



FSMA UPDATE: THE ROLE OF 3-A IN YOUR PREVENTIVE CONTROLS PLAN

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ALTERNATE TITLE:
WHERE DOES 3-A
FIT IN WITH FSMA



"You fit in. You just don't match."

FDA FOOD SAFETY MODERNIZATION ACT (FSMA) -2011

[HTTP://WWW.FDA.GOV/FOOD/GUIDANCEREGULATION/FSMA/UCM247548.HTM](http://www.fda.gov/food/guidanceregulation/fsma/ucm247548.htm)

***“BUILDING A NEW FOOD SAFETY SYSTEM
BASED UPON PREVENTION” (FDA)***

A green highway sign with white text and an arrow. The sign is mounted on a metal structure against a blue sky and a blurred horizon. The word "Changes" is written in a large, white, sans-serif font. Below it, the words "NEXT EXIT" are written in a smaller, white, sans-serif font, followed by a white arrow pointing diagonally upwards and to the right.

Changes

NEXT EXIT



Old Law

- Reactive
- U.S.-centric
- Focused toward on-market products

New Law

- Proactive
- Global Implications
- More *PROCESS/PREVENTION* oriented
 - Early identification of risk
 - Supplier emphasis
 - Increased communication

KEY PROVISIONS OF THE ACT – WITH RESPECT TO 3-A SSI

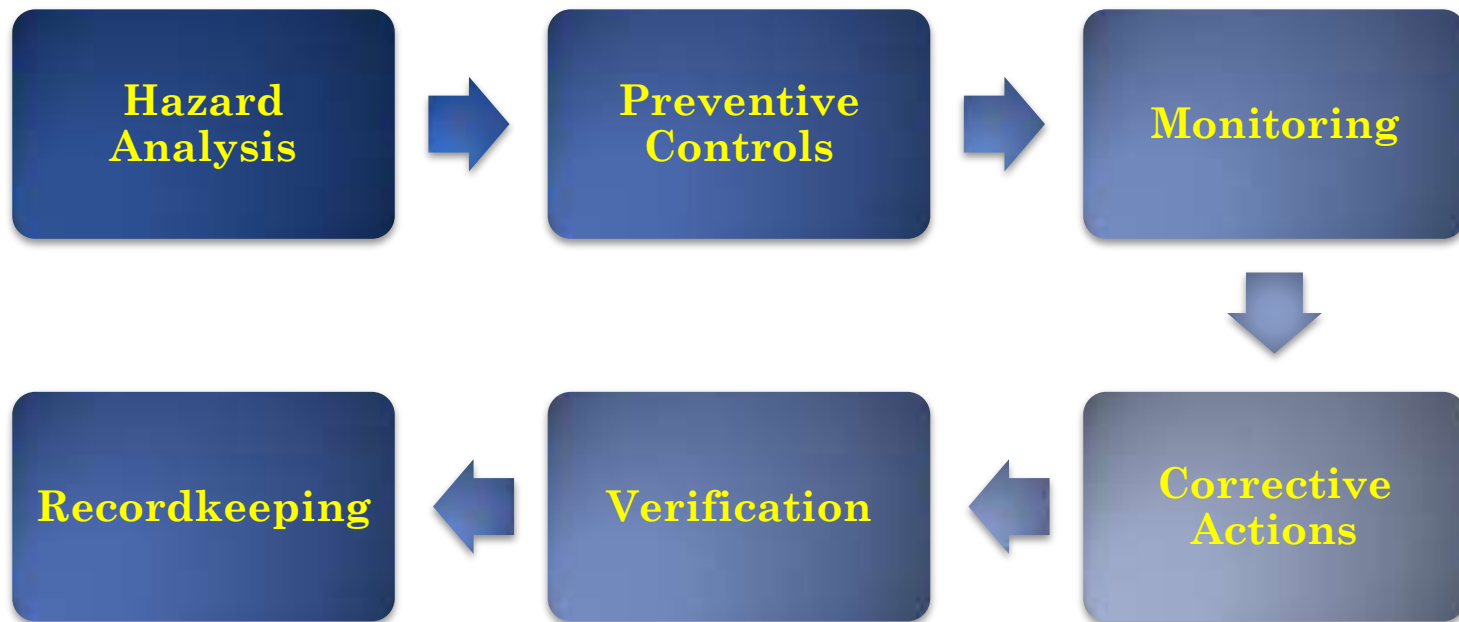
TITLE I: IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

- Sec. 101. Inspection of Records
- Sec. 102. Registration of Food Facilities
- Sec. 103. Hazard Analysis and Risk Based Preventative Controls
- Sec. 104. Performance Standards
- Sec. 105. Standards for Produce Safety
- Sec. 106. Protection against intentional adulteration
- Sec. 107. Authority to Collect Fees
- Sec. 108. National Agriculture and Food Defense Strategy
- Sec. 109. Food & Agricultural Coordinating Councils
- Sec. 110. Building Domestic Capacity
- Sec. 111. Sanitary Food Transportation
- Sec. 112. Food allergy and anaphylaxis management
- Sec. 113. New Dietary Ingredients
- Sec. 114. Guidance relating to post harvest Processing of Raw Oysters
- Sec. 115. Port Shopping
- Sec. 116. Alcohol-related facilities

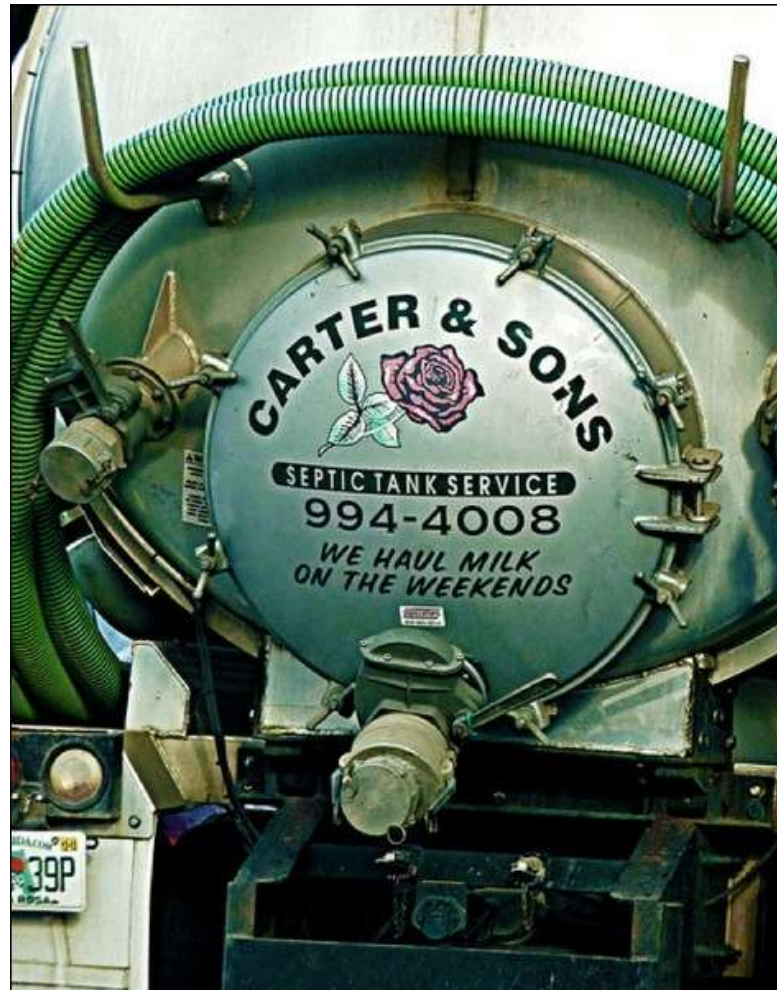
FSMA SEC. 103. HAZARD ANALYSIS AND RISK BASED PREVENTATIVE CONTROLS (HARPC)

- **Facilities Required To Develop and Implement A Written Preventive Controls Plan (aka HARPC Plan)**

ELEMENTS OF THE PREVENTIVE CONTROLS PLAN (PER FSMA)



SEC. 111. SANITARY FOOD TRANSPORTATION



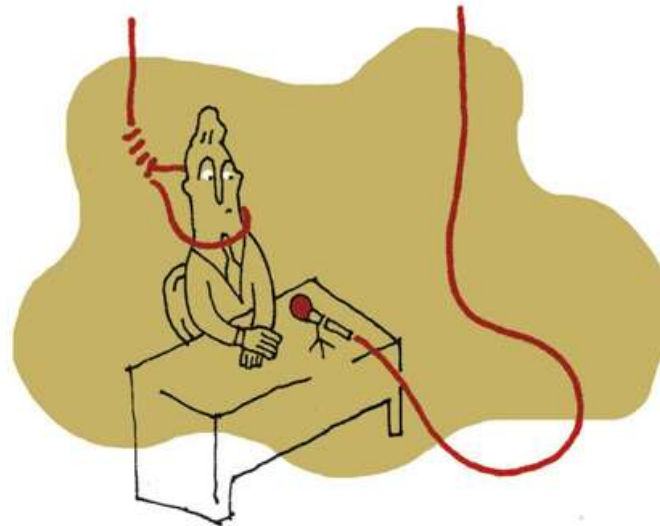
Florida
Plate



PREVIOUS ACTIVITY – SANITARY FOOD TRANSPORTATION

- *Sanitary Food Transportation Act (SFTA) - 1990*
 - *US Dept. of Transportation (DOT)*
- *Sanitary Food Transportation Act (SFTA) - 2005*
 - *Moved From US Dept. Of Transportation (DOT) To FDA*
- **FDA Activity**
 - *Advance Notice Of Proposed Rule (ANPR) – (April 2010)*
 - *FDA Guidance For Industry: Sanitary Transportation Of Food*
 - **Now — FSMA Implementation**

FDA REGULATIONS FOR IMPLEMENTING FSMA



WHICH PROPOSED REGULATIONS MAY HAVE 3-A SSI CONNECTION?

- Preventive Controls (Comments sent)
- Sanitary Transportation (Comments sent)

PROPOSED RULE -- CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

- **Timeline**
 - Proposed Rule: Jan. 16, 2013
 - Suppl. Prop. Rule: Sept. 29, 2014
 - Final Rule Expected: **Aug. 2015**
- **Expected Outcome**
 - Amend cGMPs (21CFR117)
 - Establish requirements for Preventive Controls Plan

PROPOSED RULE -- CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

○ Timeline

- **Proposed Rule: Oct. 29, 2013**
- **Supplemental Proposed Rule: Sept. 29, 2014**
- **Final Rule Expected: Aug. 2015**

○ Expected Outcomes

- **Establish and/or Clarify cGMPs for Animal Foods**
- **Establish requirements for Preventive Controls Plan**

KEY PROVISIONS OF PREVENTIVE CONTROLS PROPOSED RULE(S)

- **Hazard Analysis -- More Emphasis on Risk Assessment**
 - **Biological, Physical, Chemical, Radiological, Allergens**
- **Control Measures -- Emphasis on Non-CCPs (e.g. Prerequisite Programs or PRPs)**
- **Monitoring**
- **Corrective Actions**
- **Verification – Emphasis on Validation**
- **Documentation and Records**

ADDITIONAL PROVISIONS (STILL PENDING)

- **Product Testing**
- **Environmental Sanitation and Monitoring**
 - **For Microbiological and Allergen Control**
- **Recall and Trace-back**
- **Supplier Controls**
- **Economic Adulteration**
 - **Possible introduction of hazards**

IS HARPC HACCP WITHOUT SAYING “HACCP”?

- **Almost HACCP (AHACCP)?**
- **“HACCP Emphasizes CCPs. HARPC Includes More Emphasis on Non-CCPs**

COMPARISON HARPC & HACCP – HAZARD ANALYSIS

HACCP	HARPC– Proposed
<u>Elements -</u>	<u>Elements -</u>
	Hazard Identification Hazard Evaluation (Risk Assessment)
<u>Hazards-</u>	<u>Hazards-</u>
Biological Chemical Physical	Biological Chemical Physical Allergens Radiological

COMPARISON HARPC & HACCP – CONTROL MEASURES

HACCP	HARPC – Proposed
<p><u>Critical Control Points (CCPs)</u></p>	<p><u>Preventive Controls</u></p>
<ul style="list-style-type: none"> • Based Upon Decision Tree • Must Have Definable and Realistic Critical Limit which can be Monitored and Verified 	<ul style="list-style-type: none"> • Include CCPs and “Non-CCPs” • Include Sanitation Programs (SSOPs)
<p><u>Prerequisite Programs (PRPs)</u></p>	
<ul style="list-style-type: none"> • Required as Foundation to HACCP <ul style="list-style-type: none"> • Include Sanitation Programs (SSOPs) • May be used to Control Hazards when Impractical to Identify as CCP 	

KEY WORDS IN PREVENTIVE CONTROLS PROPOSED RULE

- **Risk Assessment**
- **Validation**

PROPOSED RULE – *SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD* FEB 5, 2014)



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Part II

Department of Health and Human Services

Food and Drug Administration
21 CFR Part 1
Sanitary Transportation of Human and Animal Food; Proposed Rule

- **Issued:**
 - **Feb. 5, 2014**
- **Final Rule
Expected:**
 - **March 2016**

PROPOSED TRANSPORTATION RULE

- **Requirements for Transportation Vehicles and Transportation Operations**
- **Recordkeeping and Documentation Requirements**
- **Waivers for Certain Industry Segments**
 - **Grade A Milk and Milk Products under the Pasteurized Milk Ordinance (PMO)**
 - **Others Possible?**
 - **Juice Processors Assoc (JPA) Tanker Wash Program??**

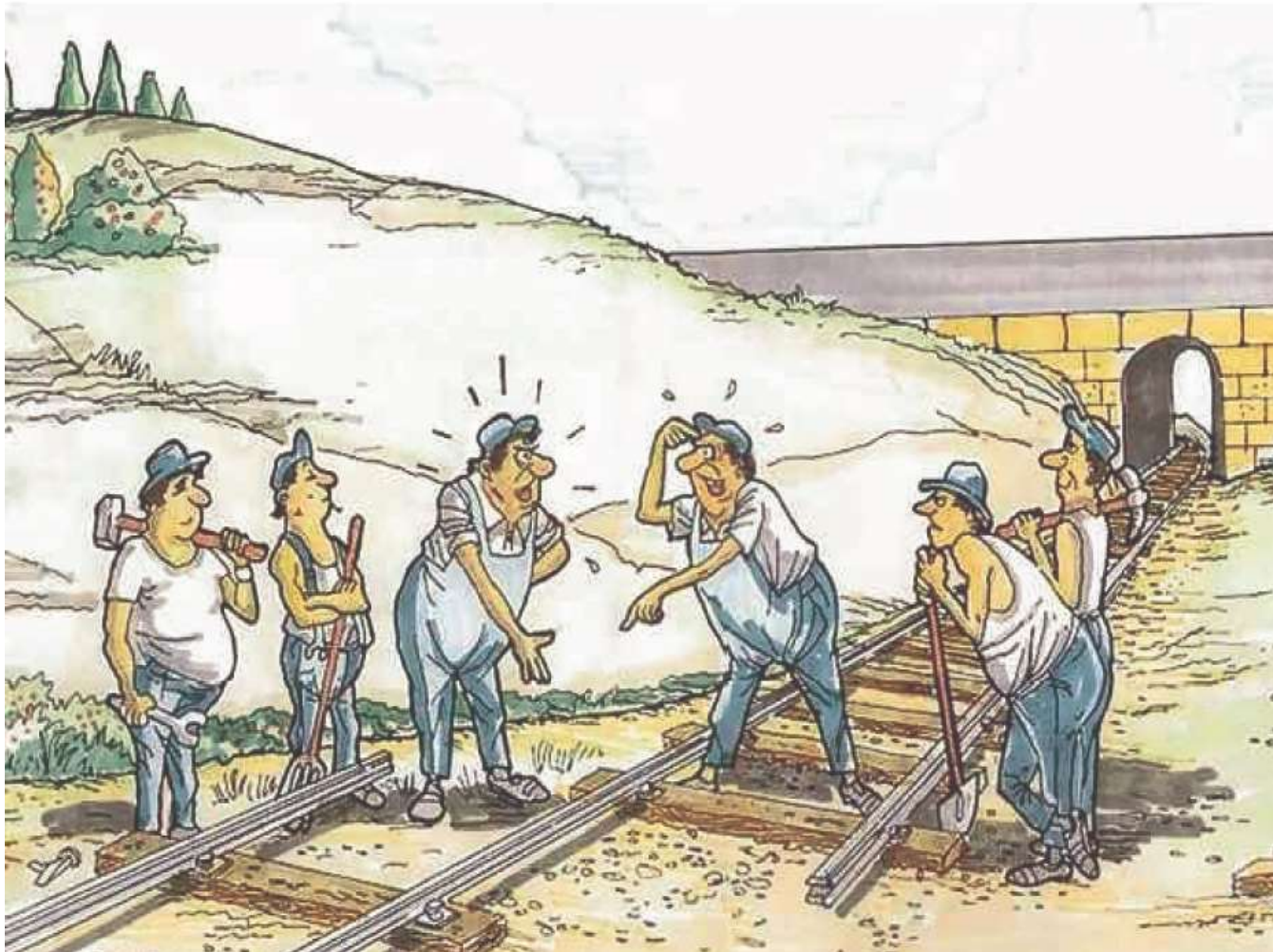
3-A SSI GENERAL POSITION REGARDING THE PROPOSED RULES

- 3-A Sanitary Standards should be recognized as meeting the intent of the proposed rules.**
- 3-A Sanitary Standards should be recognized as a foundation upon which to validate preventive controls related to equipment**
- Conformance with hygienic design and construction principles improves and facilitates cleaning and sanitation programs**
- Conformance with hygienic design and construction principles facilitates validation**
- Without proper hygienic design and construction, validation is difficult, if not impossible.**

A FEW WORDS ABOUT VALIDATION RELATIVE TO HACCP

*Validation is that Element of
Verification Focused on
Collecting and Evaluating Scientific
and Technical Information
to Determine Whether the HACCP Plan,
When Properly Implemented, Will
Effectively Control the Identified Food
Hazards*

WE DID VERIFICATION... WHAT HAPPENED?



ELEMENTS OF HACCP VALIDATION (USDA)

Element 1: Scientific or Technical Support (Design)

- Identify supporting documentation
- Identify critical operational parameters from supporting documentation relevant to process

Element 2: In-plant Demonstration (Execution)

- Implement critical parameters from supporting documentation
- Gather data demonstrating the effectiveness of the HACCP system

EQUIPMENT VALIDATION ISSUES RELATIVE TO PREVENTIVE CONTROLS

○ Prescriptive-based Elements

- Assurance that equipment meets hygienic design principles
 - Conforms to standards (where appropriate or where they exist)

○ Performance-based Elements

- Installation
- Operation Programs
- Maintenance Program
- Moving Equipment in and out of facility
- Cleaning and Sanitation Programs and Systems
 - Standard Operating Procedures (SOPs)
 - PRPs

ADAPTING THE HACCP VALIDATION MODEL TO FOOD EQUIPMENT PROGRAMS

Element 1: Scientific or Technical Support (Design)

- **Identify supporting documentation**
- **Application of hygienic design standards in equipment manufacture**

Element 2: In-plant Demonstration (Execution)

- **Equipment purchasing programs**
- **Proper installation and maintenance**
- **Gather data demonstrating the effectiveness of the equipment cleaning and sanitation system and hazard control**

PART 2: OBSERVATIONS FROM AN AGING ACADEMICIAN



CURRENT TRENDS IN REGULATORY AND THIRD PARTY AUDITING PROGRAMS

- **Increased Focus on “Performance-based” Elements**
- **Very general with regard to auditing of food equipment and hygienic design**
 - **Interpretation and scrutiny varies with the knowledge and background of the auditor**

FURTHER THOUGHTS

The current emphasis on “performance-based” auditing programs is a good thing, in fact it is commendable, but don’t forget those “prescriptive-based” elements... Ahh this is where 3-A fits in.

PUSH BACK ON PRESCRIPTIVE EQUIPMENT STANDARDS – FROM A VARIETY OF SOURCES

- **Too Expensive**
 - Save a buck now... pay later
- **3-A is Dairy and not Applicable to Many Industries**
 - Say “Listeria in Cantaloupes” 100 times.
- **Too Restrictive**
 - No comment
- **Standards stifle creative genius**
 - OMG, LOL
- **Equipment, when installed and/or modified, loses its conformance with 3-A (or NSF or other) standard**
 - Is this a reason not to have the standard? Jeez Louise!!!

Creative Genius Design Innovation 1032 – Warm Water for Hand-washing Sink



Designed by Schonrock Enterprises, Ltd.





**HOW FAR HAVE
WE COME SINCE
“BACK IN THE
DAY”?**

Validate This!!



VALIDATE THIS!!!



VALIDATE THIS?

Smooth, Impervious, Nonabsorbent Surfaces



QUESTIONS/ COMMENTS?

