Food Recalls 2016
New Rules and Old Rules

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The Regulatory Climate

- Use of whole genome sequencing
- Lack of FSMA funding driving FDA
- CDC driving FDA actions
- Listeria and expanded recalls
- OIG report on FDA recalls
- Mandatory recalls
2nd Quarter 2016: A Recall Record

- 167% increase in FDA recalls over 1st quarter
- Mostly CRF Frozen Foods
- Whole genome sequencing linked frozen vegies to illnesses over 3 year period
FSMA
Produce safety and Preventive Controls Rules

• FSMA covers all facilities that register with FDA
• Criteria – Manufacture, process, pack or hold (with some exemptions)
• “Ordered Product Withdrawal” = Mandatory Recall
FSMA
Produce Safety Rule
Reasons for “Exemption” Withdrawal

- Active outbreak investigation where farm directly linked
- FDA determines necessity to protect public health
- Inspection of farm gives cause
- In “Intentional Adulteration” incidents, recalls are primary tool
Chapter 15 of PC Training – “Recall Plan”

• All entities manufacturing, processing, packing human food need a recall plan.
• So how do you make one?
Constructing a Recall Plan

- Follow Chapter 15 in FSPCA training
- Records access increased for trace forward, traceback.
- Traceback rendered somewhat moot by whole genome sequencing
- Obtain UF’s “Food Recall Manual” for more complete instructions
- Food Recall Manual originally released in 2005-6
- Updated Manual will be released in mid-September, free, on-line via EDIS
Take Home Points

- FSMA is here, it’s real, and you are likely subject to the rules.
- PC for Human Food mandates a Food safety Plan
- Part of the Food safety Plan is a Recall Plan
- UF/IFAS “Food Recall Manual” available by Sept. 15 on EDIS