

Part of the  
TEXAS PRODUCE CONVENTION 2011



*Texas*  
**FOOD SAFETY**  
**Traceability & Recall**  
*Pre-Convention Workshop*

**AUGUST 17, 2011 1:30 - 4:30 PM**  
**ISLA GRAND BEACH HOTEL & RESORT**  
**SOUTH PADRE ISLAND, TX**

Responding to Regulatory Requests

# Are You Prepared?

For a call from FDA or CDC or State  
epidemiologist.

# Call from Regulatory Agency

- Be Friendly, calm, collected,
- Verify the callers name and agency
- Capture phone number
- Let them Identify product
  - Brand
  - Product
  - Type
- Let them Identify issue
- Take notes – Date and time...

# Call from Agency

- If they are reporting illnesses, ask how many and geographical locations and general conditions of individuals
- Ask if they have laboratory confirmation
- Have they tested product?
  - Consumer open container
  - Sealed package
  - Ask for laboratory report
- Where was the package obtained from?

# Call from Regulatory Agency

- Do you have a product code?
- Where was the sealed package procured from?
- Listen for other concerns...
- Then ask will you need to investigate and get back to them.
- Exchange contact information
  - Office, cell phone, email, after hours contact info

# Time to go to Work!

- Check your complaints
  - Document (Record)
- Check shipments to this geographical area for the time period in question.
- If you have a code pull production records
- Any unusual events note in the records?
- Look at your controls
  - Temperatures
  - Sanitizers
  - Micro records

# Time to go to Work!

- At this time this is an Incident Investigation
- Put the recall team to work in pulling all records as if you were in recall mode.
  - Also a good time to practice under a real life event
- Pull together shipping records and contact information

# Time to go to Work!

- If your research did not find a problem
  - Report back to the caller
  - Note the tone of the call
  - Expect an FDA or State Investigator to follow up
- If your research showed a problem
  - You are more than likely headed to a recall
  - Advise the agency you will be putting together a recall, ask who you need to talk with regarding the recall
  - This means today and not tomorrow

# Time to go to Work!

- Recall Mode
  - By now you should have a lot code identified.
  - Next test is to determine if your documentation isolates this code only
    - Process
    - Ingredients
    - Raw materials
    - Clean up
    - Sanitizing records
    - Micro testing

# Got your Act Together?

- Have you looked under “every” rock?
- Have you verified?
- Feel Comfortable
- You want to do what is right for the consumer!
- You do not want a multiple recall!
- Will your records support your decision?
- Expect FDA to Challenge on site
- Expect all these records will be copied by FDA

