Welcome to the Introduction to the Food Safety Modernization Act Seminar

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Extension and Outreach
Agenda

- Background
- Timeline of Action
- Fee Assessment
- Food Safety Plan Preparation
- Review and Question Section
FSMA

Background of Ruling
Brief History of Food Law

• 1906-Pure Food and Drug Act
  – collecting samples of products, collecting evidence of the interstate shipment
• 1938-The Federal Food, Drug, and Cosmetic Act
• 1952-FDA consumer consultants appointed in each field district
• 1958-Food Additives Amendment & GRAS
• 1969-Sanitation Programs began in milk, shellfish, food service
Brief History of Food Law

• 1973-Low-acid food processing regulations issued following botulism outbreaks from canned food
• 1988-Department of Health and Human Services
• 1990-Nutrition Labeling and Education Act requires all packaged foods to bear nutrition labeling and all health claims
Brief History of Food Law

- 1995 - Seafood HACCP (Hazard Analysis Critical Control Point)
- 1998 - Juice HACCP rule
- 2000 - Safe handling statement for shell eggs be put on egg cartons
- 2006 - Food Allergen Labeling and Consumer Protection Act
Brief History of Food Law

• 2009 - Egg Safety (final) Rule issued – establishes requirements for control of S. Enteritidis in eggs from production through distribution

• 2010 - Implementation of the Egg Safety Rule began in July 2010 for large (50,000 layers+) producers;

• 2012 - Smaller producers must be in compliance
Foodborne Illness

- About 48 million (1 in 6 Americans) get sick every year
- 128,000 Hospitalized
- 3,000 Death
Statistics

• FDA is responsible for about 79% of the US food supply
• 15% of all foods consumed in the U.S. is imported
  – 75% seafood, 20% vegetables, 50% fruit
• FDA is only responsible for about 1% of all imported foods in the U.S. (1997)
FSMA: Purpose

• The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4th, 2011

• It aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing i
Pillars of Legislation

50 New Rules under this mandate

• Prevention Standards
• Inspections, Compliance, and Response,
• Import Safety
• Enhanced Partnerships
Four Key Areas

1. Prevention
   – Mandatory preventive controls for food facilities
   – Mandatory produce safety (science based)
   – Authority to prevent intentional contamination
   – Transportation
Four Key Areas

2. Inspection, Compliance, and Response
   – Mandated inspection frequency
   – Mandatory recall
   – Expand records access
   – Suspension of registration
   – Enhanced product tracing abilities
   – Testing by accredited laboratories
   – Expanded administrative detention
Four Key Areas

3. Imports
   – Importer accountability
   – Third Party Certification
   – Certification for high risk foods
   – Voluntary qualified importer program
   – Authority to deny entry
Four Key Areas

4. Enhanced Partnerships
   – State and local capacity building
   – Foreign capacity building
   – Reliance on inspections by other agencies
   – Improved foodborne illness surveillance
   – National agriculture and food defense strategy
   – Consortium of laboratory networks
Six Teams

- Prevention Standards-Don Kraemer
- Inspection and Compliance-Barbara Cassens
- Imports-David Elder
- Federal/State Integration-Joe Reardon
- Fees-David Wardrop
- Reports and Studies-David Dorsey
Sec. 103: Hazard analysis and risk-based preventive controls

Requires human and animal food facilities to:

• Evaluate hazards that could affect food safety;
• Identify and implement preventive controls to prevent hazards;
• Monitor controls and maintain monitoring records; and
• Conduct verification activities.
Examples of Compliance with Prevention Standards

- Sanitation
- Training for supervisors and employees
- Environmental controls and monitoring
- Food allergen controls
- Recall contingency plan
- Good Manufacturing Practices (GMPs)
- Supplier verification activities
WHO IS NOT AFFECTED BY LAW?
Modified Requirements for Qualified Facilities (Sec. 103)

Facility is exempt if:

• Defined as very small business;

  OR

• The facility has a limited annual monetary value of sales

Slide from FDA FSMA: Focus on Prevention
Power point
Modified Requirements for Qualified Facilities (Sec. 103)

Limited annual monetary value of sales is defined as:

- During the last 3 years, sales were less than $500,000;

  AND

- Sales to "Qualified End Users" exceed sales to others
Tester’s Act Exceptions (Sec. 103)

• Qualified end-users are consumers, restaurants, or retail food establishments that sell directly to consumers and are located in the same state as the qualified facilities or located no further than 275 miles from them
Exemptions, continue

- Exempts all those regulated under the Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act
WHO IS AFFECTED
Affected Parties

• Registered under The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act)
• Gross over $500,000
• Safety of all imported and domestic food products sold in interstate commerce that do not fall under the jurisdiction of the FSIS
Specifics

- Dietary supplements and ingredients
- Infant formula
- Beverages
- Fruits and vegetables
- Fish and seafood
- Dairy products
Specifics

- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack foods, candy
- Animal feeds and pet food
IMPORTANT

• Qualified facilities must still demonstrate they have identified potential hazards associated with their production and implementation of preventive controls for the identified hazards
• AND must provide documentation of compliance with state, local or county food safety laws
Why was I invited?

- Represent one of the given types of companies
- Required to include many of the aspects within the ruling
FSMA

Timeline of Actions
January 2011

1. Sec. 101 Inspections of records
2. Sec. 107 Authority to collect fees
3. Sec. 201 Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report
4. Sec. 206 Mandatory recall authority
5. Sec. 303 Authority to require import certifications for food
January 2011, cont.

6. Sec. 307 Accreditation of third party auditors
7. Sec. 309 Smuggled Food
Sec. 101 Inspections of Records

- Key Words: reasonable probability and reasonably believes is likely to be affected will cause serious adverse health consequences or death to humans or animals, each person
- Who: Manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person
What does it mean?

- Must PROVE compliance (Assume non-compliance)
- More INSPECTIONS → more violations
- Shift from federal government back to the state
- Emphasis on contamination hazards and test results
- Must keep records for at least two years
- Assumption of an established Food Safety Plan
- FOCUS IS ON FOREIGN IMPORTS
Sec. 107 Authority to collect fees

- Key Words: Fees for Re inspection, Recall, and Importation Activities
- Who: Domestic facilities and U.S. Agents of the foreign facilities
- Fees: $224 per hour domestic/$325 per hour if foreign
- Allowed to October 1st, 2011
Sec. 201 Targeting of inspection resources

• Key Word: Known safety risk, compliance history, facility's hazard analysis and risk-based preventive controls,

• Who: Facility that manufactured, processed, packed, or held such food has received a certification
What does it mean?

• Domestic High Risk Facility: Effective within 5 years and inspection every 3 years
• Domestic Non-Risk Facility: Effective within 7 years and inspection every 5 years
• Foreign Facility: Effective after 1 year (now)
  – FDA will double inspection until reach 10,000 per year
• Definition of what “High Risk Facility”/ “High Risk Food” is in comment session now
Sec. 206 Mandatory recall authority

• Key Words: Refuses to or does not voluntarily cease distribution or recall
• Who: Manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling
• Where an article is adulterated or misbranded and exposure to such article will cause serious adverse consequences to consumer
What does this mean?

• Unless you are not willing to pull a product, it means little
• Recall scheme of events will still occur before these powers will be employed
Sec. 303 Authority to require import certifications for food

- Key Words: Conditions of granting admission, required certification, known risk associated with food and the country or region AND scientific, risk based evidence
- Who: Foreign Facilities: certified facilities that manufacture, process, pack, or hold such food
What does it mean?

- Information to make a better decision of what products to admit into the country
- FDA has an updated database to track products coming into the country
Sec. 307 Accreditation of third party auditors

- Key Words: Accredited third party auditor, foreign government/ cooperatives, may be individual,
- Who: Foreign importers
- In 2 years establish a system for the recognition of accreditation bodies
What does it mean?

- Must agree to issue a written and, as appropriate, electronic food certification
- 3rd Party may not perform a regulatory audit of an eligible entity if such agent has performed a consultative audit or a regulatory audit of such eligible entity during the previous 13-month period
- New conflict of interest rules
Sec. 309 Smuggled Food

- Key Words: 10 days after, reasonably believe exposure, reasonably believe that entered domestic commerce, fraudulent means or intent to defraud or mislead
- Who: Foreign suppliers
- What does it mean?
  - Criminal action potential along with fines
  - Labeling problems and clerical errors will be fined
July 2011

1. Sec. 102 Registration of food facilities
2. Sec. 113 New dietary ingredients
3. Sec. 207 Administrative detention of food
4. Sec. 304 Prior notice of imported food shipments
Sec. 102 Registration of food facilities

• Key Words: Permit to inspect; Food manufactured, processed, packed, received or held; Reasonable probability

• Who: Domestic and U.S. Agents for Foreign Producers
What does it mean?

- Must have current information for traceability to inspect
- Most already for registration under the 2003 legislation
- New form to fill out for registration
- Re-register facilities every 2 years, during the period beginning on October 1 and ending on December 31 in even numbered years
  - Oct-Dec 2012
Sec. 113 New dietary ingredients

• Key Words: Anabolic steroid or analogue, 180 days to publish guidance (Jan. 2012)

• Who: Those wanting to market a new dietary ingredient

• FDA is still working on guidance document
  – Need to establish what “published articles” or other scientific articles are required to support safety of ingredients

• Open comment period is currently going
Sec. 207 Administrative detention of food

• Key Words: Reason to believe; Credible evidence; FDA will publish interim final rule in 120 days (Dec. 2011)
• Who: General Rule
• Detention for 20 days +10 day extension (for legal actions)
• Comment period ended Aug. 3, 2011
What does it mean?

- Order can be completed during an inspection, examination, or investigation
- Specific guidelines that need to be in the detention order
- FDA will issue the administrative detention order to the owner, operator, or agent in charge of the location where the article of food is being detained.
Sec. 304 Prior notice of imported food shipments

- Key Words: Any country that refused entry; Interim final rule in 120 days and effect in 180 days (Jan. 2012)
- Who: Importers of animals and human foods
- Submitted electronically through Automatic Broker Interface (CBP) or Prior Notice System Interface (FDA)
What does it mean?

• Higher border control
• U.S. will no longer accept rejected product from other countries
• Stronger international communication
October 2011

• Sec. 204 Enhancing tracking and tracing of food and recordkeeping
Sec. 204 Enhancing tracking and tracing of food and recordkeeping

- Within 270 days will establish pilot programs for 5 years with 3 different commodity
- Within 2 years FDA will propose recordkeeping standards (includes handling multiple types of food)
  - Within 1 year definition of a high-risk foods
What does it mean?

• EFFECTIVE 2014ish
  – Small Businesses: not later than 90 days after 1 year of the effective date
  – Very small businesses: not later than 90 days after 2 years of the effective date
• NO effect on non-high risk foods
What does it mean?

• Limitations to:
  – Farm to school program
  – Grocery stores hold records for more than 180 days
  – Farmers to consumers do not have to keep records
  – Farmer’s must provide records if an active investigation and severe threat to humans
January 2012

1. Sec. 105 Standards for produce safety
2. Sec. 106 Protection against intentional adulteration
Sec. 105 Standards for produce safety

• FDA will establish minimal standards
• Within 1 year (Jan. 2012) publish updated GAP’s and guidance for the safe production and harvesting of specific types of fresh produce
• Adulteration definition includes “grown, harvested, processed, packed, sorted, transported or held under conditions”
  – “holding, sorting, packing, processing, and transporting and not just growing and harvesting of raw fruits and vegetables
What does it mean?

- Provisions for small and very small business and direct farm marketing
- Provisions for variance requests detailed
- Organic Foods Production act of 1990 protects practice standards as long as public health protection is consistent
  - Do not act as a barrier to organic production and organic conversion
Sec. 106 Protection against intentional adulteration

• Within 18 months regulations will be provided and 1 year guidance documents will be available

1. Implement mitigation strategies or measures intended to protect against the intentional adulteration of food

2. Specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points, as appropriate
July 2012

1. Sec. 103 Hazard analysis and risk-based preventive controls
2. Sec. 106 Protection against intentional adulteration
3. Sec. 302 Voluntary qualified importer program
4. Sec. 306 Foreign offices of the FDA
   • Remember Re-Registration occurs October-December 2012
January 2013

1. Sec. 202 Laboratory accreditation for analyses of foods
2. Sec. 204 Enhancing tracking and tracing of food and recordkeeping
3. Sec. 301 Foreign supplier verification program
4. Sec. 306 Inspection of foreign food facilities
5. Sec. 308 Foreign offices of the FDA
OPEN DOCKETS FOR COMMENTS
Comment Areas

• Preventive Controls for Registered Human Food and Animal Food/Feed Facilities- Dec. 20\textsuperscript{th}
• What You Need to Know About Administrative Detention of Foods-Anytime
• Implementation of the Fee Provisions of the FDA Food Safety Modernization Act-Anytime
• Fish and Fishery Products Hazards and Controls Guidance-Anytime
Preventive Controls for Registered Human Food and Animal Food/Feed Facilities

- December 20\textsuperscript{th}, 2012
- Document ID: FDA-2011-N-0238-0001
  Document Type: Notice, Docket ID: FDA-2011-N-0238
Preventive Controls for Registered Human Food and Animal Food/Feed Facilities

• We are requesting comments that will inform the development of guidance on the following:
  – Hazard identification (biological, chemical, radiological, and physical) and
  – Control measures associated with specific types of food or specific methods of manufacturing, processing, packing, or holding food.
Preventive Controls for Registered Human Food and Animal Food/Feed Facilities

• Conducting a hazard analysis to determine the hazards associated with specific human food or animal food/feed and processes
  – Procedures

• Implementing process controls
  – Acceptable processes

• Validating food/feed safety controls
  – Procedures used

• Implementing sanitation controls for human food and animal food/feed
  – Procedures to control contamination
Preventive Controls for Registered Human Food and Animal Food/Feed Facilities

• Implementing supplier controls
  – Raw material and ingredients
• Allergen control (human food)
  – ingredients accurately on the label
  – procedures and practices to prevent the unintentional incorporation of allergen cross contact
Preventive Controls for Registered Human Food and Animal Food/Feed Facilities, cont.

• Environmental monitoring for Salmonella and for Listeria monocytogenes for specific types of food facilities
  – RTE and Pet Food
• Specific biological, chemical, radiological, and physical hazards and controls for food types such as (but not limited to) spices, nuts, ready-to-eat food, bakery products, fresh-cut produce, milk products, and medical food.
Preventive Controls for Registered Human Food and Animal Food/Feed Facilities

• Specific biological, chemical, radiological, and physical hazards and controls for animal food/feed including feed ingredients.

• Preventive control approaches and practices (e.g., for validation, supplier controls) that are practical for small and very small businesses to implement.
Administrative Detention of Foods

• Submit at any time
• Guidance for Industry; Docket Number: FDA-2011-D-0643
Administrative Detention of Foods

- Enacted law prior to comments because much of this guidance remains the same as the guidance issued in November 2004 and seeks to remove any confusion that might arise due to the existence of a guidance document that is inconsistent with the FD&C Act and its implementing regulations.
Implementation of the Fee Provisions of the FDA Food Safety Modernization Act

• Submit at any time
• Guidance for Industry; Docket Number: FDA-2011-D-0721
Implementation of the Fee Provisions of the FDA Food Safety Modernization Act

• Guidance document was already prepared because the fee provisions of FSMA are currently being implemented, and guidance is needed to help effectuate the implementation
Fish and Fishery Products Hazards and Controls Guidance

• Submit at any time
• Guidance for Industry; Docket Number: FDA-2011-D-0287
Fish and Fishery Products Hazards and Controls Guidance

• FDA published the first edition of the guidance in September 1996 (about 1 year before the fish and fishery products regulations became effective),
  – third edition in June 2001 (Feb 2008 updated)
  • include ciguatera fish poisoning guidance
Fish and Fishery Products
Hazards and Controls Guidance

• Current information
  – Potential hazards associated with the known commercial species of vertebrate and invertebrate seafood,
  – potential hazards associated with certain processing operations,
  – HACCP strategies that may be used to control the potential hazards
Fish and Fishery Products Hazards and Controls Guidance

New Chapters

– guidance for the control of pathogen survival through processes designed to retain raw product characteristics;
– food safety hazards are identified for additional species;
– new control recommendations are listed for the natural toxin action level for diarrhetic shellfish poisoning;
– tolerances for additional chemical hazards are listed.
Section 107: Fee Provisions

Effective Oct. 1st, 2011
Effective October 1st, 2011

- Key Words: Fees for re-inspection, Recall, and Importation Activities
- Who: Domestic facilities and U.S. Agents of the foreign facilities
- Fees: $224 per hour domestic/$325 per hour if foreign
Specifics

1. The responsible party for each domestic facility and the US agent for each foreign facility subject to a re-inspection to cover re-inspection-related costs;

2. The responsible party for a domestic facility and an importer who does not comply with a recall order issued under section 423 or 412(f) of the FD&C Act, to cover food recall activities associated with such order performed by FDA;
Specifics, more

3. Each importer subject to a re-inspection, to cover re-inspection-related costs.
What they will do?

- Begin the process of tracking, assessing, and collecting facility re-inspection fees related to domestic and foreign facilities and fees for failure to comply with recall orders.
- FDA will distribute an information sheet during the initial inspections outlining the circumstances under which a facility re-inspection fee could be collected (available online).
What will they do? Cont.

- The firm will be informed at the time of the initial inspection that they could be assessed a fee for a re-inspection, if the initial inspection is classified OAI and the violations are materially related to a food safety requirement of the FD&C Act.
- Begin to send out invoices for any such fees prior to January 1, 2012.
Non compliance examples

• Foodborne pathogens in ready to-eat products
• Pesticide residues on a food or feed product above tolerance levels
• Failure to declare the presence of a major food allergen (e.g., peanuts) in product labeling
• Lack of adequate hazard controls for seafood or juice
Fees

• For Fiscal Year 2012, the hourly rate is $224 if no foreign travel is required and $325 if foreign travel is required.

• The total fee that is assessed will depend on the number of hours FDA spends directly on the re-inspection-related activities or food recall activities associated with a recall order.
Fee associated with re-inspection

- Conducting compliance re-inspection at the facility
- Making preparations and arrangements for the re-inspection
- Traveling to and from the facility
- Analyzing records and samples
- Preparing reports or examining labels
- Performing other activities as necessary to determine compliance with the requirements found to be violated in the initial inspection
Fee associated with recalls

- Conducting recall audit checks
- Reviewing periodic status reports
- Analyzing the status reports and the results of the audit checks
- Conducting inspections
- Traveling to and from locations
- Monitoring product disposition
Number of People Required

• Case-by-case basis based on the:
  – size of the firm,
  – number of products,
  – number and nature of the violations observed in the initial inspection,
  – expected resources needed to evaluate the firm’s corrective actions
  – current state of compliance
Estimated Cost

- $40,000 for re-inspection is the estimate
Limits to Fees

• General annual limitation on the collection of fees of:
  – $20 million for fees for non-compliance with recall orders
  – $25 million for fees for domestic and foreign facility re-inspection and importer re-inspection

***certain exceptions
PREPARATION SUGGESTIONS
Suggestions

• Open communication with inspectors
  – Discuss any new processes and equipment
  – Discuss new products or potential products

• Access current food safety plan
  – Record Keeping
  – Personnel Training
  – Validate microbial testing methods

• Training Sessions
  – All employees are ready for change
  – Focus on Critical Control Points

• Utilize third party audits or fresh set of eyes

• Avoid re-inspection/recalls
FSMA

Food Safety Plans: MORE THAN HACCP
Culture of Food Safety

• Comprehensive approach to ensure the safeness of the food products
• Daily Expectation from all workers
• Supported and acknowledged throughout the process (farm/suppliers to outlet)
  – Willingness to reject or recall items due to food safety standards
Prevention Control Plan Idea

• Final requirements will be provided January 2012
• More than HACCP
• HACCP Prerequisite Plans are now included in plan with monitoring, corrective actions, documentations
• Radiological, Allergen, and Recall Plans are also included with same provisions
Concept of Proof

• New attitude toward prevention
• Inspectors will assume contamination
• Companies will have to prove their product is safe
  – Record Keeping and Trends
Food Safety Plan/HACCP like plan

• Based on Prevention
  – Biological contamination: bacteria, virus, yeast, molds, toxins, etc.
  – Physical: glass or other foreign materials
  – Chemical: sanitation, ingredients
  – Allergens: proper allergen warnings
  – Radiological: X-ray, additives, technology
Within Plan: Company Must

- Evaluate the hazards that could affect food manufactured, processed, packed or held by facility
  - Known or reasonably foreseeable hazards
  - Biological, chemical, physical, radiological, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives
Company’s Must, cont.

• Identify and implement preventive controls to significantly minimize or prevent the occurrence of hazards
• Monitor the performance of these controls and maintain records of these monitoring controls on a routine basis
Items to Include in Food Safety Plan

• Good Agricultural Practices
• Good Manufacturing Practices/Process Control
• Sanitation
• Personnel Hygiene
• Environmental monitoring
• Food allergen control
• Recall plan
• Supplier verification
Preventive Controls

• Risk based, reasonably appropriate procedures, practices and processes that a “person knowledgeable” about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazard identified.
Specific

- Verification activities for preventative controls
- Description of record keeping procedures
- Recall procedures for voluntary and required recalls
- Procedures for tracing the distribution history of articles of food (traceability)
- Procedures to ensure safe and secure supplier chain
- Procedures on how to implement science-based performance standards
Summary Food Safety Plan

• Based on prevention of biological, physical, chemical and allergen contamination
• Companies must evaluate known and reasonably foreseeable hazards
• Specific SCIENCE and RISK-BASED prevention methods, monitoring, and record keeping
• Key words: Traceability, description, procedures, verification, assurance
Food Safety Team

• Consisting of:
  – All areas of production (include suppliers and outlets)
  – Reward system (extra duties)
  – Constant members (supervisors)
  – Rotating members (fresh eyes and energy)
Flow Diagrams

• Farm through the end user
• More details the better the chart works
• Can group but be cautious
• Includes all farms or companies for each ingredient, flow throughout plant with all possible deviations (end of day, shift changes, stoppage of production, power outages), trucking, suppliers (alternative outlets)
Written Checklist and Protocol

- New employee
- New suppliers
- New equipment
- New outlets
Written Procedures

• The standard operating procedures (SOP’s)
• Easy to follow (1,2,3 guide)
• Needs to have scientific support if a critical control point is within the procedure
Scientific based

- Assumption of hazard presence in process. Must prove otherwise.
- Record keeping is key for in process control
- Validation of critical control step
  - Literature for support
  - Require in house data
  - Third party data
Literature Based

- Need more details (no generic)
  - Specific products or ingredient or chemical
  - Specific parameters
  - Specific bacteria
- Encourage companies to allow data to be published anonymously
Validation

• Chemical
  – Cleaning agents
  – Ingredients control

• Physical
  – Metal or glass detectors
  – Visual assessments
Validation

- Biological
  - Water and soil quality
  - Environmental samples
  - Ingredient control (data from received ingredients)
  - Temperature control (always a hot or cold spot)
    - Ovens, receiving, room or refrigerator or freezer temperatures
SUGGESTED AREAS
Good Agricultural Practices

• Traceability
• Water and soil quality
• Manure management
• Sanitation: Equipment, trucks, personnel
• Hygiene Training
• Harvesting practices/Transportation
• Policies for visitors
Good Manufacturing Practices/Process Control

• Knowledge of exact process (flow diagram)
• Control of parameters (i.e. water temperature, concentration, cook temperature/time)
• Established back-up plan
• Monitoring technique (with back up plan)
• Practical record keeping strategy
  – Data management
• Personnel Control (intentional contamination)
Sanitation

• Extremely important
• Prevent chemical, physical, and biological hazards
• New products mean new guidelines
• Monitor concentrations and effectiveness
• Equipment and plant design
• Pest control
• Example: chlorine/organic matter, fat/biofilms
Personnel Hygiene

- Respond to culture differences
- Standards to your company
- Consistent policy
- Health and wellness
  - Policy on sick days
- Appearance and upkeep
  - Strategy to handle personnel’s needs
Environmental monitoring

- Sampling plan with frequency with budget
- Facility: walls, floors, drains, handles
- Air quality (filters, air pressure)
- Humidity and temperature control
  - Growth bacteria, mold and yeast (shelf life)
- Condensation in coolers and kitchens
Food allergen control

• Allergen control (cross contamination)
• Sanitation and validation
• Supplier ingredient control
• Awareness of food allergens present in facility (personnel knowledge)
• Appropriate labeling
Recall plan (voluntary/mandated)

• Traceability
  – who do you need to call
• Updated contact information of outlets for food
  – old phone numbers
• How to handle media
  – Spokesperson (special qualities)
• Action plan to re-gain consumer confidence
  – Mission of company, statement
Suppliers verification

• More than a letter of certification
• In a recall, who is to blame
• Confidence that your food safety standards are being applied
  – Continuous monitoring
  – Awareness of problems by suppliers
  – Audits
  – Record keeping by them
Other Items to Consider

• Variances
  – Must meet safety standards regardless
  – Request must be made in person
REVIEW OF SEMINAR
Summary of Current

- Inspection Records from past 2 years
- Fees for re-inspection, recalls, and labeling
- Mandatory Recalls
- Smuggled Foods Clause
- Database for Foreign Facilities (On going)
- Accreditation for Foreign Facilities (Now-1 yr)
Summary of Upcoming

• Rule for Detention Foods (Dec. 2011)
• January 2012
  – Food Safety Plan Required
  – Definition of High Risk Foods
  – Dietary Ingredients Guidance
  – Imported Food Shipment Refusal
January 2012

1. Sec. 105 Standards for produce safety
2. Sec. 106 Protection against intentional adulteration
3. Sec. 204 Enhancing tracking and tracing of food and recordkeeping (tomato and complex food trials will begin)
July 2012

1. Sec. 103 Hazard analysis and risk-based preventive controls
2. Sec. 106 Protection against intentional adulteration
3. Sec. 302 Voluntary qualified importer program
4. Sec. 306 Foreign offices of the FDA
January 2013

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2. Sec. 204 Enhancing tracking and tracing of food and recordkeeping
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4. Sec. 306 Inspection of foreign food facilities
5. Sec. 308 Foreign offices of the FDA
Fees Summary

- Effective October 1st, 2011
- Bills administered after January 1st, 2011
- Domestic facilities and U.S. Agents of the foreign facilities
- Fees: $224 per hour domestic/$325 per hour if foreign
- Re-inspection and Recall Activities
- Estimated at $40,000 for re-inspection
Food Safety Plan

• Based on prevention of biological, physical, chemical and allergen contamination
• Companies must evaluate known and reasonably foreseeable hazards
• Specific SCIENCE and RISK-BASED prevention methods, monitoring, and record keeping
• Key words: Traceability, description, procedures, verification, assurance
Open Dockets for Comment

- Preventive Controls for Registered Human Food and Animal Food/Feed Facilities - Dec. 20th
- What You Need to Know About Administrative Detention of Foods - Anytime
- Implementation of the Fee Provisions of the FDA Food Safety Modernization Act - Anytime
- Fish and Fishery Products Hazards and Controls Guidance - Anytime
QUESTION AND ANSWER PERIOD
Survey of Knowledge Gained

• Check your email a Survey will be sent Friday afternoon
• Voluntary Survey
• All provided personal information will be separated from results
• Survey will take about 5 minutes
• Please provide feedback as well as suggestions for future seminar/webinar topics in area of Food Safety
Contact Information

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