How the Fresh Produce Industry is Preparing for FSMA

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Overview

• Industry perspective
• Three approaches that have been used to reduce anxiety
• What have the associations been telling members
• Steps that have already been taken
General comments we have made concerning the FDA to members

- Prevention not reaction
- Risk assessment and actions
- Documentation
- Rely on industry strengths
  - Produce Traceability Initiative
  - LGMA
  - United Fresh Harmonized Audit
- Growers/Processors should be prepared
  - Food Safety Program
- Identification of risk categories
  - Incentives for change
• Plan to hold face to face meetings
• Looked to Associations for answers to difficult questions
• Are not planning to shake up industry
Industry Perspective

• In the beginning
  – FDA is going to interfere more than ever with our business
    ➢ Lots of lots of audits
    ➢ Increase recalls due to mandatory recall authority
    ➢ Demand all types of new documentation
    ➢ Will increase product testing

• One item not fully understood
  – Tester amendment and exemptions
  – There must be a minimum standard that every producer should meet
  – Buyers to drive change
Where is the industry today

• How did we get here
  – FDA webinars, face to face meeting and materials on the website
  – Associations meeting with members
    ➢ United Fresh Produce Association
    ➢ Produce Marketing Association
    ➢ Western Growers Association
    ➢ Local organizations
      – Grower Shipper Association – Salinas
    ➢ Trade Associations
      – Tree fruit, citrus, watermelon, tomato, etc
    ➢ Foreign Producer Associations
Industry Today

• Continues to be anxiety
  – The “unknown” and, why is this taking so long to publish...you can tell me what is the problem!
  – 600 – 700 pages

• There is also acceptance
  – We asked for regulations so bring it on
  – Should address
    - Consumer confidence
    - Stop customers from going their own way
    - Create standardization
    - Identify areas that we must understand better
Industry has been active

- Guidance documents
- Education
- Awareness
- Stopping rumors
- Addressing concerns as they develop
- Associations working together
  - One message
Commodity-Specific GAPs and Food Safety Audit Checklists

- Melon
- Tomato
- Stone fruit
- Mushroom
- Lettuce & Leafy Greens
- Culinary Herbs
- Green Onions
- Sprouts
- Almond
- Citrus
- Strawberry
- Watermelon
- Blueberries
- Asparagus
Produce Safety Alliance

- Over 400 people signed on
- Most of industry focused on
  - Production
  - Harvesting
  - Postharvest handling
  - How to educate
What have been the concerns

- Mandatory recall authority
  - Answer: no real changes, in about every case we follow the recommendation for a voluntary recall

- Import standards
  - Answer: FDA wants a strong preventative approach. Programs and documentation followed in the USA should be nearly the same for foreign suppliers. Think about expanding the use of electronic communications for documentation
What have been the concerns

• Food Safety Plan
  – Answer: Most already have one, but may need to be updated. This is most likely what the FDA will review and then ask for supporting documentation. We expect the FDA will outline the detail needed. Industry will hold training and preparation sessions.

• Documentation
  – Answer: This is nothing new to our industry. There maybe new information that the FDA will ask for, but this is well understood. Remember import suppliers
What have been the concerns

• Costs
  – Answer: Yes, there will be additional costs. These will be outlined. Domestic costs will be lower than foreign. We are waiting for specifics.

• Audits
  – The frequency of audits has been covered in many talks. Our understanding is that the FDA will conduct nearly all domestic audits and foreign audits will most likely be conducted by other than the FDA. Audit criteria standardization is a concern.
Produce GAP’s Harmonization

- Project started by United Fresh about 5 years ago
- Objective
  - Reduce audit fatigue
  - 14 audits reviewed
    - Over 90% of questions about the same
- Supported by total process chain
- Over 138 audits conducted to determine where improvements needed
- More information
  - unitedfresh.org
What have been the concerns

• Risk assessment
  – Answer: A critical component of the new program. The primary tool to address prevention. We know very little about the requirements at this time, but everyone should be thinking of a comprehensive program with a focus on corrective actions

• Traceability
  – Answer: FDA supports the PTI approach the industry has taken. We do not expect major changes. Emphasis is on how will this information be communicated. In September we expect more specifics
An Honest Self-Appraisal is Critical
Preparation

- United Fresh has formed three groups to immediately review and lead comment gathering
  - Produce Rule
  - Facilities
  - Imports

- Associations will try not to overlap, but compliment each other
We’ve just begun...

"CONGRATULATIONS! NOW GET TO WORK."
Follow Murphy's Law

Anything that can go wrong will go wrong
Otoole’s Law

Murphy was an optimist