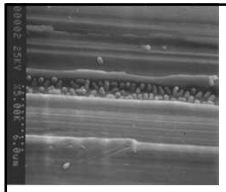


Allen Sayler
Managing Partner
Center for Food Safety &
Regulatory Solutions

The 3-A Advantage in Preventive Controls

How does 3-A design criteria and sanitary standards oversight benefit processors and consumers?

3-A SSI 2013 Education Program,
May 21, 2013
Clarion Hotel, Milwaukee, WI

CFSRS
Improving Food Safety
One Plant at a Time

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

Background:

- 30 years serving the US Dairy Industry as government regulator & industry advocate
- 12 years w/International Dairy Foods Association (IDFA) serving as primary HACCP, SQF and food safety trainer, advocating industry views with FDA, USDA and state dairy regulatory agencies and writing industry position papers
- Certified HACCP Trainer
- Experienced SQF & BRC Trainer & Consultant
- 2009 IAFP Harold Barnum Award Winner

Education:

BSc Biology & Human Physiology, University of Mary
Additional Course Work in Civil Engineering

2013 CFSRS Webinar Schedule

1.Food Safety Modernization Act (FSMA):
- **June 17th @ 1:30 pm (EDT)**
- **Sept. 9th @ 2:30 (EDT)**
- **Dec. 2nd @ 2:30 pm EST**

2.What to Do When FDA Knocks On Your Door:
- **June 17th @ 4:00 pm EDT**
- **Sept. 9th @ 5:00 pm EDT**
- **Dec. 2nd @ 5:00 pm EST**

3.Advanced & Practical Food Defense Strategies Series: July 2013

4.Crisis Communication "Best Practices": TBD

CFSRS
Improving Food Safety
One Plant at a Time

2013 CFSRS Workshop Schedule

1. Food Safety Modernization Act (FSMA)
June 17th (Monday) 1-5 pm EDT Greensboro, NC,
Sept. 9th (Monday) 1–5 pm CDT Springfield, MO,
Dec. 2nd (Monday), 1-5 pm CST Houston, TX

2. CFSRS Advanced HACCP Implementation Workshop
June 18th – 19th Greensboro, NC;
Sept. 10th – 11th Springfield, MO; Dec. 3rd – 4th Houston, TX

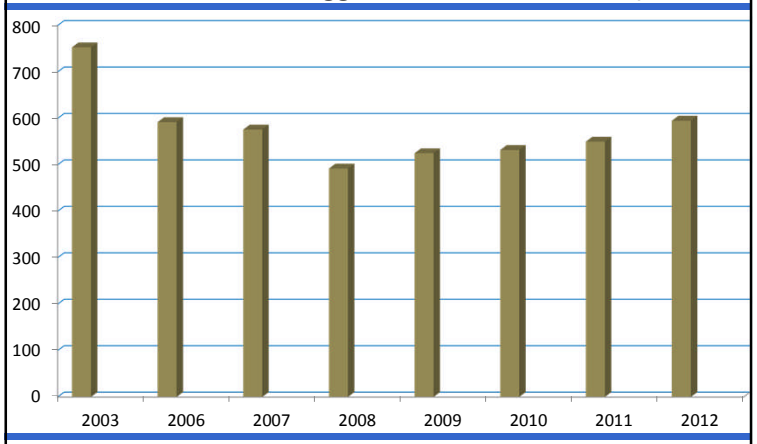
3. Implementing SQF 2000 Systems Workshop
June 20th – 21th Greensboro, NC;
Sept. 12th – 13th Springfield, MO; Dec. 5th – 6th Houston, TX

DISCLAIMER as a 21 Year Resident of the Washington, DC Area

This Presentation does contain any information on:

- IRS “Tea Party” Scandal
- Benghazi Attack on US Embassy
- Raid of the AP News Offices
- Sequestering Impact on the US Dairy Industry
- Solutions to the US Federal Government Budget Deficit
- Immigration Reform

3-A Symbol Holders (71 Dairy Standards, 10 Dairy Practices, 2 Egg & 3 Pharma Standards)



European Hygienic Engineering & Design Group (EHEDG)

- Consortium of equipment manufacturers, food industries, research institutes as well as public health authorities and was founded in 1989 with the aim to promote hygiene during the processing and packing of food products.
- Principal goal of EHEDG is the promotion of safe food by improving hygienic engineering and design in all aspects of food manufacture.
- EHEDG is recognized by EU legislation, particularly related to the use of hygienically-designed equipment for the handling, preparation processing and packaging of food (EC Directive 2006/42/EC for Machinery, EN 1672-2 and EN ISO 14159 Hygiene requirement).

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U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) Equipment Review Process

- Developed requirements for dairy processing equipment for those dairy companies that intended to sell dairy products for U.S. government purchase.
- Heavy emphasis on conformance to 3-A Sanitary Standards for equipment design but does not require a 3-A Symbol.
- If the routine inspection reveals deficiencies with materials, design, fabrication, or workmanship, which appear to violate the applicable 3-A Sanitary Standards, USDA will request the fabricator to make appropriate modifications & notify 3-A

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American Meat Institute's (AMI's) "Principles of Sanitary Design" (PDF)

- Provide some direction on recommendations for meat processing equipment.
- In addition, AMI's "Equipment Sanitary Design Checklist" (PDF) has more specific details particularly related to acceptable materials, finishes, joints, seals, etc.

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Top 10 Food Safety "Problems": 1998 - 2003

6. **Difficult-to-clean equipment**
7. Post-process contamination (plant)
8. Contamination during processing
9. Poor employee hygiene
10. Incorrect labelling or packaging

Comparison of Regulations			
	US	EU	ASEAN
Introduction	X	X	X
Quality System	X	X	X
Personnel	X	X	X
Training	X	X	X
Premises	X	X	X
Equipment	X	X	X
Sanitation/Hygiene	X	X	X
Production/Manufacturing	X	X	X
Purchasing		X	
Quality Management		X	
Quality Control	X	X	X
Documentation	X	X	X

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

Food Plants Exempt from FSMA

a. Storage facilities for raw agricultural commodities
b. Seafood, juice beverages and low acid canned foods (micro only) covered under existing FDA regulations (
c. Dietary supplements - exempt from "preventative controls, but most of the remaining provisions of FSMA apply (Note: Probably of more impact to the dietary supplements industry is the New Dietary Ingredient Notifications and Related Information released by FDA in July 2011)
d. Alcohol-Related Facilities - covered by ATF
e. Storage of raw agricultural commodities – receiving & transfer stations that to not "process" the milk

Plant Registration

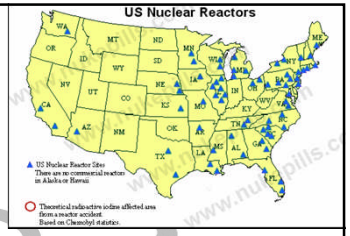
- Failure to register could result in FDA declaring facility is "suspended.
- Secretary of Health & Human Services only person authorized to suspect facility's registration
- FDA will conduct informal hearing and make determination
- Facility has 2 business days to appeal suspension in writing to FDA
- If FDA suspension notice upheld, facility cannot manufacture, process, package, receive or store food/feed and faces possibility of FDA detaining or seizing food/feed
- Registration fee ???

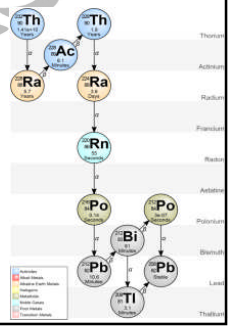
Major Provisions of Proposed Rule on Current GMPs & Hazard Analysis & Risk-Based Preventative Controls

- Written Food Safety Plan
- Hazard Analysis
- Preventative Controls for Hazards Reasonably Likely to Occur
- Monitoring Records to Prove Controls Effective
- Corrective Actions
- Verification
- Validate Controls
- Other Records

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 **"Performance Controls"**

a. Supplier Management

b. Environmental Monitoring Program – as part of a plant's verification program that could include finished product testing and a consumer complaint program.

c. Allergen Control Program

d. GMP Program as defined in 21 CFR 110

e. Product Traceability/Recall

f. Food Defense

g. Employee Training (GMPs, HACCP, sanitation, allergens, environmental monitoring, food defense, food regulations, chemical use)

h. Processing Equipment Cleaning & Sanitizing

FSMA Required **"Performance Controls**

i. Recall Plan

J. Finished Product Testing – FDA is requested additional comments

K. Environmental Monitoring Program – no specific testing requirements – FDA requesting additional comments.

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

M. 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
- **$221 starting Oct.1, 2012** if no foreign travel is required
- **$289 starting Oct.1, 2012** 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.

FSMA – Mandatory Recall Program

- Voluntary Option Available – Usually Class I & II. If industry disagrees with FDA will take action toward a mandatory recall including issuing public notice based on if food product presents a "**serious adverse health consequences or death**." Effective immediately and only authorized by FDA Commissioner.
- Industry responsible in an official recall to notify state regulatory agency, FDA District Recall Coordinator and file report on-line with FDA Reportable Food Registry (Class I & II)
- **Failure to comply: Possible $50,000 penalty per individual** and a $250,000 penalty per company so the total would not exceed $500,000.

Note: You do not want FDA to write the public recall notice

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**

FSMA Food Defense Requirements

- **Food Defense –** FDA working with the Department of Homeland Security and USDA to perform food vulnerability assessments and publish regulations to prevent the intentional adulteration of food products.
- **Intentionally Introduced Hazards – deferred**
- **FDA website on food defense:** Good tools to evaluate your vulnerability and develop multi-layered program for food defense that relies on:
  - physical barriers (fences, locked doors & windows, etc.)
  - procedures (sign-in, visitor picture ID requirements, etc.)
  - employee training-reporting suspicious activity
- Industry needs to **challenge system once per year**

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. **Mandated records of critical tracking events (CTEs) and key data elements (KDEs). FDA to establish electronic submission systsm for CTEs & KDEs and se to prioritize inspections/investigations**
2. **Product tracing plan mandated and tested**
3. **More that one-step forward & one step back.**
4. **FDA to coordinate traceback investigations and possibly share information with state and local health and regulatory agencies.**

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

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

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.

21 CFR 110.40 Equipment

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food contact surfaces shall be maintained to protect food from being contaminated by any source, **including unlawful indirect food additives.**

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 110.40 Equipment

(b) Seams on food-contact surfaces shall 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.

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

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 110.40 Equipment

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall 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 shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, **and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.**

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 110.40 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 shall be accurate 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 shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

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.

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)

ISO 22716 Cosmetic GMPs for Equipment

Equipment should be suitable and used for its intended purpose. It should also be easily cleaned, maintained and sanitized if needed. When installing or using process equipment:

- Equipment should be designed to avoid contamination of product
- Transfer hoses and accessories (utensils, scrappers, etc.) should be cleaned, sanitized if necessary and stored properly
- Material of construction should be compatible with the product
- Installation of equipment should allow for proper drainage, cleaning, movement of material, accessible and identifiable
- Equipment in production and laboratories must be calibrated and identifiable.
- Equipment should be subject to cleaning at appropriate intervals and with appropriate cleaning agents as to not contaminate product

Table E-1: Comparison of Pharmaceutical GMPs, Medical Device GMPs, ISO 9001:2000, and ASQ Quality System to Food GMPs

Food GMPs	ISO 9001:2000	ASQ Quality System	Medical Device GMPs	Pharmaceutical GMPs
Key Provisions				
• Personnel - Disease control - Cleanliness - Education and training, supervision • Plants and grounds - Grounds - Plant design and construction • Sanitary operations - General maintenance - Substances used for cleaning - Pest control - Sanitation of food-contact surfaces - Storage and handling. • Sanitary facilities and controls - Water supply - Plumbing - Sewage disposal - Toilet facilities - Hand-washing facilities - Rubbish and offal disposal • Equipment and utensils • Processes and controls - Raw materials - Manufacturing operations • Warehousing & distribution	• Management responsibility - Management commitment - Customer focus - Quality policy - Planning - Responsibility, authority, and communication - Management review • Resource management - Provision of resources - Human resources - Infrastructure - Work environment • Product realization - Planning of product realization - Customer-related processes - Design and development - Purchasing - Production and service provision - Control of monitoring and measuring devices • Measurement, analysis, and improvement - Monitoring and measurement - Control of nonconforming product - Analysis of data - Improvement • Quality management system - Documentation requirements	• Management responsibility • Marketing • Specification and design • Procurement • Production and production control • Product verification • Measuring and test equipment • Nonconformity • Corrective action • Handling and post-production • Documentation and records • Personnel • Product safety and liability • Quality methods	• QS Requirements - Management responsibility - Quality audit - Personnel • Design Control • Document Controls • Purchasing Controls • Identification and Traceability • Production and process Controls • Acceptance Activities • Nonconforming Product • Corrective and Preventative Action • Labeling and Packaging • Handling, Storage, Distribution, and Installation • Records • Servicing • Statistical Techniques	• Organization and Personnel - Responsibilities of quality control unit - Personnel qualifications and responsibilities • Buildings and facilities - Design & construction - Sanitation & maintenance • Equipment - Design, size, & location - Construction, cleaning, & maintenance • Control of components and drug product containers and closures • Production & process controls - Written procedures, deviations - Change in components - Equipment identification - Sampling and testing of in-process materials and drug products - Control of microbiological contamination - Reprocessing • Packaging and labeling control • Holding & distribution • Laboratory controls - Testing and release for distribution - Stability testing • Records and reports

FDA Regulations on Food Transport

FDA Regulations on Food Transport

Sec. 111. Sanitary Transportation of Food

Addresses implementation of the Sanitary Food Transportation Act of 2005, which requires persons engaged in food transportation to use sanitary transportation practices to ensure that food is not transported under conditions that may render it adulterated.

FDA Initiative on Food Transport - April 30, 2010

FDA requested input regarding the food transportation industry and its current practices such as characteristics of firms subject to the FSTA, including:

- The types of vehicles used
- Current sanitation practices
- Communication and information sharing among parties involved in transportation of food
- The practice of transporting food and nonfood in the same vehicle (simultaneously or consecutively)
- Possible criteria to exempt certain classes of persons and vehicles from the new regulations
- Data and information concerning the past contamination of transported food and the risk for food borne illness.

FDA Initiative on Food Transport - 15 Problems

1. **Improper refrigeration or temperature control of food products (temperature abuse), intentional (abuse or violation of practices by drivers, i.e., turning off refrigeration units) or unintentional (due, for example, to improper holding practices or shortages of appropriate shipping containers or vessels).**
2. Improper management of transportation units or storage facilities to preclude cross-contamination, including improper sanitation, backhauling hazardous materials, not maintaining tanker wash records, improper disposal of wastewater, and aluminum phosphide fumigation methods in railcar transit.
3. Improper packing of transportation units or storage facilities, including incorrect use of packing materials and poor pallet quality.

FDA Initiative on Food Transport - 15 Problems

7. Poor pest control in transportation units or storage facilities.
8. Lack of driver/employee training and/or supervisor/ manager/owner knowledge of food safety and/or security.
9. **Poor transportation unit design and construction.**
10. Inadequate preventive maintenance for transportation units or storage facilities, resulting in roof leaks, gaps in doors, and dripping condensation or ice accumulations.

Hauler Requirements

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

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Sanitation

1. The vehicle should be rinsed with warm water, washed with 160°F water & cleaning solution, then sanitized with FDA & EPA accepted sanitizer. All surfaces that come in contact with food products should be cleaned and sanitized also: pallets, forklifts, hand trucks, conveyors, loading docks, and other loading and securing equipment.
2. Vehicles must be used only for food, a single item if possible, and marked "for food use only.“
3. Follow correct procedures for the properly handling and disposal of spoiled or contaminated products.

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Vehicle Inspection

Food transporting trucks should be inspected before loading with the following checklist.

- Check for food residues from earlier loads.
- Check for cleaning and sanitizing residues.
- Check the cooling unit for proper function.
- Check trailer insulation and door seals.
- Pre-cool the unit for at least an hour at the required temperature for the food.
- Check that the ribbed floors and air chutes are clean and unclogged.

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Consequences: New Prohibited Acts

It is a prohibited act to:

- Fail to establish or maintain records
- Refuse access to or verification or copying of any such required record
- Fail to make records available to FDA as required by section 414 or 704(a) of the act and this regulation

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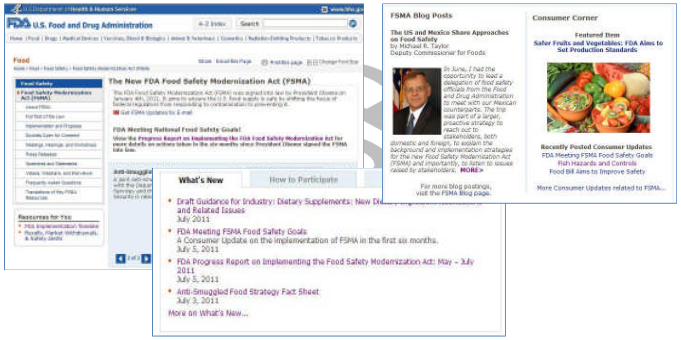
Comment Due by Sept. 16th, 2013 On: (http://www.regulations.gov)

1. Finished Product Testing
2. Environmental Monitoring
3. Food Warehouses Storing Only Packaging Goods without Temperature Requirements
4. FDA Enforcement Dates for Large, Small and Very Small Businesses
5. Definition of Very Small Business
6. Time-temperature relationship for refrigeration or "hot-holding" of food

FUTURE OPPORTUNITIES FOR 3-A

1. Commenting on the FSMA Preventative Controls
2. New Standards to Covers All Major Pieces of Processing Equipment
3. Practice on CIP Cleaning Systems for Bulk Transport Tankers
4. Streamlining the Standards and Practices process

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



Thank You!

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Who Has the First Question ?