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."

From the Conde Nast Collection. Poster available at www.art.com
FDA Food Safety Modernization Act (FSMA) -2011

HTTP://WWW.FDA.GOV/FOOD/GUIDANCEREGULATION/FSMA/UCM247548.HTM
“BUILDING A NEW FOOD SAFETY SYSTEM BASED UPON PREVENTION” (FDA)
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
Facilities Required To Develop and Implement A Written Preventive Controls Plan (aka HARPC Plan)
ELEMENTS OF THE PREVENTIVE CONTROLS PLAN (PER FSMA)

- Hazard Analysis
- Preventive Controls
- Monitoring
- Recordkeeping
- Verification
- Corrective Actions
Sec. 111. Sanitary Food Transportation
**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**
  - *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
  - 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

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## COMPARISON HARPC & HACCP – CONTROL MEASURES

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<td><strong>Critical Control Points (CCPs)</strong></td>
<td><strong>Preventive Controls</strong></td>
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| • Based Upon Decision Tree  
  • Must Have Definable and Realistic Critical Limit which can be Monitored and Verified | • Include CCPs and “Non-CCPs”  
  • Include Sanitation Programs (SSOPs) |
| **Prerequisite Programs (PRPs)** | |
| • Required as Foundation to HACCP  
  • 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

- 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!!!

Fabric Belt

Wood
VALIDATE THIS?

Smooth, Impervious, Nonabsorbent Surfaces
QUESTIONS/COMMENTS?