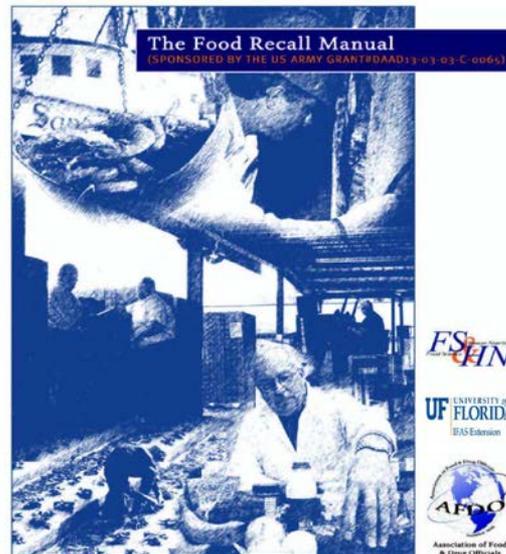


# Recalls and Food Tampering (and the new Food Recall Manual) (Let's call it "A Practical Guide to Food Recalls")

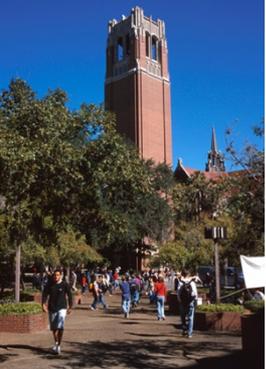
KEEP  
DOUG ON  
THE COVER



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# The Regulatory Climate

- Lack of FSMA funding driving FDA
- CDC driving FDA actions
- Listeria and expanded recalls
- OIG report on FDA recalls
- Mandatory recalls
- Use of whole genome sequencing



# Watchdog agency: FDA food recall process too slow

[Liz Szabo](#), USA TODAY 3:43 p.m. EDT June 9, 2016

Contaminated food has remained on the shelf for months because the Food and Drug Administration sometimes moves too slowly to force food manufacturers to recall it, according to a report released Thursday by a watchdog agency inside the Department of Health and Human Services.

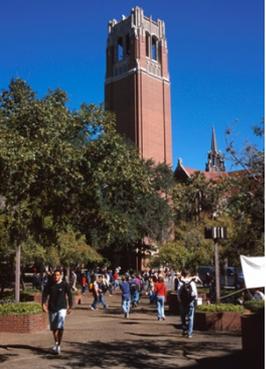
In one case, the manufacturer of a nut butter took 165 days to recall a product contaminated with salmonella, a bacteria that can be deadly, according to the report from the Office of the Inspector General, which looked at 30 recalls between 2012 and 2015. Fourteen people in 11 states became ill in the outbreak

**"Consumers remained at risk of illness or death for several weeks after FDA knew of potentially hazardous food,"** according to a preliminary report from an ongoing audit.



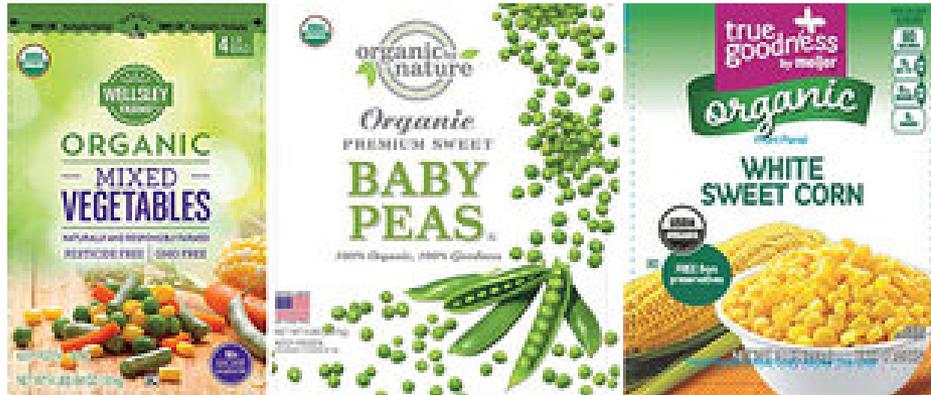
# 2<sup>nd</sup> Quarter 2016: A Recall Record

- 167% increase in FDA recalls over 1<sup>st</sup> quarter
- Mostly CRF Frozen Foods
- Whole genome sequencing linked frozen vegies to illnesses over 3 year period



# *Huge Recall of Frozen Fruits and Vegetables After Listeria Outbreak*

By CHRISTOPHER MELEMAY 22, 2016



**The Products**

**The Company**



# EXPANDED VEGETABLE RECALL



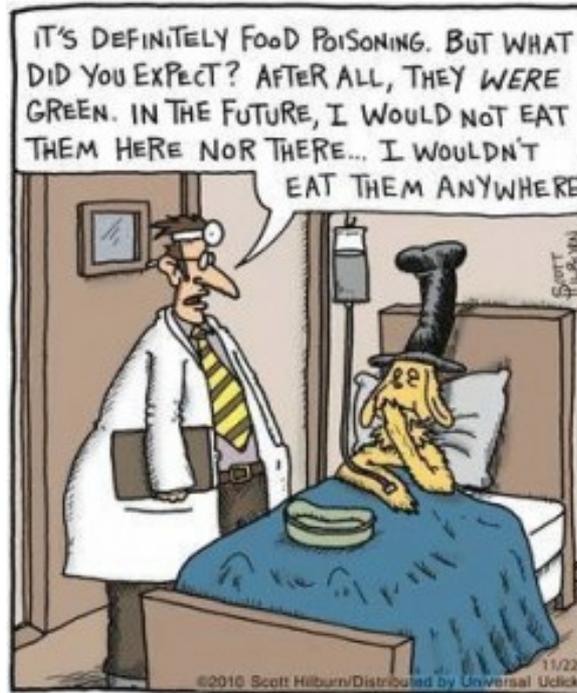
# RECALL ON FROZEN VEGGIES

Affects 358 Items under 42 Different Brands



# Why are recalls done?

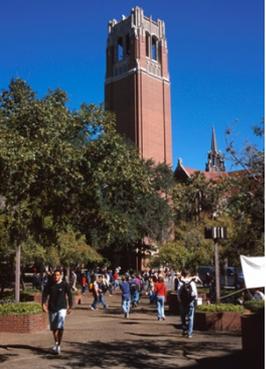
**To protect the consumer's health**



# 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

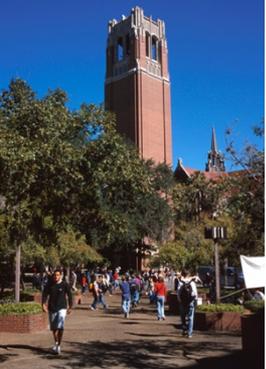
### Reasons for “Exemption” Withdrawal

- 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

# FSPCA

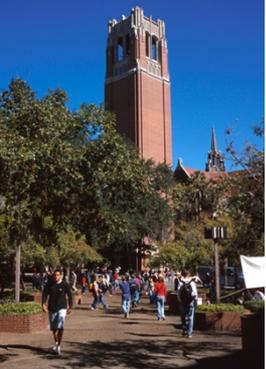
## Chapter 15 of PC Training – “Recall Plan”

- All entities manufacturing, processing, packing human food **need a recall plan.**
- So how do you make one?



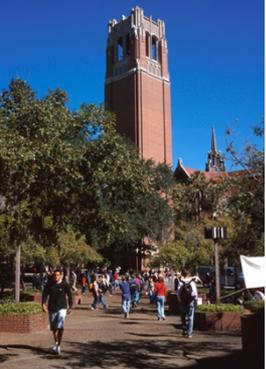
# Constructing a Recall Plan

- 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



# The new Food Recall Manual (**A Practical Guide to Food Recalls**) table of contents

- Intro – Why “**A Practical Guide to Food Recalls**”?
- **Section 1 – Food safety and your legal responsibility**
- **Section 2 – Before the Recall: Prevention and Planning**
- **Section 3 – The Recall Begins: Investigation and Cooperation**
- **Section 4 – After the Recall: Legal Liability and Rebuilding Trust**
- **3 “My Best Advice”**
- **Glossary of terms**
- **Appendices – useful info and forms**



# 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 soon (?) on EDIS

