GFSI AND FSMA: WILL ONE SATISFY THE OTHER?

Presented to the
Almond Board of California
Modesto, CA
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Richard F. Stier
Consulting Food Scientist
Sonoma, CA
rickstier4@aol.com
NEW FOOD SAFETY LAW

1. HACCP/preventive controls mandatory
2. Supply chain management
3. Record maintenance
4. Recalls
5. Intentionally introduced hazards
6. Stronger FDA enforcement
7. Fees

*Food Safety Modernization Act of 2010 – HR 2751*
Food safety regulations pass on bipartisan vote

By Andrew Ayers

WASHINGTON — The most significant changes to food safety regulations in 70 years were approved by Congress on Tuesday, giving food safety powers to the Food and Drug Administration to stop the unscrupulous and pre-empting consent of disease in the nation's food products in a system.

The law also contains other provisions to small, local farmers in California and elsewhere from the strictest of new regulations — an exception for non-GMO use and some of the requirements that increase costs for small producers.

Approved as a 308-page bipartisan House rule, the new regulations include FDA's tightened standards and the first time federal food inspectors had implemented food in the same standards as domestic food.

Signed into law January 2011.

This is an act of Congress. FDA needed to write the regulations to enforce the law.

San Francisco Chronicle
December 23, 2010

Signed into law January 2011.
DRAFT REGULATION for PREVENTIVE CONTROLS

- Issued January 16, 2013
- Scope
- Definitions
- Exemptions
- Updates GMPs
- Risk-based controls
- Record Requirements
## FSMA Foundational Rules

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Proposal</th>
<th>Final (consent decree)</th>
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<tbody>
<tr>
<td>Preventive Controls (Human Food)*</td>
<td>January 16, 2013</td>
<td>August 30, 2015</td>
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<tr>
<td>Preventive Controls (Animal Food)*</td>
<td>October 29, 2013</td>
<td>August 30, 2015</td>
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<td>Produce Safety*</td>
<td>January 16, 2013</td>
<td>October 31, 2015</td>
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<tr>
<td>Foreign Supplier Verification Program*</td>
<td>July 29, 2013</td>
<td>October 31, 2015</td>
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<td>Third Party Accreditation</td>
<td>July 29, 2013</td>
<td>October 31, 2015</td>
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<tr>
<td>Intentional Adulteration</td>
<td>December 24, 2013</td>
<td>May 31, 2016</td>
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| Traceability (Pending)                         | *Supplemental proposals published September 2014*
Part 117 Current Good Manufacturing Practice
Hazard Analysis and Risk Based Preventive Controls for Human Food

Issued August 31, 2015
THE QUESTION IS....

IF MY COMPANY HAS SPENT THE TIME AND EFFORT TO IMPLEMENT A GFSI AUDIT SCHEME, WILL THEY MEET THE REQUIREMENTS IN FSMA? ESPECIALLY THE PREVENTIVE CONTROLS REGULATION???
AUDIT SCHEMES & STANDARDS

- Must adhere to pertinent laws and regulations
- So, all United States processors and exports to the USA must adhere to the provisions in FSMA
- **ISO 22000** – “*conforms with both statutory and regulatory requirements and with mutually agreed food safety requirements of customers*”
APPROVED GFSI AUDIT SCHEMES

- FSSC 22000 ✓
- BRC ✓
- SQF ✓
- IFS ✓
- CanadaGAP
- PrimusGFS
- Global Red Meat Standard
- Global Aquaculture alliance for Seafood Processing
- Dutch HACCP and Synergy 22000 (Dropped)
# COMPARISON OF STANDARDS

<table>
<thead>
<tr>
<th>Element</th>
<th>SQF Version 7</th>
<th>FSSC 22000</th>
<th>BRC</th>
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<tbody>
<tr>
<td>Levels</td>
<td>Three</td>
<td>One</td>
<td>One</td>
</tr>
<tr>
<td>Quality requirements</td>
<td>Yes at Level 3 CQP</td>
<td>None</td>
<td>Yes</td>
</tr>
<tr>
<td>Prerequisite programs</td>
<td>Detailed and prescriptive</td>
<td>Less prescriptive</td>
<td>Very detailed and prescriptive</td>
</tr>
<tr>
<td>Building and Equipment Design</td>
<td>Detailed and prescriptive</td>
<td>Less prescriptive</td>
<td>Very detailed and prescriptive</td>
</tr>
<tr>
<td>HACCP</td>
<td>Food safety and quality</td>
<td>Food safety only</td>
<td>Food safety only</td>
</tr>
<tr>
<td>Exclusions</td>
<td>Allows for exclusions supported by risk analysis</td>
<td>Allows for exclusions supported by risk analysis</td>
<td>Request needs CB approval</td>
</tr>
<tr>
<td>Personnel</td>
<td>Trained SQF Practitioner responsible for program</td>
<td>Food Safety Coordinator</td>
<td>Food Safety Team Leader</td>
</tr>
</tbody>
</table>

Eagle Certification Group, (2014), Food Safety Standards: The Basics
DEFINITIONS
HAZARD

means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.
PREVENTIVE CONTROLS means 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.
PREVENTIVE CONTROLS

QUALIFIED INDIVIDUAL means a qualified individual 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.
Subpart C
Hazard Analysis and Risk Based Preventive Controls
FOOD SAFETY PLAN

117.126

- Food safety plan – Owner, operator or agent in charge responsible for plan
- Must be prepared by a qualified individual(s)
- Plan must include;
  - Hazard analysis
  - Implementing & monitoring preventive controls
  - Corrective actions
  - Verification
  - Supply chain management
  - Recall program
  - Records
GFSI AUDIT SCHEMES

- Documented food safety management system
- HACCP/Food safety team lead by qualified person
- Risk assessment on ingredients, raw materials and packaging
- Hazard analysis
- Supply chain
- Sanitation
- Recall
HAZARD ANALYSIS
117.130

a) Requirement for Hazard Analysis
   i. Identify & evaluate known or foreseeable hazards
   ii. Must document hazard analysis

b) Hazard Identification
   i. Biological, chemical (including radiological), & physical

c) Hazard Evaluation
   i. Hazards likely to occur/severity of illness
   ii. Environmental pathogens
   iii. Potential hazards in food
   iv. Intentionally introduced for economic gain
GFSI AUDIT SCHEMES

- Hazard analysis for biological, chemical & physical hazards (No radiological)
- Assessment of ingredients, packaging and raw materials
- Assess each step in the process
- Documented procedures and results
- No specific requirements for environmental monitoring
PREVENTIVE CONTROLS

117.135

a. Identify & implement preventive controls, including CCPs

b. Must be written

c. Preventive controls must include
   - Parameters to control identified hazards
   - Maximum/minimum values to control identified hazards

d. Preventive controls must include as appropriate
   - Process controls
   - Food allergen controls
   - Sanitation controls
   - Recall plan
GFSI AUDIT SCHEMES

- Identify controls (CCPs and critical limits) and specific hazards
- Documented
- Road map
- Programs for:
  - Allergen management
  - Recalls
  - Supply chain management
  - Process controls
RECALL PLAN
117.139

a. Establish written recall plan for foods with preventive controls

b. Must include procedures and assign responsibility

Notify consignees
Notify the public
Evaluate efficacy
Appropriate disposal of recalled food
GFSI AUDIT SCHEMES

- Mandated recall plan
- Forward and back trace
- Must be documented
- Full tracability
- Disposal of recalled product
MONITORING

117.145

a. Must establish written procedures for monitoring preventive controls

b. Monitor preventive controls with sufficient frequency to ensure they are consistently performed

c. Records - Monitoring must be documented
GFSI AUDIT SCHEMES

- Documented protocols to monitor critical control points
- Maintain records of monitoring
- Include
  - What
  - When
  - How
  - Who
CORRECTIVE ACTIONS

117.150

a. Establish documented corrective actions that must be taken if preventive controls are not implemented & steps to be taken

   Actions to be taken to correct problem and prevent a reoccurrence

   Ensure all affected food is evaluated for safety

b. Corrective action procedures must describe actions to be taken in the even of an unanticipated problem

c. All corrective actions must be documented in records subject to verification
GFSI AUDIT SCHEMES

- Documented corrective action plans
- Review corrective actions as part of verification
- Include:
  - Corrections
  - Preventive actions
  - Follow-up activities
(1) Validation in accordance with § 117.160.

(2) Verification that monitoring is being conducted as required by § 117.140 (and in accordance with § 117.145).

(3) Verification that appropriate decisions about corrective actions are being made as required by § 117.140 (and in accordance with § 117.150).

(4) Verification of implementation and effectiveness in accordance with § 117.165; and

(5) Reanalysis in accordance with § 117.170.

(b) *Documentation.* All verification activities conducted in accordance with this section must be documented in records.
GFSI AUDIT SCHEMES

- Mandated verification activities including validation of all CCPs
- Must be documented
- Monitoring
- Corrective actions
- Calibration
- Internal audits
- Validation
- Re-assessment
a. Must validate process preventive controls
   Must be done by or overseen by a qualified individual
   Before implementation of the food safety plan or within 1\textsuperscript{st} 6 weeks.
   Science based
   Whenever a change is contemplated

b. Do not need to validate allergen controls, sanitation controls, recall and supply chain program
GFSI AUDIT SCHEMES

- All CCPs must be validated
- Sanitation procedures must be validated
- Efficacy of any controls are validated
REANALYSIS
117.170

a. Done every three years
b. Whenever a change is contemplated
c. When a preventive control is ineffective
d. Done by a preventive controls qualified individual
e. New hazards
GFSI AUDIT SCHEMES

- Re-assessment every year
- As needed
QUALIFIED INDIVIDUAL 117.180

a. Qualified individuals must develop or oversee
   - Food safety plan
   - Validation of preventive controls
   - Record review and corrective actions
   - Reanalysis of food safety plan

b. Must have successfully completed FDA recognized training

c. Training must be documented
GFSI AUDIT SCHEMES

- Food safety team leader
- HACCP team
- Trained/educated team
- Training documented
- Build and manage the FSMS
The following records must be maintained:

- Written food safety plan
- Monitoring preventive controls
- Corrective actions
- Verification records
  - Calibration records
  - Environmental monitoring
- Validation
- Corrective actions
- Records review
- Reanalysis

- Training records for qualified individual
GFSI AUDIT SCHEMES

- All program must be documented and records maintained
- HACCP plan and support documentation used in developing the plan
- Records of CCP monitoring
- Records of corrective actions
- Records of verification activities
  - Including validation data
- Calibration records
- Prerequisite programs
  - Cleaning & sanitizing
  - **Allergen control**
  - Any that have been determined to affect product safety in your hazard analysis
- Training
FSSC 22000 Required Procedures

- Document Management & Control
- Quality Records
- Management Responsibility
- Communications
- Emergency Preparedness
- Competence Awareness & Training
- Infrastructure
- Work Environment
- Corrections and Corrective Action
- Control of Nonconforming Product

- Prerequisite Programs
- Preliminary Steps Hazard Analysis
- Food Safety Team
- HACCP
- Verification Planning
- Traceability
- Validation of Control Measures
- Control of Monitoring and Measuring
- FSMS Verification
- Internal Audits
WHAT FSMA DOES NOT MANDATE.....
MAINTAINING THE PROGRAM: MANAGEMENT COMMITMENT
Former peanut exec gets 28 years in prison for salmonella outbreak
Food Safety Management System (FSMS)
ISO 22000 : 2005

4.1 General Requirements
4.2 Documentation
4.2.1 General Requirements
4.2.2 Control of Documents
4.2.3 Control of Records

5.1 Management Commitment
5.2 Food Safety Policy
5.3 FSMS Planning
5.4 Responsibility & Authority
5.5 Food Safety Team Leader
5.6 Communication
5.7 Emergency Preparedness
5.8 Management Review

6.1 Provision of Resources
6.2 Human Resources
6.3 Infrastructure
6.4 Work Environment

7.1 General Requirements
7.2 Prerequisite Program (PRP)
7.3 Preliminary Steps Hazard Analysis
7.4 Hazard Analysis
7.5 Establish OPRP’s
7.6 Establish HACCP Plan
7.7 Update Preliminary PPR’s & HACCP Plan
7.8 Verification Planning
7.9 Traceability System
7.10 Control of Nonconformity

8.1 General Requirements
8.2 Validate Control Measure Combinations
8.3 Control of Monitoring & Measuring
8.4 Verification of FSMS
8.5 Improvement
8.6.1 Internal Audits
8.6.2 Eval. Indiv. Verif. Results
8.6.3 Analyze Verific. Results
8.6.4 Continual Improvement
8.6.5 Updating the FSMS

5.6.1 External Communication
5.6.2 Internal Communication
5.8.1 General
5.8.2 Review Input
5.8.3 Review Output

6.2.1 General
6.2.2 Competence, Awareness, Training
ROLE OF MANAGEMENT ISO 22000
WHAT IS FSSC 22000?

F – Food
S – Safety
S – System
C - Certification
<table>
<thead>
<tr>
<th>ISSUE</th>
<th>FSMA</th>
<th>FSSC 22000</th>
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<tbody>
<tr>
<td>PRPs</td>
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<td>YES</td>
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<td>MANAGEMENT</td>
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<td>HACCP LEADER</td>
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<td>HAZARD ANALYSIS</td>
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<td>RISK BASED</td>
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<td>VERIFICATION</td>
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<td>• Internal Audits</td>
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<td>VALIDATION</td>
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<td>RECALL</td>
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<td>RE-ASSESSMENT</td>
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<td>VENDOR QUALITY</td>
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CONCLUSION

If your company has developed, documented, implemented and maintained a Food Safety Management System (FSMS) and meet the requirements of one of the GFSI Audit Schemes or ISO 22000, your company should fulfill most of the requirements of the final FSMA regulations.