

FSMA UPDATE: 3-A EQUIPMENT IN YOUR PREVENTIVE CONTROL PLAN

3-A Sanitary Standards Inc. Educational Session

Clarion Hotel, Milwaukee, WI

May 13, 2014

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3-A Sanitary Standards, Inc.



3-A SSI is an independent, not-for-profit corporation dedicated to advancing hygienic equipment design for the food, beverage, and pharmaceutical industries. We represent the interests of three stakeholder groups with a common commitment to promoting food safety and the public health — regulatory sanitarians, equipment fabricators and processors.

Online registration for the 2013 Annual Meeting is now closed.
On-site registration begins May 20 at 2:00 pm.

Featured Video

More Than Just a Symbol

This is a great introduction to the 3-A Sanitary Standards organization and the 3-A Symbol licensing program.

See other videos in our Video Resources

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3-A Sanitary Design Connections

2nd Quarter 2013
Industry Needs 3-A: Let's Respond
1st Quarter 2013
FSMA and 3-A Hygienic Design Criteria
Voluntary Consensus Standards Serve Critical Role

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See information about 3-A SSI's 2013 Annual Meeting

Allen R. Sayler
Managing Partner, Center for Food Safety & Regulatory Solutions (CFSRS)

- 30 years serving the US Food Industry as government regulator & industry advocate
- 12 years w/International Dairy Foods Association (IDFA) serving as Advanced HACCP, SQF and food safety trainer, providing solutions to the US Dairy processing industry
- 16 years combined with FDA, USDA and state dairy regulatory agencies as inspector, standardizing officer & drafter of new state, NCIMS & FDA regulations
- Certified HACCP & SQF Trainer
- Experienced SQF & BRC Consultant
- 2009 IAFP Harold Barnum Award Winner
- Task Force Chair & Board Member – Dairy Practices Council

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2014 CFSRS Webinar Schedule

(see www.cfsrs.com for current list, & dates):

1. FSMA Preventive Controls, FSV, TPC & Intentional Contamination Update
2. Rights & Responsibilities During an FDA Investigation
3. Crisis Management & Test Scenarios
4. Food Defense Strategies Addressing FSMA's Intentional Contamination
5. Characteristics & Management of Food Pathogens – Latest Updates
6. SQF Practical Implementation Strategies
7. Surviving SQF Audits: Perspectives from an SQF Auditor
8. Overview of Changes: 2013 Grade A Pasteurization Milk Ordinance
9. Internal Auditing of Food Processing Plants
10. Rapid Detection Technology: ATP and Drug Residues
11. Pasteurization Technology for Fluid Processors
12. Food Processing Instrumentation: Improving Control, Data and Cost Management
13. Enterprise Management Solutions for Food Processing Plants

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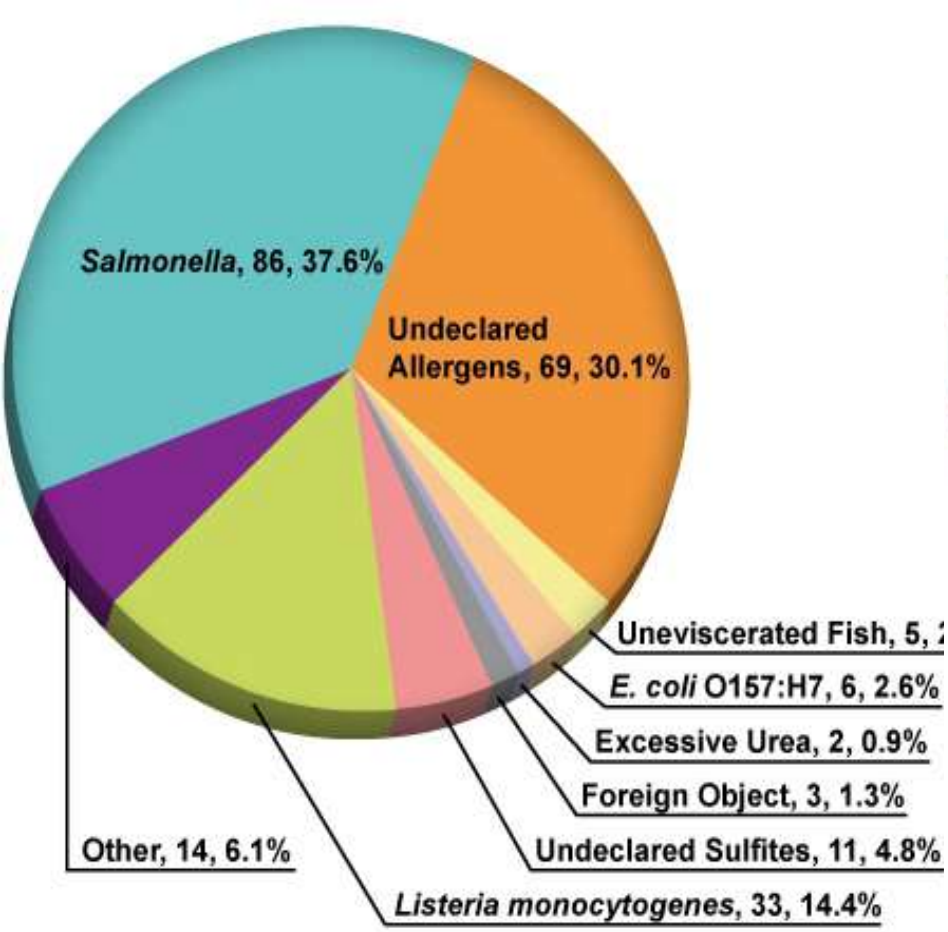
2014 CFSRS Workshop Schedule

- **June 26th – 30th near Wash. Dulles Airport: ½-day FSMA Update, 2-day Advanced HACCP/HARPC & 2-Day SQF 7.2**
- **July 14th – 18th in Rosemont, IL: ½-day FSMA Update, 2-day Advanced HACCP/HARPC & 2-Day SQF 7.2**
- **Oct. 13th – 17th in Las Vegas, NV: ½-day FSMA Update, 2-day Advanced HACCP/HARPC & 2-Day SQF 7.2**

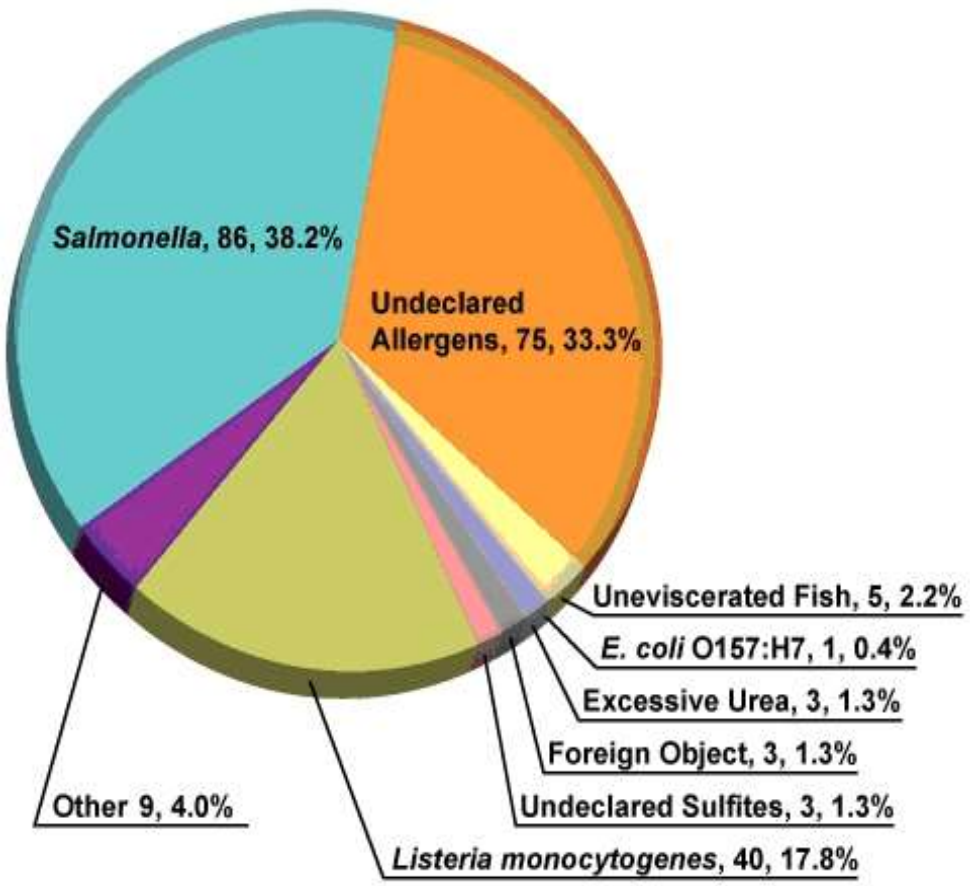
Other Workshops Will be Added in mid-2014

FDA Reportable Food Registry Statistics

Commodities	2010	2011	2012	2013
Bakery	16	20	18	22
Beverages	3	2	1	1
Dairy	18	16	20	10
Dressings/Sauces/Gravies	6	8	5	6
Egg	2	2	2	0
Frozen Foods	9	11	3	10
Fruit/Vegetable Products	12	9	5	3
Nuts/Nut Products/Seeds	16	16	13	15
Oil/Margarine	1	0	0	0
Produce - Fresh Cut	13	9	23	13
Produce – RAC	14	27	33	10
Seafood	17	18	17	19
Spices and Seasonings	17	25	8	12
Total	229	225	224	202

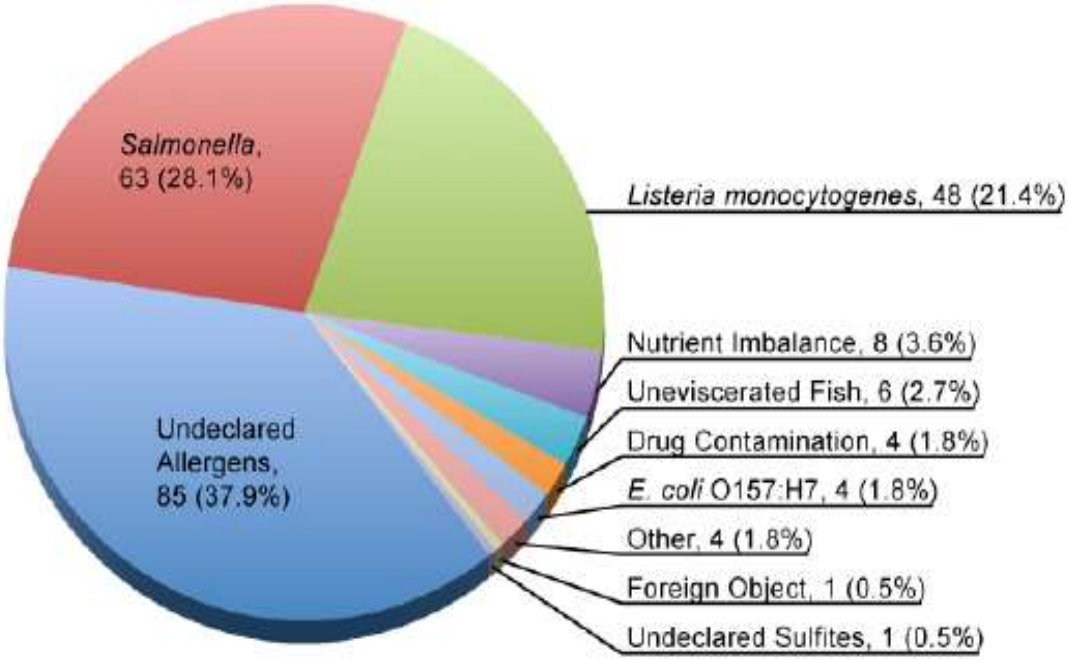


FY 2010 - Distribution of 229 Primary RFR Entries by Food Safety Hazard

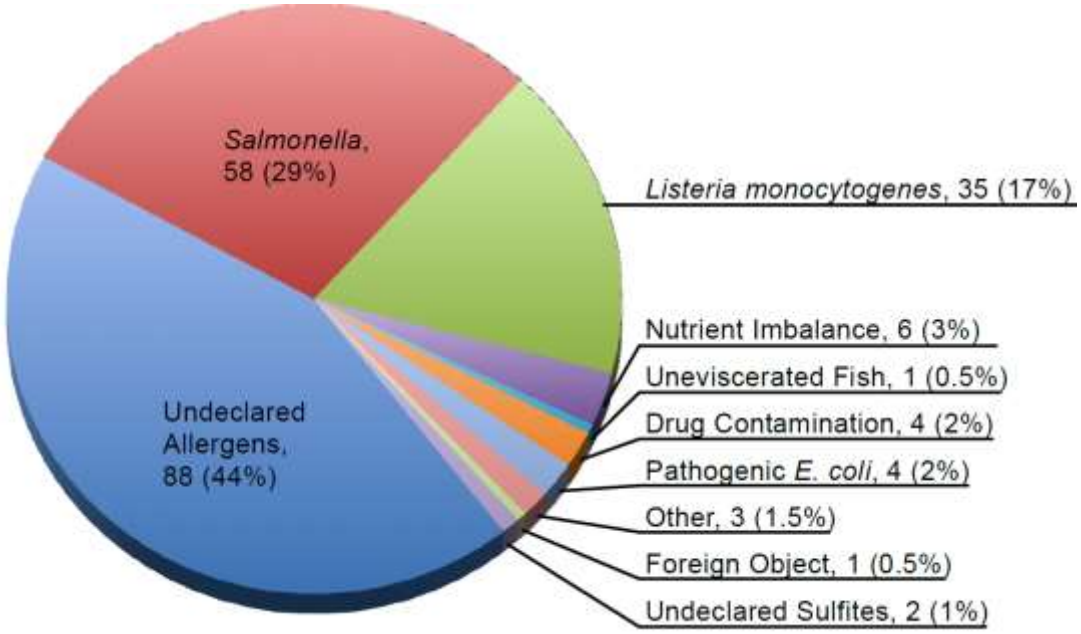


FY 2011 - Distribution of 225 Primary RFR Entries by Food Safety Hazard

Infant Formula & Dietary Supplements Excluded from Reporting



FY 2012 – Distribution of 224 Primary RFR Entries by Food Safety Hazard



FY 2013 - Distribution of 202 Primary RFR Entries by Food Safety Hazard

Infant Formula & Dietary Supplements Excluded from Reporting

A PERIODIC TABLE OF DAIRY FOODS AND BEVERAGES

M Whole Milk	**Fm** Flavored milk								**I** Ice cream
Mlo Reduced -fat Milk	**Eg** Egg Nog								**Im** Ice milk
Ms Skim Milk	**Cf** Coffee beverage								**G** Gelato
Cr Cream	**Sm** Smoothie	**B** Butter	**Bm** Buttermilk	**K** Kefir					**Ku** Kulfi
Clc Clotted Cream	**Mpr** Probiotic Milk		**Yo** Cup-set Yogurt	**Bb** Butter blend	**C** Natural Cheese	**Cf** Fresh white cheese	**Br** Brined Cheese		**Cu** Frozen custard
Hh Half-and-Half	**Mlf** Lactose-free Milk		**YoS** Swiss-style Yogurt	**Sc** Sour Cream	**Pc** Processed cheese	**Cw** Whey cheese	**Blu** Blue-veined Cheese		**Dd** Frozen Dairy Dessert
Wc Aerosol whipped cream	**Ma** Acidophilus Milk		**Gyo** Greek Yogurt	**Cc** Cottage cheese	**Cpa** Cold Pack Cheese	**Cso** Soft cheese	**Chd** Cheddar-style Cheese		**Sh** Sherbet
Me Evaporated Milk	**Fo** Infant Formula		**Yd** Drinkable Yogurt	**Crc** Cream cheese	**Crd** Cheese Curd	**Cs** Semi-hard cheese	**CH** Eyed Cheese		**Fryo** Frozen Yogurt
Mc Condensed Milk	**Mr** Meal Replacement		**Ypr** Probiotic Yogurt	**Di** Dairy Dip	**Str** String Cheese	**Ch** Hard Cheese	**Cm** Molded Cheese		**Nv** Novelties

Source: Dairy Foods Magazine Website

DAIRY INGREDIENTS

Wmp Whole Milk Powder	**Smp** Skim Milk Powder	**Wh** Sweet Whey	**Wpc** Whey Protein Concentrate/ Isolate	**Wd** Dry whey	**Wp** Whey permeate
Mw Milk Derived Whey	**An** Anhydrous Milkfat/ butter oil	**Ca** Micellar Casein	**Mpc** Milk Protein Concentrate/Isolate	**Al** Milk Albumin	**La** Lactose

FDA Reportable Food Registry – Dairy

	E. coli O157:H7	List. Mono.	Salmonella	Staph. aureus	Foreign Object	Allergens /Intoler-ances	Other (including chemical)	Total
RFR FY10	1	8	1	0	0	8	0	18
Dairy %	5.6%	44.4%	5.6%	0%	0%	44.4%	0%	100%
All Food %	2.6%	14.4%	37.6%	0%	1.3%	30.1%	14.0%	100%
RFR FY11	0	7	3	0	0	6	0	16
Dairy %	0%	43.8%	18.8%	0%	0%	33.3%	0%	100%
All Foods	0.4%	17.8%	38.2%	0%	1.3%	33.3%	9.0%	100%
RFR FY12	0	11	2	0	0	7	0	20
Dairy %	0%	55%	10%	0%	0%	35%	0%	100%
All Foods	1.8%	21.4%	28.1%	0%	0.5%	37.9%	10.3%	100%
RFR FY13	1	4	0	0	0	5	0	18
Dairy %	0.5%	1.99%	0%	0%	0%	2.48%	0%	100%
All Foods	2.0%	17.3%	28.7%	0%	0.5%	43.6%	1.495	100%

Food Safety Modernization Act (FSMA) PL 111-353, 124 Stat. 3885

- Enacted January 4, 2011
- Sweeping new enforcement authority for FDA
- Self-enacting provisions and FDA deadlines on issuing regulations
- Lack of targeted funding
- FDA Structure for Enforcement

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Seven (7) Foundation FSMA Rules

1. Human Food preventive controls
2. Animal Feed preventative controls
3. Produce rules – will set standards for farm growing practices
4. 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.
5. Accredited Third Party Certification of Foreign Suppliers.
6. Safe Food Transport rules
7. Intentional Adulteration provision

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FDA's Most Recent Timeline

FSMA Regulation	Comment Period Closure	Final Publica-tion	Effec-tive Date	Industry Compliance Date(s)
Preventive Controls for Human Food - Current GMPs	11/22/33	No later than 8/30/15	60 days after publication of final rule	Very Small Businesses - 3 year after publication: 1. Less than $250,000, or 2. Less than $500,000, or 3. Less than $1,000,000 Small Business (fewer than 500 persons & does not qualify for exemption) - 2 years after publication All Other Businesses - 1 year after publication.
Current GMPs & Preventive Controls for Animal Food	3/31/14	No later than 8/30/15		Very Small Businesses - 3 years after the publication Option 1 less than $500,000 in total annual sales of animal food Option 2 less than $1 million in total annual sales of animal food; or Option 3 less than $2.5 million in total annual sales of animal food. Small Businesses - fewer than 500 persons - 2 years after publication. All Other Businesses - 1 year after the publication.

FDA's Most Recent Timeline

FSMA Regulation	Comment Period Closure	Final Publication	Effective Date	Industry Compliance Date(s)
Intentional Adulteration (Food Defense)	3/30/14	No later than 5/31/16	60 days after publication of final rule	Very Small Businesses - less than $10,000,000 in total annual sales of food - 3 years after the publication. Small Businesses - fewer than 500 persons - 2 years after the publication. All Other Businesses - 1 year after the publication.
Sanitary Transportation of Human & Animal Food	5/31/14	No later than 5/31/16		Small Businesses - employs fewer than 500 persons and motor carriers having less than $25.5 million in annual receipts - 2 years after the publication. All Other Business - 1 year after the publication.

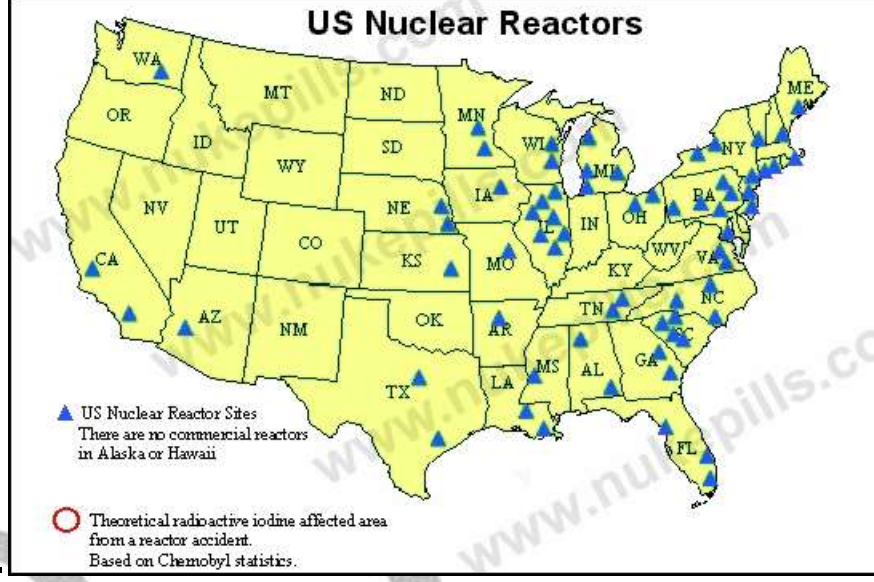
FDA's Most Recent Timeline

FSMA Regulation	Comment Period Closure	Final Publica-tion	Effec-tive Date	Industry Compliance Date(s)
Draft Methodological Approach to Identifying High-Risk Foods under Section 204(d)(2) of the FSMA	4/ 7/14	??????? ???????	Immediately after publication	

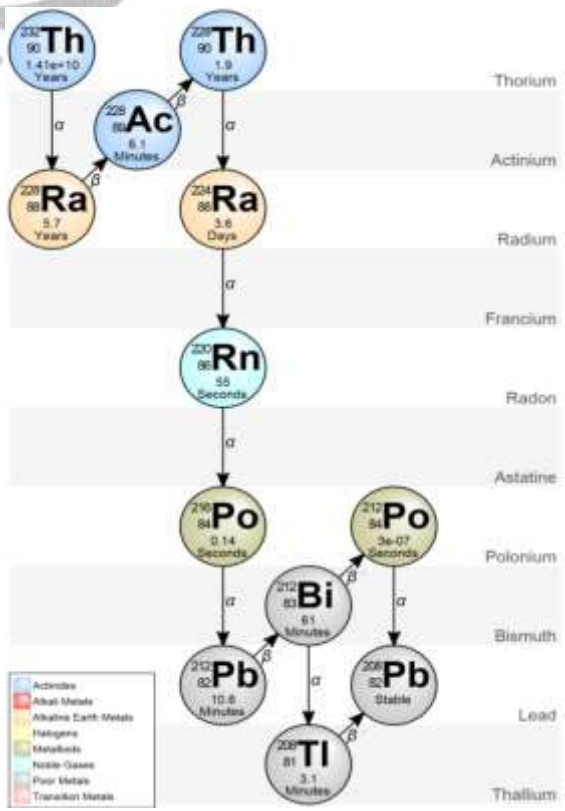
FDA's Most Recent Timeline

FSMA Regulation	Comment Period Closure	Final Publication	Effective Date	Industry Compliance Date(s)
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals	1/27/14	No later than 10/31/15	60 days after publication of final rule	The importer would have to comply 6 months after the domestic compliance date for the Preventive Controls Regulations
Accreditation of Third-Party Auditors	1/27/14	No later than 10/31/15	The FDA intends to implement the program at the earliest date possible after publication of the final rule and the final Model Accreditation Standards.	

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**" Processing Equipment Impacts

1. **Supplier Management**
2. **Allergen Control Program**
3. **Process Controls**
4. **GMP Program as defined in 21 CFR 110 (117)**
5. **Product Traceability**
6. **Recall Plan**
7. **Intentional Contamination – Food Defense**

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

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FSMA Required "**Preventive Controls**"

10. **Employee Training (GMPs, HACCP, sanitation, allergens, environmental monitoring, food defense, food regulations, chemical use)**
11. **Validation of**
    a. **Processing Equipment Cleaningent Cleaning & Sanitizing**
    b. **Pathogen Reduction Method**
12. **Processing & Laboratory Equipment Calibration**
13. **Review of Records**

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

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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

What about equipment records?

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Preventive Measure – FDA Requesting Comments

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. **Consumer Complaints**

21 CFR 117 to replace 21 CFR 110 in approximately 3 years

- "Shall" replaced with "Must"
- "Should" removed or use minimized.
- FDA plans to provide written guidance on all "should" items in 117.

They are "umbrella" rules to help prevent food safety defects

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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.

New food GMP Terms (pages 256 – 257)

Qualified individual

- Person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.
- Must directly supervise or prepare the plant's food safety plan

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.

New food GMP Terms (pages 256 – 257)

Reasonably Foreseeable Hazard

- Potential biological, chemical, physical, or radiological hazard that may be associated with the facility or the food.

New food GMP Terms (pages 256 – 257)

Preventive Controls

Those 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 hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

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.

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21 CFR 117.40 Equipment

(a)(1) All plant equipment and utensils must be so designed and of such material and workmanship as to be adequately cleanable, and must be properly maintained.

(2) The design, construction, and use of equipment and utensils must preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

21 CFR 117.40 Equipment

(a)(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents.

(6) Food-contact surfaces must be maintained to protect food from cross-contact and being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and cross-contact.

(c) Equipment that is in the manufacturing or food-handling area and that does not come contact with food must be so constructed that it can be kept in a clean condition.

21 CFR 117.40 Equipment

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

21 CFR 117.40 Equipment

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

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.

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New GMP Additions (21 CFR 117) (pages 563 – 617)

1. Emphasize protection against cross-contamination
2. Require employee training program particularly for staff responsible for identifying sanitation failures or food contamination incidents
3. On-site waste treatment & disposal systems to not contaminate food, packaging or ingredients
4. Protection for ingredients or in-process product stored in outside vessels
5. Adequate lighting, ventilation, & screening against entry of pests
6. Limitation of types of chemicals that can be stored in food processing plant

New GMP Additions (21 CFR 117) (pages 563 – 617)

7. Food packaging receiving, storage, handling and use addressed
8. Compressed air & gases must be addressed by preventative controls
9. Work-in-progress & rework protections required
10. Written food safety plan requirements
11. Written Preventative Controls program including food allergens, sanitation controls, recall plan, corrective action procedures, verification and validation plans,
12. Responsibilities of “qualified individual” (p.603)
13. Minimum categories of records (p 604 & 616 – 617))
14. Qualified facility exemptions (p. 606 – 615)

FDA Regulations on Food Transport

Sec. 111. Sanitary Transportation of Food

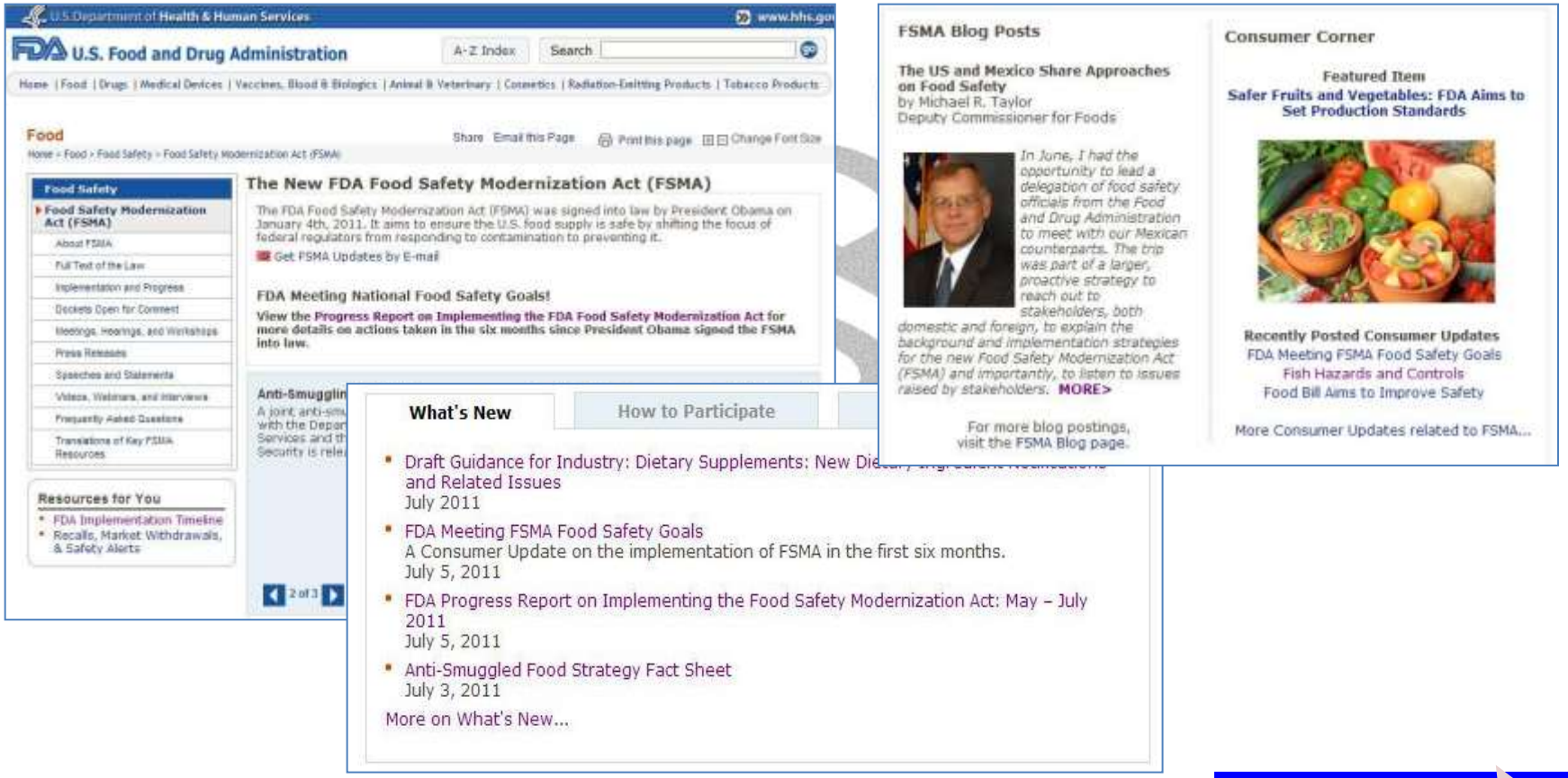
1. Temperature control
2. Sanitation
3. Loading & Unloading
4. Segregation & Prior Cargo
5. Training of transport staff
6. Recordkeeping

U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

FDA Regional & District Offices

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



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