Meeting GFSI and FSMA Requirements with SQF

ACCP Consulting Group, L.L.C. ®

Cathy Crawford
Cathy@foodssafety1.com
Agenda

- Global Food Safety Initiative (GFSI) Changes
- Safe Quality Food (SQF) Code Updates Associated with the Food Safety Modernization Act
- Other Important SQF Updates
Changes to GFSI Guidance

- Guidance Changes
- Impact on GFSI Schemes
GFSI Code Update


- Major changes - added sectors and scheme management requirements.

- All existing GFSI recognised schemes were required to resubmit for benchmarking by the end of December 2011
Developing sector-specific requirements along the entire supply chain, as prioritized by the GFSI Board, for inclusion in the GFSI Guidance Document.

<table>
<thead>
<tr>
<th>Year</th>
<th>Focus Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>• Feed</td>
</tr>
<tr>
<td></td>
<td>• Animal Handling</td>
</tr>
<tr>
<td></td>
<td>• Packaging</td>
</tr>
<tr>
<td>2012</td>
<td>• Storage and Distribution/Services</td>
</tr>
<tr>
<td></td>
<td>• Equipment Manufacturing</td>
</tr>
<tr>
<td>2013</td>
<td>• Catering</td>
</tr>
<tr>
<td></td>
<td>• Retail Outlets</td>
</tr>
<tr>
<td></td>
<td>• Brokers</td>
</tr>
<tr>
<td>2014</td>
<td>• Revision of Scopes A, B, C, D, E and L</td>
</tr>
<tr>
<td>2015</td>
<td>• Issue Guidance Document 7</td>
</tr>
</tbody>
</table>
Recognized Schemes 2011

Manufacturing Schemes:
- SQF 2000 Level 2
- BRC Global Standard Version 5
- FSSC 22000
- Global Aquaculture Alliance BAP Issue 2 (GAA Seafood Processing Standard)
- Global Red Meat Standard Version 3
- International Food Standard Version 5
- Dutch HACCP Option B
- Synergy 22000

Primary Production Schemes:
- SQF 1000 Level 2 CanadaGAP
- GlobalG.A.P IFA Scheme V3

Primary and Manufacturing Scheme:
- PrimusGFS
Changes to SQF

- Reorganized
- Removed and eliminated duplication, repetition and redundancy in the Code
- Clarified areas of concern or ambiguity
- Added new requirements
Implementation

Initial Certifications (desk audit required)

- Desk audits prior to /on June 30\textsuperscript{th} 2012 - SQF 1000 / 2000
- Facility audits prior to /on July 31\textsuperscript{st} 2012 - SQF 1000 / 2000

- Desk audits on or after July 1\textsuperscript{st} 2012 - Edition 7

- Desk audits prior to July 1\textsuperscript{st} 2012 (SQF 1000 / 2000) with site audit after July 31\textsuperscript{st} 2012, which must be to Edition 7, document changes considered on site.

Re-certifications (no desk audit required)

- All facility audits prior to or on June 30\textsuperscript{th} 2012 - SQF 1000 / SQF 2000
- All facility audits on or after July 1\textsuperscript{st} 2012 - Edition 7

Implementation of the SQF Code, Edition 7 effective July 1, 2012
Creating One SQF Code
SQF Format Revised

Part A: Implementing and Maintaining the SQF Code

Part B: The SQF Code
  Module 1: Scope, References, and Definitions
  Module 2: SQF System Elements
  Modules 3 – 15: Food Safety Fundamentals
  Module 16: Multi-site Program
  Appendix 1: Food Sector Categories
  Appendix 2: Glossary
SQF Code Change Map

- A list of changes is available here -

- Do not rely on this tool.

- You must carefully read the code to ensure compliance.
### Part B – The SQF Code, Edition 7

<table>
<thead>
<tr>
<th>Module 2</th>
<th>SQF System Elements (applies to all Suppliers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 3</td>
<td>GAP for Single Feed Production (TBD)</td>
</tr>
<tr>
<td>Module 4</td>
<td>GAP for Compound Feed Production (TBD)</td>
</tr>
<tr>
<td>Module 5</td>
<td>GAP for Farming of Animal Products</td>
</tr>
<tr>
<td>Module 6</td>
<td>GAP for Farming of Fish</td>
</tr>
<tr>
<td>Module 7</td>
<td>GAP for Farming of Plant Products</td>
</tr>
<tr>
<td>Module 8</td>
<td>GAP for Farming of Grains and Pulses</td>
</tr>
<tr>
<td>Module 9</td>
<td>GMP for Pre-processing of Animal Products</td>
</tr>
<tr>
<td>Module 10</td>
<td>GMP for Pre-processing of Plant Products</td>
</tr>
<tr>
<td>Module 11</td>
<td>GMP for Processing of Food Products</td>
</tr>
<tr>
<td>Module 12</td>
<td>GMP for Transport and Distribution of Food</td>
</tr>
<tr>
<td>Module 13</td>
<td>GMP for Production of Food Packaging</td>
</tr>
<tr>
<td>Module 14</td>
<td>GMP for Food Brokers (TBD)</td>
</tr>
<tr>
<td>Module 15</td>
<td>GMP for Food Retail, Food Service (TBD)</td>
</tr>
<tr>
<td>Module 16</td>
<td>SQF Multi-site Program</td>
</tr>
</tbody>
</table>

Supplier selects relevant module(s)
<table>
<thead>
<tr>
<th>SQF FSC</th>
<th>Category (Suppliers Scope of Certification)</th>
<th>GFSI Industry Scopes</th>
<th>Applicable SQF Code Modules</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Production, Capture and Harvesting of Livestock and Game Animals</td>
<td>Al: Farming of Animals</td>
<td>Module 2: System elements, Module 5: GAP for farming of animal products</td>
</tr>
<tr>
<td>3</td>
<td>Growing and Production of Fresh Produce</td>
<td>Bl: Farming of Plant Products</td>
<td>Module 2: System elements, Module 7: GAP for farming of fruit and vegetable products</td>
</tr>
<tr>
<td>4</td>
<td>Fresh Produce Pack house Operations</td>
<td>D: Pre-processing of Plant Products</td>
<td>Module 2: System elements, Module 10: GMP for pre-processing of plant products</td>
</tr>
<tr>
<td>5</td>
<td>Extensive Broad Acre Agriculture Operations and Seed Production</td>
<td>Bll: Farming of Grains and Pulses</td>
<td>Module 2: System elements, Module 8: GAP for farming of grains and pulses</td>
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<tr>
<td>6</td>
<td>Harvest and Intensive Farming of Fish</td>
<td>All: Farming of Fish and Seafood</td>
<td>Module 2: System elements, Module 6: GAP for farming of fish</td>
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<tr>
<td>7</td>
<td>Slaughterhouse, Boning and Butchery Operations</td>
<td>C: pre-process handling of animal products</td>
<td>Module 2: System elements, Module 9: GMP for pre-processing of animal products</td>
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<tr>
<td>8</td>
<td>Processing of Manufactured Meats and Poultry</td>
<td>El: Processing of Perishable Animal Products</td>
<td>Module 2: System elements, Module 11: GMP for processing of food products</td>
</tr>
<tr>
<td>9</td>
<td>Seafood Processing:</td>
<td>El: Processing of Perishable Animal Products</td>
<td>Module 2: System elements, Module 11: GMP for processing of food products</td>
</tr>
</tbody>
</table>
## SQF Certified Sites by Module

<table>
<thead>
<tr>
<th>Module</th>
<th>SQF Certified Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 3: GAP for single feed production</td>
<td>0</td>
</tr>
<tr>
<td>Module 4: GAP for compound feed production</td>
<td>10</td>
</tr>
<tr>
<td>Module 5: GAP for farming of animal products</td>
<td>116</td>
</tr>
<tr>
<td>Module 6: GAP for farming of fish</td>
<td>1</td>
</tr>
<tr>
<td>Module 7: GAP for farming of fruit and vegetable products</td>
<td>165</td>
</tr>
<tr>
<td>Module 8: GAP for farming of grains and pulses</td>
<td>0</td>
</tr>
<tr>
<td>Module 9: GMP for pre-processing of animal products</td>
<td>158</td>
</tr>
<tr>
<td>Module 10: GMP for pre-processing of plant products</td>
<td>284</td>
</tr>
<tr>
<td>Module 11: GMP for processing of food products</td>
<td>2,844</td>
</tr>
<tr>
<td>Module 12: GMP for transport and distribution of food products</td>
<td>231</td>
</tr>
<tr>
<td>Module 13: GMP for production of food packaging</td>
<td>69</td>
</tr>
<tr>
<td>Module 14: GMP for brokers or agents</td>
<td>27</td>
</tr>
<tr>
<td>Module 15: GMP for food catering, wholesale, and retail</td>
<td>12</td>
</tr>
</tbody>
</table>
Key Changes in Edition 7

- Re-numbering of code to align with GFSI industry scopes
- Some System Elements are Mandatory and some have just moved (Allergen Management, Approved Suppliers and Training)
- Removed scoring of Opportunities for Improvement
Mandatory Sections

- Management Policy
- Management Responsibility
- Food Safety Management System
- Management Review
- Document Control
- Records
- Food Legislation
- Food Safety Fundamentals
- Food Safety Plan
- Product Release
- Validation /Effectiveness

- Verification of Monitoring
- Corrective and Preventive Action
- Internal Audits
- Product Identification
- Product Trace
- Product Recall
- Food Defense
- Training
Non-Mandatory Sections

- Complaint Management
- Business Continuity Planning
- Product Development and Realization
- Raw and Packaging Materials
- Contract Services
- Contract Manufacturers
- Finished Product
- Food Quality Plan
- Incoming Goods and Services
- Nonconforming Product and Equipment
- Product Rework
- Responsibility / Methods for Verification
- Verification Schedule
- Product Sampling and Analysis
- Identity Preserved Foods
- Allergen Management
2.4.2.2 The Supplier shall ensure the Food Safety Fundamentals described in the relevant Modules are applied, or excluded….

according to a detailed risk analysis outlining the justification for exclusion or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.

- Must be included in Supplier’s documentation to the CB prior to the audit
Risk Assessment Details

- Document justification of exclusion or evidence of effectiveness

- Examples:
  - Rework - not used at this facility
  - Product Development and Realization – corporate function

Include:
- Biological, Chemical, Physical Hazards
- Regulatory Concerns
- Customer Concerns
- Quality Concerns
SQF and FSMA

- FSMA Still in OMB
  - ‘HACCP’ for food and feed
  - Foreign Supplier Verification
  - Produce Safety Rule

- Some SQF changes will assist with FSMA compliance
FSMA Section 103: Hazard Analysis and Risk-Based Preventive Controls

- **Includes:**
  - All registered facilities

- **Excludes:**
  - Seafood or juice HACCP, low-acid canned foods, fresh produce, dietary supplement, alcoholic beverage facilities, certain on-farm activities and “qualified facilities” (i.e. a small business - average annual value less than $500,000).
FSMA and HACCP

Prepare a Hazard Analysis and Risk-Based Preventive Controls

- All registered facilities must conduct a hazard analysis and develop and implement a written preventive controls plan.

- “Facilities …will be required to establish …preventive controls … consistent with internationally recognized principles of Hazard Analysis and Critical Control Points (HACCP) … Congress used some different terms … but these proposed rules will seem familiar to those who are currently following Codex…” Michael Taylor
SQF and HACCP

• SQF 2000  Section 4.4.3
  • A food safety plan prepared in accordance to the HACCP method

• SQF Edition 7  Section 2.4.3
  • A food safety plan prepared in accordance to the steps in CODEX or NACMCF.
  • Must describe methods and results of a hazard analysis to identify hazards associated with all inputs and process steps including rework.
FSMA and Records

- Section 101 expands FDA authority to inspect records (excludes farms and restaurants).

- Each person who manufactures, processes, packs, distributes, receives, holds, or imports an article of food must permit inspection of records where FDA believes that there is a reasonable probability of serious adverse health consequences or death.

- In effect now. Exclusions?
SQF and Records

• Requirements:
  • Define methods and responsibility for monitoring, activities, verifying and retaining records
  • Includes inspections, analyses, and essential activities
  • Must legible, authorized, accessible, stored properly, retained

• Minimal change:
  • “Authorized” replaces “signed and dated”
  • Note about initials being acceptable was removed
FSMA - Trace and Recall

- Section 206: Mandatory Recall Authority
- Section 207: Administrative Detention of Foods
- Effective now
SQF - Trace and Recall

- Requirements
  - Trace finished product, raw materials and other inputs (rework, processing aids, packaging)
  - Communication Plan
  - Two types of test

- Change - “traceable to the supplier and date of receipt”
FSMA and Food Defense

• Section 106 / 108: Protection Against Intentional Adulteration
  
  • FDA to regulate protection against intentional adulteration
  
  • Guidance in Jan 2012, regulated in July 2012
SQF and Food Defense

- No changes in Edition 7

- Ensure the plan covers
  - Storage of product and ingredients
  - Storage and management of chemicals
  - Monitoring or identification of non-employees
  - Validation of the plan
FSMA and Transportation

- **Section 111: Sanitary Transportation of Food**
  - Requires the FDA to regulate sanitary transportation
  - July 2012
  - Guidance has been available on the FDA website. Regulations are likely to be similar.
SQF and Transportation

- SQF Requirements
  - Inspect prior to loading or unloading
  - Minimize exposure
  - Maintain temperature
  - Maintain records

- One change in Edition 7: during unloading “product temperatures” not “core product temperatures” are to be checked.
Key Changes to Module 2

- Goals and objectives
- Continuous Improvement
- R&D now at Level 2
- Expanded Corrective Action
# Changes in Module 2 (continued)

<table>
<thead>
<tr>
<th>Clause</th>
<th>Level</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1.1iii</td>
<td>Levels 1, 2, 3</td>
<td>Establish and review goals and objectives</td>
</tr>
<tr>
<td>2.1.2.9</td>
<td>Levels 1, 2</td>
<td>Continuous improvement requirement</td>
</tr>
<tr>
<td>2.1.5.2</td>
<td>Levels 2, 3</td>
<td>Complaints - “Trends …. shall be investigated and analysed”</td>
</tr>
<tr>
<td>2.3.1</td>
<td>Level 2</td>
<td>Product development and realization</td>
</tr>
<tr>
<td>2.3.2.4</td>
<td>Levels 2, 3</td>
<td>Validation of raw and packaging materials</td>
</tr>
<tr>
<td>2.3.2.5</td>
<td>Levels 2, 3</td>
<td>Greater detail on validation of packaging materials</td>
</tr>
<tr>
<td>Clause</td>
<td>Level</td>
<td>Change</td>
</tr>
<tr>
<td>--------------</td>
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<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>2.3.4</td>
<td>Level 2</td>
<td>Contract manufacturers now at Level 2 and L3</td>
</tr>
<tr>
<td>2.4.1</td>
<td>Levels 1, 2, 3</td>
<td>Greater detail on legislative requirements – allergens, residue limits</td>
</tr>
<tr>
<td>2.5.2.1 v</td>
<td>Levels 2, 3</td>
<td>Validation of critical safety (and quality) limits at least annually</td>
</tr>
<tr>
<td>2.5.5</td>
<td>Levels 2, 3</td>
<td>Corrective action for noncompliance of critical food safety limits and deviations from food safety requirements</td>
</tr>
<tr>
<td>2.5.6.1.iv</td>
<td>Levels 2, 3</td>
<td>Requirement for external labs to be ISO 17025 or equivalent</td>
</tr>
</tbody>
</table>
Key Changes to Module 11

- High Risk Consolidated
- Environmental Monitoring
- Air Quality Monitoring
# Changes in Module 11

<table>
<thead>
<tr>
<th>Clause</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.2.3.1</td>
<td>Added “and shall be kept clean” (walls, ceilings, doors)</td>
</tr>
<tr>
<td>11.2.4.1</td>
<td>Added “and shall be kept clean” (stairs and catwalks)</td>
</tr>
<tr>
<td>11.2.5.2</td>
<td>Added “in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where product is exposed”</td>
</tr>
<tr>
<td>11.2.5.2</td>
<td>Added “where fittings cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials and addressed in the cleaning and sanitation program”</td>
</tr>
<tr>
<td>11.2.5.3</td>
<td>Light fittings in warehouses and other areas where product is protected shall be designed to prevent breakage.</td>
</tr>
<tr>
<td>Clause</td>
<td>Change</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>11.2.13.1.v</td>
<td>New sub-clause – confirm concentrations of detergents and sanitisers</td>
</tr>
<tr>
<td>11.2.13.8</td>
<td>New clause – record of pre-operational hygiene inspection</td>
</tr>
<tr>
<td>11.3.2.4</td>
<td>Changed to “prominent position” rather than “adjacent to hand wash stations”</td>
</tr>
<tr>
<td>11.3.2.5</td>
<td>Added “including staff, contractors and visitors” (hand washing… exclusion?)</td>
</tr>
<tr>
<td>11.3.10.2,v</td>
<td>Added “kept clean and free from waste materials and pests” (break areas)</td>
</tr>
</tbody>
</table>
## Changes in Module 11 (continued)

<table>
<thead>
<tr>
<th>Clause</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.5.7</td>
<td>Two clauses about air quality added – compressed air must be clean and monitored for purity.</td>
</tr>
<tr>
<td>11.6.4.2</td>
<td>New clause “processing utensils… not stored in areas used to store hazardous chemicals”</td>
</tr>
<tr>
<td>11.7.4.1.v</td>
<td>New sub-clause “environmental monitoring program”</td>
</tr>
<tr>
<td>11.7.5.7</td>
<td>New clause “knives and cutting instruments used in processing and packaging operations shall be controlled, and kept clean and well maintained”</td>
</tr>
</tbody>
</table>
Summary – SQF, GFSI and FSMA

- GFSI initiated change and is likely to remain more influential than FSMA for some time

- Compliance with GFSI will ensure FSMA compliance

- Key action items for SQF updates:
  - Ensure clear exclusions
  - Implement a measureable continuous improvement program
  - Continue Verification Efforts
THANK YOU!

Cathy Crawford
757.371.5832 / Cathy@food safety1.com

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