FDA and FSMA Inspections: What We Have Learned and How to Prepare

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Disclaimer – This is my opinion

- FDA thought is ever evolving
- Training has changed
- Industry vs. Government training
- State vs. Federal
- State vs. State
- Inspector vs. Inspector

What *are* they being trained?

- How to do a hazard analysis
  - Based on a draft guidance
  - Of 16 chap. and 4 appx. (50% complete)
  - Non- Binding
  - Not for implementation (sound familiar)

- Where can you find it?
  - Original Hazard Analysis Guidance 8/16
  - Appendix 1
  - May also find useful Appendix 2

How do you use it?

- Series of tables
  - 233 pages (abbreviated)
- First, find your Category: (for instance, Fruits and Vegetables are under H)
- Then your subcategory (Fresh Cut, Refrigerated Fruits and Vegetables) = H1
- You can then carry that subcategory thru the subsequent tables.
  - Table 1 is about Biological
  - Table 2 is about Chemical
  - Table 3 is process related hazards
- So if you were looking at hazards for Fresh Cut Refrigerated Fruits and Vegetables, you would look in tables : 1H1, 2H1 and 3H1

What does it say?

- Using our example of refrigerated pickles
- Table 1H Biological Hazards
  - page 42 Category #9a
  - *C. botulinum, Salmonella spp., L. monocytogenes, S. aureus*
- Table 2H Chemical Hazards
  - Page 117 Category #9a
  - none
  - Out of Undeclared allergens, Drug residues, Heavy metals, Industrial Chemicals, Mycotoxins/Natural toxins, Pesticides, Unapproved colors & additives, and Radiological

What does it say?

- Table 3H Process-Related Hazards
  - page 191 Category #9a

Contains Non-binding Recommendations
Draft-Not for Implementation

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Further Processed	9a	Acidified Vegetables	Refrigerated		X	X		X	X			X	X	X	Pickled Cucumbers, Pickled Beets, Cocktail Onions, Pickled Turnips, Hearts of Palm, Capers, Roasted Peppers, Roasted Tomatoes, Salsa

What does it mean?

- You *may* have at a *minimum* 7 process controls
- All process controls (as well as sanitation, allergen or others) must comply with the PC rule to include adequate monitoring, corrections, corrective actions, verification
- Don't forget recordkeeping (really important)
- Don't forget calibration (pH, temp, time)
- Validation

How/When will it be enforced?

- Dependent on your state
  - Oftentimes there is poor communication
- Inspector to inspector
- Risk level
- Inspection is to be a teaching opportunity not a enforcement action

What about the other parts of the rule?

- Animal feed
- Sanitary Transport
  - Fermented stock
- FSVP
  - various methods to comply

What should we do?

- Depends upon you and your companies approach

- Be defiant
  - Better have good scientific validation
  - Good for you doesn't mean good for your inspector
  - The “industry standard” route

- Be compliant

Questions?