manure vs. compost vs. non-animal)
  – But there is no consideration, or allowance, for commodity-specific risks (commodities that have never been linked to foodborne illness)

• Variances could allow for future science
  – But only state/foreign governments are allowed (almond FMO?)
Meanwhile, what about facilities?

Part 117 — *Current Good Manufacturing Practice And Hazard Analysis And Risk-based Preventive Controls For Human Food*

- Applies to operations that manufacture/ process, pack or hold food for sale in the U.S. (i.e., facilities required to register with FDA)
- Including “farm mixed-type facilities”
When is a farm not a farm?

• When it:
  – Is registered with FDA
  – Does any processing (e.g., cutting, cooking)
  – Packs produce other than that grown on the farm
  – Is not in the same general location as the farm
  – Does non-farming activities, like waxing, fumigation, sprouting control, hulling/shelling

• But Produce Safety already covers transport, buildings, tools, equipment, other food contact surfaces, sanitation, plumbing, toilet/handwashing facilities, trash, pests
When is a farm not a farm?

Any operation that handles and ships only raw, intact produce should be covered by Produce Safety rule (may require a legislative fix).
But isn’t hulling/shelling processing?

- Shelling almonds is fundamentally a harvesting activity
  - No change in hazard evaluation
    (Salmonella, etc. are *reasonably likely to occur*, with or without shell)
  - Not a risk mitigation/pathogen control

- Similar to “top and tail”, “clean and core”
- Not the same as fresh-cut, pitted, sliced and wrapped, dried, acidified, pasteurized
What about the rest?

• Update of GMPs
  – Includes almost everything in existing 21 CFR part 110, current Good Manufacturing Practices
  – Adds prevention of “cross contact” and other allergen controls
  – Eliminates most of “how to comply”

• No significant concerns by operations already following GMPs (fresh-cut)
What about the rest?
What about the rest?

- Some confusion about HARPC
  - What has to be written?
  - How is this different from HACCP?
  - Is everything a CCP?
  - Records access?
  - What has to be validated?
  - What does “validated” mean?

- This will all have to be clarified in the final rule and guidance
So what’s next?

- Don’t forget the other rules!
- Foreign Supplier Verification Programs
  - How will production and handling of the “0.5-1% of almonds sold in the U.S.” be regulated?
  - What if someone wants to sell raw?
  - Will operations < $25,000 be exempt?
  - What about U.S. goods returned?
  - Even if regulated the same as U.S.:
    - Who gets verified? Grower? Handler?
    - How will it be verified? Audits? Testing?
Preventive Controls for Animal Feed??

• Culls, sheller/huller waste
  – Who’s covered, who’s exempt?
  – Additional hazards, controls, monitoring and corrective action records for Preventive Controls food safety plan?

• Comment period closes Feb 26, 2014
Rulemaking Process

- FDA publishes proposed rule
- Public comment period
- FDA publishes final rule (July 2015)
- 1-2 year implementation
- Dates to be staggered for small and very small operations
Rulemaking Process

- FDA publishes proposed rule
- Public comment period
- FDA publishes second proposed rule
- Public comment period
- FDA publishes final rule
- 1-2 year implementation
- Dates to be staggered for small and very small operations
And when it’s final...

- Training, outreach begins in earnest
  - Produce Safety Alliance
  - Food Safety Preventive Controls Alliance
    - What is a Qualified Individual?
  - State agencies, Extension, Universities
  - Trade associations, Commodity groups
  - Private sector consultants

- Already seeing this (webinars, workshops) but be careful!
And when it’s final...

- What if FDA agrees? Disagrees?
- Who will write the Guidance?
- Science, proposals to support Variances
  - Will commodity groups be allowed?
  - What level of “science” is needed?
- Who gets to review Alternatives?
  - Even if extended to all requirements...