FSMA's Update: Proposed

Preventive Controls, Foreign Supplier Verification & Third Party Certification

Allen Sayler, Vice President,

Center for Food Safety & Regulatory Solutions, (*CFSRS*)

Woodbridge, Virginia

asayler@cfsrs.com 202-841-1029

CFSRS
Improving Food Safety

2013 CFSRS Webinar Schedule

1.Food Safety Modernization Act (FSMA):

Nov. 18th 5:30 pm EST; Dec. 2nd @ 4:30 pm EST

2.What to Do When FDA Knocks On Your Door:

Nov. 18th 2:30 pm EST; Dec. 2nd @ 7:00 pm EST

Others: Dec. 2013, Jan – March 2014

- **Advanced & Practical Food Defense Strategies Series**
- **Crisis Communication "Best Practices":**
- **Dairy Plant Compliance with the Pasteurized Milk Ordinance**
- **Environmental Monitoring FSMA-Based "Best Practices"**
- **Pasteurization (5-Log Reduction) Technology for Fluid Processors, Common Microbiological Hazards in Foods**
- **Enterprise Management Solutions (EMS) for Food Processing Plants**

2013 CFSRS Workshop Schedule

1. **Food Safety Modernization Act (FSMA)**

Nov. 18th, (Monday), 1-5 pm CST, Kansas City, MO

Dec. 2nd (Monday), 1-5 pm PST City of Industry, CA

2. **CFSRS Advanced HACCP Implementation Workshop**

Nov. 19th – 20th (Tuesday – Wednesday), Kansas City, MO

Dec. 3rd – 4th (Tuesday – Wednesday) City of Industry, CA

3. **Implementing SQF 7.1 Systems Workshop**

Nov. 21st – 22nd (Thursday – Friday), Kansas City, MO

Dec. 5th – 6th (Thursday – Friday) City of Industry, CA

2011 Food Safety Modernization Act

Foundation FSMA Regulations

1. **Human Food preventive controls**
2. **Animal Feed preventative controls**
3. **Foreign Supplier Verification Proposed Rule –** importer accountability program to ensure imported foods are produced under the same standards/level of protection, as our new preventative control of produce standards.
4. **Accredited Third Party Certification of Foreign Suppliers.**
5. **Traceability**
6. **Safe Food Transport rules**
7. **Intentional Adulteration provision (Food Defense)**

CFSRS
Improving Food Safety, One Plant at a Time

Table 2. –The Effect of Activities on RACs That Are Foods

Activities That Change a RAC into a Processed Food	Activities That Do Not Change the Status of a RAC
Canning	Application of pesticides (including by washing, waxing, fumigation, or packing)
Chopping	Coloring
Cooking	Drying for the purpose of storage or transportation
Cutting	Hydro-cooling
Drying that creates a distinct commodity	Otherwise treating fruits in their unpeeled natural form
Freezing	Packing
Grinding	Refrigeration
Homogenization	Removal of leaves, stems, and husks
Irradiation	Shelling of nuts
Milling	Washing
Pasteurization	Waxing
Peeling	Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant
Slaughtering animals for food and activities done to carcasses post-slaughter, including skinning, eviscerating, and quartering	
Slicing	
Activities that alter the general state of the commodity	

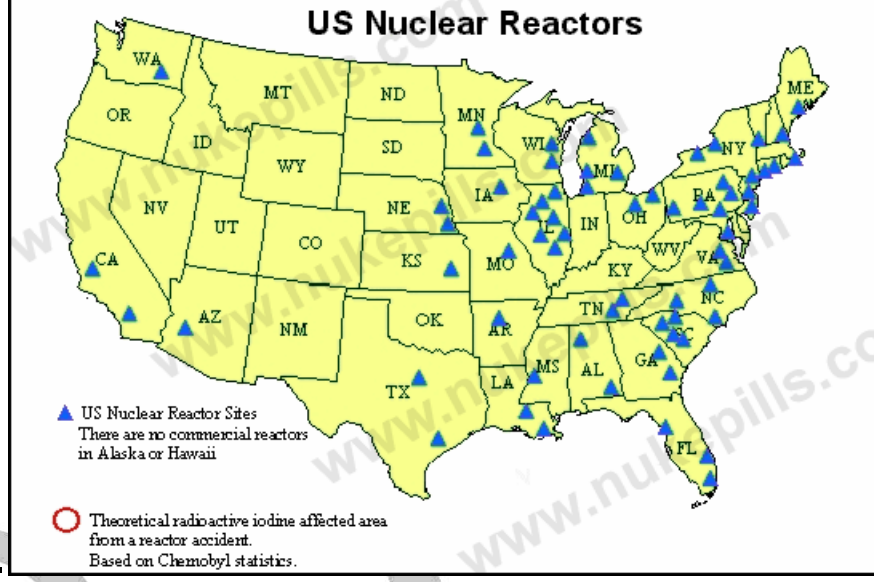
Suspension of Registration:

Section 415(b) of the FD&C Act, amended by FSMA, allows FDA to suspend the registration of a food facility if FDA determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

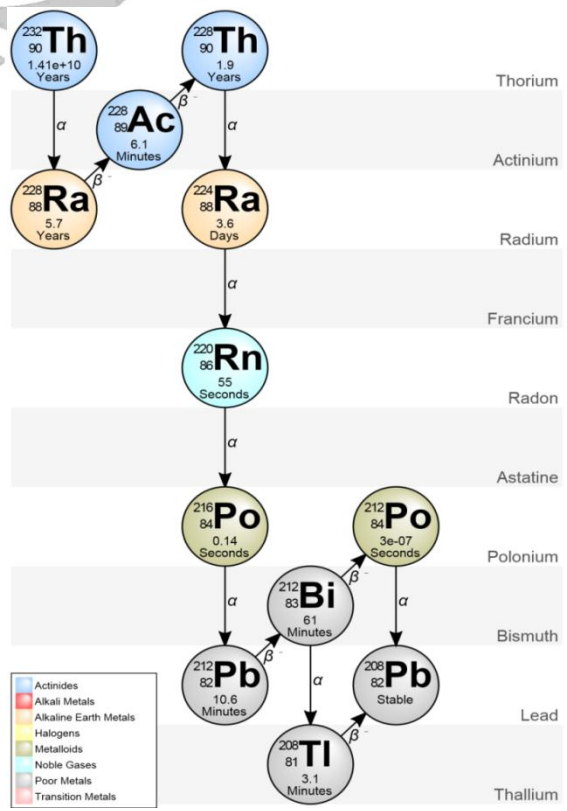
1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

CFSRS
Improving Food Safety, One Plant at a Time

Sources of Radiological Hazards



- Luminous watches and clocks contain Tritium or Promethium-147
- Releases from Nuclear Power Plants
- Radiological dyes from medical procedures
- Natural Radon gas usually found in poorly ventilated below-ground rooms and storage areas



FSMA Required "**Preventive Controls**"

a. **Supplier Management**
b. Allergen Control Program
c. **GMP Program as defined in 21 CFR 110 (117)**
d. Product Traceability/Recall
e. Recall Plan
f. Food Defense
g. Employee Training (GMPs, HACCP, sanitation, allergens, environmental monitoring, food defense, food regulations, chemical use)
h. **Processing Equipment Cleaning & Sanitizing**

All Preventive Controls listed above must be monitored, verified and have corrective action documentation.

CFSRS
Improving Food Safety, One Plant at a Time

FSMA Required "**Performance Controls**

I. **Finished Product Testing –** FDA is requested additional comments

J. **Environmental Monitoring Program –** as part of a plant's verification program that could include finished product testing and a consumer complaint program. No specific testing requirements – FDA requesting additional comments.

K. **Warehouse Exemptions –** none for refrigerated products, but will require temp. controls, monitoring records and verification of monitoring records.

L. **Food Safety Plan** must be signed and dated by the owner, operator or person in charge of the plant initially and after any modification.

FSMA "RECOUPMENT "FEES

Fees – limited to $20 million annually for recall expenses and $25 million for re-inspection related fees

a. No Registration or civil penalty fees

b. Re-inspections & Recalls
- **$237 starting Oct.1, 2013** if no foreign travel is required
- **$302 starting Oct.1, 2013** if foreign travel is required

(Note: fees not being charged for foreign food suppliers)

c. Other Fees – not yet established by FDA
- Export Certificate processing fee
- Import "Fast Lane" fee

IMPORTANT: FDA does not intend to issue any invoices for re-inspection or recall order fees until it has published a guidance document to outline the process through which small businesses may request a reduction of fees.

CFSRS
Improving Food Safety, One Plant at a Time

FDA Administrative Detention Regulation

FDA needs to demonstrate "**credible evidence or information indicating [that the article of food] presents a threat of serious adverse health consequences or death**" or "**reason to believe** [that the article of food] is adulterated or misbranded

- Decision can be made by lower level "qualified" employee of FDA.
- Detention order effective for **up to 30 days**
- Detention order must be issued "in writing", in the form of a detention notice, signed and dated by "qualified" employee of FDA.
- A detention order can be **appealed by any person who would be entitled to be a claimant** of the held product, but a notice of intent to file an appeal and request a hearing must be filed within 4 days for non-perishable foods, and within 2 days for perishable. The actual appeal, with or without a hearing request, must then be submitted with 10 days of receipt of the detention order.

Records Protected under FSMA

- Records from farms
- Records from restaurants
- Recipes, as defined in 21 CFR 1.328 - A “recipe" is the formula, including ingredients, quantities, and instructions necessary to manufacture a food. Because a recipe must have all three elements, a list of the ingredients used to manufacture a food, without quantity information and manufacturing instructions, is not a recipe.
- Financial data
- Pricing data
- Personnel data
- Research data
- Sales data other than shipment data regarding sales

CFSRS
Improving Food Safety, One Plant at a Time

FSMA – Traceability

IFT Report on "Pilot Projects for Improving Product Tracing Along the Food Supply System" Released on mid-March 2013 with 10 recommendations:

1. **FDA should require firms that manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain records of critical tracking events (CTEs) and key data elements (KDEs) as determined by FDA.**
2. **FDA should develop standardized electronic mechanisms for the reporting and acquiring of CTEs and KDEs during product tracing investigations.**
3. **FDA should accept summarized CTE and KDE data that are submitted through standardized reporting mechanisms and initiate investigations based on such data.**

CFSRS
Improving Food Safety, One Plant at a Time

FSMA Updated Timeline

- **Ninth Circuit Court of Appeals - denied a motion by FDA to delay issuing a draft FSMA rules - However, in light of the 'government shutdown "... publish a notice of proposed intentional adulteration rule by December 20, 2013 ..."**

- **Previously ordered FDA to "... publish all proposed regulations in the Federal Register no later than November 30, 2013, with the comment period to close no later than March 31, 2014**
  - **Sanitary transport - published in Federal Register no later than January 31, 2014, with the comment period to close no later than May 31, 2014**
  - **All final regulations in the Federal Register no later than June 30, 2015 ..."**

21 CFR 110 vs 117

21 CFR 110 – Current Food Good Manufacturing Practices (cGMPs)	21 CFR 117 – Proposed Food Good Manufacturing Practices (pGMPs)
	117.1 Applicability and status.
110.3 - Definitions.	117.3 Definitions.
110.5 - Current good manufacturing practice.	117.5 Exemptions.
110.10 - Personnel.	117.10 Personnel.
110.19 - Exclusions.	
110.20 - Plant and grounds.	117.20 Plant and grounds.
110.35 - Sanitary operations.	117.35 Sanitary operations.
110.37 - Sanitary facilities and controls.	117.37 Sanitary facilities and controls.
110.40 - Equipment and utensils.	117.40 Equipment and utensils.
110.80 - Processes and controls.	117.80 Processes and controls.
110.93 - Warehousing and distribution.	117.93 Warehousing and distribution.
110.110 - Natural or unavoidable defects in food for human use that present no health hazard	117.110 Defect Action Levels
	Subpart C—Hazard Analysis and Risk-Based Preventive Controls
	117.126 Requirement for a food safety plan.
	117.130 Hazard analysis.
	117.135 Preventive controls for hazards that are reasonably likely to occur.
	117.137 Recall plan for food with a hazard that is reasonably likely to occur.
	117.140 Monitoring.
	117.145 Corrective actions.
	117.150 Verification.

Processing Equipment Requirements

Sanitation controls: Where necessary to significantly minimize or prevent hazards that are reasonably likely to occur (including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard) sanitation controls must include procedures for the:

- (A) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;
- (B) Prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

CFSRS
Improving Food Safety, One Plant at a Time

Validation of Processing Equipment FSMA Base Requirements

21 CFR 117.110 (a) Validation: The owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

(1) Must be performed by (or overseen by) a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur.

CFSRS
Improving Food Safety, One Plant at a Time

Validation of Processing Equipment Details

1. Upon installation: Commissioning Documentation
   a. Construction as per 3-A, USDA Plant Survey Program, NSF, etc.
   b. Proper Installation
   c. Routine Maintenance Schedule including lubrication
   d. Cleaning & Sanitizing Protocol
   e. Conformance to In-Process and Finished Product Processing Specs.
2. Periodic Re-Validation – Part of PM Documentation
   a. Routine Maintenance Schedule including lubrication
   b. Cleaning & Sanitizing Protocol
   c. Conformance to In-Process and Finished Product Processing Specs.

CFSRS
Improving Food Safety, One Plant at a Time

Food Safety Preventive Controls Alliance (FSPCA)

The alliance will:

- develop standardized hazard analysis and preventive controls training and distance education modules for industry & reg. personnel;
- design and deliver a state-of-the-art distance learning training portal at the IIT IFSH Moffett Campus in Bedford Park, Ill.;
- develop “train-the-trainer” materials
- create a technical assistance network for small- and medium-sized food companies;
- develop commodity/industry sector-specific guidelines for preventive controls;
- assess knowledge gaps and research needs for further enhancement of preventive control measures; and
- identify and prioritize the need for and compile critical limits for widely used preventive controls.

FSMA – Imported Food

- **Section 301 – Foreign Supplier Verification Program – FDA published proposed rule on July 29, 2013 – comments closes on Nov. 26, 2013**
- Section 302 – Voluntary Qualified Importer Program – "Green Light Program"
- Section 303 – Import Certifications of Food
- Section 304 – Prior notice of imports
- Section 306 – Inspection of Foreign Food Facilities
- **Section 307 – Accreditation of Third-Party Auditors - FDA published proposed rule on July 29, 2013 – comments closes on Nov. 26, 2013**

Both regulations will become enforceable by FDA 60 days after publication of the final regulation

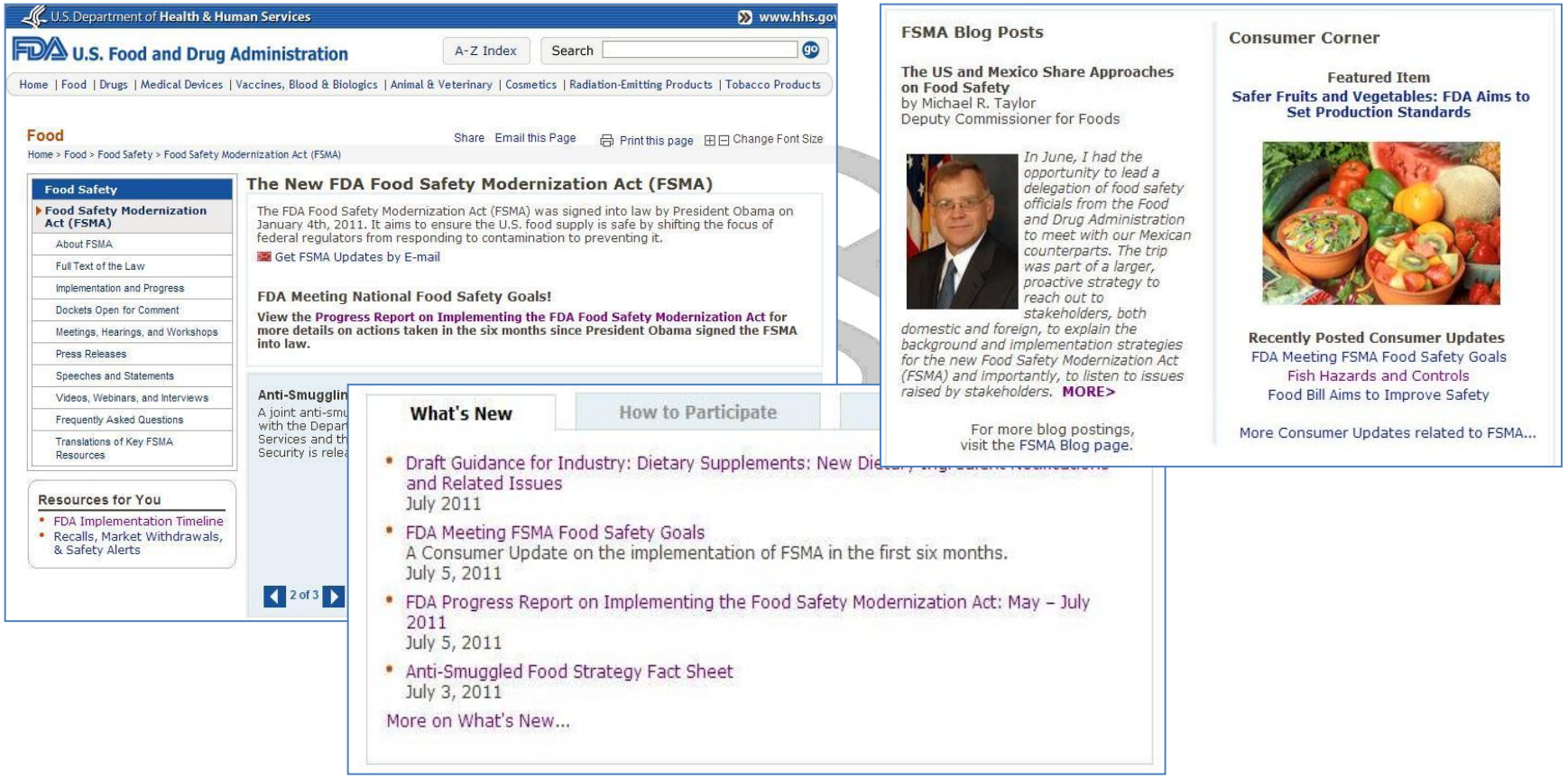
CFSRS
Improving Food Safety, One Plant at a Time

Expected FDA FSMA Safe Transport of Food Requirements

1. Temperature control
2. Sanitation
3. Loading & Unloading
4. Segregation & Prior Cargo
5. Training of transport staff
6. Recordkeeping

CFSRS
Improving Food Safety, One Plant at a Time

Snapshot of FSMA homepage elements at: http://www.fda.gov/fsma



CFSRS
Improving Food Safety, One Plant at a Time

Thank You!

asayler@

CFSRS.org

Who Has the First Question ?