Food Safety Regulations

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Why regulate wild bird food?

- Wild bird food is a subcategory of animal feed.

- **Animal Feed**: An article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal. It is not limited to a mixture intended to be the sole ration of the animal.
Regulations

- Laws – US Congress and state legislatures provide legal the authority to regulate

- Regulations – Federal and state agencies made the regulations which are the details of how the laws will be enforced.
Who Regulates?

- Federal Agencies.
  - Food and Drug Administration (FDA).
  - Environmental Protection Agency (EPA).
  - United States Department of Agriculture (USDA).

- State Agencies.
  - Generally State Department of Agriculture, but might also be Consumer Protection
Food Protection

- Two parts
  - Food Defense – Risk of intentional adulteration
  - Food Safety - Risk of unintentional adulteration
Food Defense

- **Definition** – Protecting the nation’s food supply from deliberate or intentional acts or contamination or tampering.

- FDA/USDA held training sessions on protecting the food supply from Intentional Adulteration. Online independent course that takes 1 hour and a pdf version with same material.

- A company must do everything it can to minimize the risk of deliberate or intentional adulteration.
Food Defense & Bioterrorism Act

- Bioterrorism Act of 2002
- Goal – Prevent, detect, and respond to intentional adulteration

- SAHCODHA
  Serious Adverse Health Consequence or Death to Humans or Animals
Food Defense & Bioterrorism Act

- Applies to each person that: manufactures, processes, packs, distributes, receives, holds, or imports food.
- Remember food = food for man and other animals, includes wild animals.
- Each person = each facility, not just each company.
Food Defense & Bioterrorism Act

- Bioterrorism Act of 2002
- Subtitle A. Protecting the Food Supply
  Title III
  - Facility registration (305)
  - Prior notice for imported materials (307)
  - Recordkeeping (306)
  - Administrative detention (303)
Food Defense & Bioterrorism Act

- Facility registration (305)
  - Every facility MUST be registered
  - All registrations must be kept up to date
  - Registration is free and online
  - Must know your facility’s registration #
What You Need to Know About
REGISTRATION OF
FOOD FACILITIES

FDA Food Security Information for Domestic and Foreign:
- Manufacturers or Processors
- Packers
- Holding Facilities

The Public Health Security and Bioterrorism
Preparedness and Response Act of 2002
November 2003
Food Defense & Bioterrorism Act

- Prior Notice (307)
  - Do you import food?
    - Yes, some seed is imported
  - Your or your broker must comply with prior notice requirements
  - Must notify US Customs of arrival
    - Timing varies by method
Food Defense & Bioterrorism Act

What You Need to Know About
PRIOR NOTICE OF
IMPORTED FOOD
SHIPMENTS
A Small Entity Compliance Guide

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002
April 2009
Food Defense & Bioterrorism Act

- Record keeping (306)
  - aka One up, One back
  - Required list of information for each transaction
  - Must know where you got every ingredient, where it goes under your control and where they go in every finished product goes.
Food Defense & Bioterrorism Act

What You Need to Know About Establishment and Maintenance of Records

FDA Food Safety and Security Information for Domestic Persons that:
- Manufacture, Process, Pack, Distribute, Receive, Hold, or Import Food

And Domestic and Foreign Persons that:
- Transport Food in the U.S.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002
December 2004
Record keeping (306)
- Must know where you got every ingredient, where it goes under your control and where they go in every finished product goes.

**IMPOSSIBLE** you say?
- The less thorough your tracking, the bigger the recall, the bigger exposure to bad press.
Food Defense & Bioterrorism Act

- **Record keeping (306)**
  - Must be able to access with in **24 hours** of the request from the FDA
  - May be electronic records
  - Must keep records for one year
    Most companies are keeping records for the shelf life of the product plus 3-6 months.
Food Defense & Bioterrorism Act

Record keeping (306)

- What did recent recalls teach us?
  - Be able to trace every bit of any ingredient
  - Go beyond the broker in vendor assurance
  - Check suppliers more thoroughly
  - Be sure to follow your written procedures
  - Keep records and retain samples
  - Bad things can happen to good companies
Food Defense & Bioterrorism Act

**ALERT**

- How do you **Assure** that the supplies and ingredients that you use are from safe and secure sources?
- How do you **Look** after the security of the products and ingredients in your facility?
- What do you know about your **Employees** and people coming in and out of your facility?
- Could you provide **Reports** about the security of your products while under your control?
- What do you do and who do you notify if you have a **Threat** or issue at your facility including suspicious behavior?
Food Defense & Bioterrorism Act

- Food defense
- From FDA, CDC & USDA collaboration
  - **FIRST** – Employees are the FIRST line of food defense
  - **Follow** company food defense plan.
  - **Inspect** your work area and surrounding area.
  - **Recognize** anything out of the ordinary.
  - **Secure** all ingredients, supplies and finished product.
  - **Tell** management if you notice anything unusual or suspicious
Food Safety Legislation

- Food Safety
  - A company must do everything in its power to minimize the risk of *Unintentional Adulteration* of food. Some things just come naturally.

- Learn your acronyms
  - FDAAA of 2007
  - RFR (Section 1005 of FDAAA)
  - AFSS
  - GMPs
  - HACCP
Food Safety Legislation

- FDAAA of 2007
  - Title X Section 1002
  - (1) ingredient standards and definitions with respect to pet food;
  - (2) processing standards for pet food; and
  - (3) updated standards for the labeling of pet food that include nutritional and ingredient information.

- Written to address pet food, FDA expanded some of it to **ALL** animals because they share ingredient streams and have similar processing.
Food Safety Legislation

- FDAAA of 2007
  - Ingredients – FDA has MOU with AAFCO
    Why AAFCO’s IDC is important
  - Processing – Not as clear, but some combinations of AAFCO GMPs, CFR, AFSS
  - Labeling – Used AAFCO as base
Food Safety Legislation

- FDAAA of 2007
  - Title X Section 1002

 WHEN????

“Soon…a regulatory soon”
FDA-CVM Director Dr. Dunham
Food Safety Legislation

- RFR
  Reportable Food Registry

- FDAAA of 2007 Title X Section 1005
- For **ALL** food, human and animal
- Went live **Sept. 8**
Food Safety Legislation

- **RFR**

- What is reportable?
  - **SAHCODA** (Yes, from Bioterrorism)
  - ‘Reasonable probability’
  - Essentially a Class 1 recall
  - Company makes determination

- When to report?
  - Within **24 hours** of making determination

- Penalty? Felony
Food Safety Legislation

- RFR

Critical things to know:
- Your bioterrorism facility registration #
- Where to report – online
  http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm
- Get the Report ID number – key to report
- Don’t use the browser back button
- Do page print out in case you ‘lose’ info
- One issue = ‘transfer’ of product.
Food Safety Legislation

- RFR
  Next version of Guidance Q&A due out December 8
- Cumbersome procedure that won’t change much
Food Safety Legislation

- GMPs
  AAFCO Model Good Manufacturing Practice
  Regulations for Feed and Feed Ingredients

- Note – Regulations
- Effective date AAFCO OP in 2010
  Texas adopts the latest edition of OP
- Checklist coming but not completed
Food Safety Legislation

- **AFSS**
  - Animal Feed Safety System
    - Long term work over last 5 years
    - Not a response to recent recalls
  - System which describes how animal feeds (individual ingredients and mixed feeds) should be manufactured and distributed to minimize risks to animals consuming the feed and people consuming food products from animals.
Food Safety Legislation

- AFSS
  - Risk Management, science–based system
    - For federal resource allocation such as inspections
  - Risk = health consequences x exposure
    - Health consequences = severity + potency
    - Exposure = likelihood + route
    - Complex (not really explainable) algorithm
What else????
Congress is still considering more legislation on food safety.

Keeping eyes and ears open particularly in DC. Role for NGFA. NGFA is requested to be part of congressional working sessions.