Moving from HACCP to “HARPC”

Practical Steps to Compliance

March 19, 2016
<table>
<thead>
<tr>
<th>Requirements</th>
<th>PC Rule</th>
<th>NACMCF HACCP Guidelines</th>
<th>Codex HACCP Annex</th>
<th>Federal HACCP rules for juice, seafood, and meat and poultry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written plan... Who is responsible for preparing the plan?</td>
<td>Yes ..................................................................</td>
<td>Yes ........................................................................................................</td>
<td>Yes ........................................................................................................</td>
<td>Yes. The processor.</td>
</tr>
<tr>
<td>What does the plan contain?</td>
<td>The owner, operator or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan. The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.</td>
<td>A HACCP team may need assistance from outside experts knowledgeable in the hazards associated with the product and process.</td>
<td>Individual businesses, with advice when necessary from other sources.</td>
<td></td>
</tr>
<tr>
<td>Is oversight required by a person qualified by training and experience?</td>
<td>Yes ..................................................................</td>
<td>Yes ........................................................................................................</td>
<td>Yes ........................................................................................................</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Written hazard analysis ................................</td>
<td>• Written hazard analysis ................................</td>
<td>• Written hazard analysis ................................</td>
<td>• Written hazard analysis ................................</td>
</tr>
<tr>
<td></td>
<td>• Written preventive controls</td>
<td>• Must include the hazard, the CCPs, and critical limits.</td>
<td>• Must include monitoring procedures.</td>
<td>• Must list all food safety hazards that are reasonably likely to occur, CCPs, and critical limits.</td>
</tr>
<tr>
<td></td>
<td>• Written supply-chain program.</td>
<td>• Must include corrective actions.</td>
<td>• Must include corrective actions.</td>
<td>• Must list monitoring procedures.</td>
</tr>
<tr>
<td></td>
<td>• Written recall plan ....................................</td>
<td>• Must include verification procedures.</td>
<td>• Must include verification procedures.</td>
<td>• Must include corrective action procedures.</td>
</tr>
<tr>
<td></td>
<td>• Written procedures for monitoring the implementation of the preventive controls.</td>
<td>• Must include recordkeeping procedures.</td>
<td>• Must include records ............................</td>
<td>• Must include recordkeeping procedures.</td>
</tr>
<tr>
<td></td>
<td>• Written corrective action procedures.</td>
<td>•</td>
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</tr>
</tbody>
</table>
Overview

- What’s FDA Up To?
- Where do you fall?
- Training Programs
- Evaluate & update GMPs
- Establish Preventive Controls
- Implement verification & validation
- Supply Chain updates
- Managing the process to compliance
What’s FDA Up To?

- Fact-finding!
  - Data gathering
  - Market sampling
  - Facility visits

- Inspector training
Some Things We’re Hearing

- Hand washing stations
- Recall plan
- Customer complaints program
- Environmental monitoring & product sampling
Where Do You Fall?

Rules
- Preventive Controls
- Produce Safety
- Foreign Supplier Verification & ATP
- Sanitary Transportation
- Intentional Adulteration

What You Do
- Primary Production Farm
- Secondary Activities Farm
- Mixed-Type Facility
- Processor
- PC with exemption
- Importer
Qualified Individuals

- PCQI: A PC Rule requirement
  “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.” Section 117.3

- Qualified auditors
- Qualified individuals
Training Programs

- Identify & document training needs for each position
- Matrix approach may be helpful
PCQI Tasks – 117.180

Conduct or oversee
- Plan preparation
- Plan reanalysis – 3 years
- Validation of PCs – within 90 days
- Record review – within 7 days
- Written justifications
  - If time frames above not followed
  - If validation is not required
GMP Update

- Additional Focus on allergen cross-contact!
  - Cleaning

- Review:
  - Equipment & tools usage
  - Employee practices
  - Product handling
  - Air handling

- Thorough verification of cleaning effectiveness

- Cleaning chemicals – letter of guarantee
DETERMINING PREVENTIVE CONTROLS
HACCP vs. “HARPC”: Hazard Analysis Comparison

- **HACCP: Focus = CCPs**
  - Builds on existing prerequisite programs (PRPs)
  - Analyzes potential hazards based on existing programs
  - Establishes CCPs to control remaining significant risks, after PRPs are effectively implemented

- **HARPC: Focus = All Preventive Controls**
  - Analyze potential hazards to consumers
  - Identify measures to control those hazards (CCP or other)
  - Manage controls for any “significant hazards” / “hazards requiring a preventive control,” in a manner similar to a CCP
HACCP vs. Preventive Controls

Preventive Controls = CCPs + Some PRPs

Basic GMP

PRPs

HACCP
Hazard Analysis – The Driver

- “Must be written regardless of its outcome”
- Spend time digging
  - FDA web site, RASFF, CFIA
  - USP’s food chemical codex, foodfraud.org
  - Gather data to assess your current controls
- Identify hazards requiring a preventive control
  - Known or reasonably likely to occur
  - Based on severity & likelihood
- Determine controls for them
- Team approach not required but recommended
- Should include radiological, environmental, intentional contamination hazards
Preventive controls & HACCP

Flow Diagram – Process Steps
Ingredients list

Hazard Analysis

Preventive Controls

CCPs

If present, they are a “process control”
Safety

Recalls, Market Withdrawals, & Safety Alerts

Archive for Recalls, Market Withdrawals & Safety Alerts

Search the Firm Recalls Section

Related Links

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program

Recalls & Alerts

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- FDA 101: Product Recalls
- Major Product Recalls
Complete listing of all recalls and allergy

Select from the filters below to specify which recalls you want to review. Additional information reasons filter are found in the recall glossary.

Year: Past 4 months
Reason: All
Class: All
Distribution: All
Public Warning: Yes

Go  Reset the filters
### Search

Enter a search item below.

<table>
<thead>
<tr>
<th>Unique ID</th>
<th>Regulatory Status</th>
<th>Report Type</th>
<th>Ingredient Category</th>
<th>Ingredient</th>
<th>Adulterant</th>
<th>Type of Fraud</th>
<th>Pub Year</th>
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</thead>
<tbody>
<tr>
<td>36550</td>
<td>Food Ingredients</td>
<td>Media</td>
<td>Dairy products and milk derivatives</td>
<td>Yogurt candy</td>
<td>Melamine</td>
<td>Replacement</td>
<td>2014</td>
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<tr>
<td>34198</td>
<td>Food Ingredients</td>
<td>Scholarly</td>
<td>Dairy products and milk derivatives</td>
<td>Yogurt (ovine)</td>
<td>Milk (bovine)</td>
<td>Replacement</td>
<td>2002</td>
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# The format

<table>
<thead>
<tr>
<th>Ingredient/Processing Step</th>
<th>Reasonably foreseeable food safety hazards introduced, controlled or enhanced at this step (B=biological; C=chemical, including radiological; P=physical)</th>
<th>Hazard severity</th>
<th>Is hazard a significant hazard?</th>
<th>Justify your decision for column 4</th>
<th>What preventive control(s) are applied to significantly minimize or prevent the food safety hazard?</th>
<th>Is this step a CCP?</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Ingredient/Processing Step</th>
<th>Identify potential food safety hazards introduced, controlled or enhanced at this step</th>
<th>Do any potential food safety hazards require a preventive control?</th>
<th>Justify your decision for column 3</th>
<th>What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?</th>
<th>Is the preventive control applied at this step?</th>
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Yes | No | Yes | No | Yes | No

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<tr>
<td>C</td>
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<td>P</td>
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</tbody>
</table>

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Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control
## A Combined Approach

<table>
<thead>
<tr>
<th>(1) Ingredient/Processing Step</th>
<th>(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step</th>
<th>(3) Do any potential hazards require a Preventive Control? (FSMA)</th>
<th>(4) Risk Number from Hazard Analysis Matrix (HACCP)</th>
<th>(5) Are any hazards significant? (HACCP)</th>
<th>(6) Justify your decision for columns 3/4</th>
<th>(7) What preventive control measures can be applied to significantly minimize or prevent the hazards?</th>
<th>(8) Is the Preventive Control applied at this step?</th>
<th>(9) Is this step a CCP? If so, what CCP #? (HACCP)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ingredient</strong></td>
<td>B</td>
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<td></td>
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<tr>
<td></td>
<td>C</td>
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<tr>
<td></td>
<td>P</td>
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<td></td>
</tr>
<tr>
<td><strong>Process Step</strong></td>
<td>B</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
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<td>C</td>
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</tbody>
</table>
Required Verification

As appropriate to the facility, the food, and the nature of the control:

- Validation of preventive controls – *process* PCs
- Verification of monitoring and corrective actions
- Calibration of process monitoring and verification instruments
- Product testing, environmental monitoring (exposed RTE Foods)
- Records review
Supply Chain Program

- Must have a risk-based program which ensures hazards are controlled
- Suppliers must be approved
- Must determine, document, and conduct appropriate supplier verification activities
- Controls applied in the supply chain must be verified

- Aligns with Foreign Supplier Verification rule, Accreditation of Third Party Auditors rule, Sanitary Transportation
Downstream control

- If a “hazard requiring a PC” is controlled by your customer (or their customer):
  - Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”
  - Annually obtain from your customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard.
FSV Rule

- Use FDA decision tree to determine applicability
- Controls still driven by hazard analysis
- Determine & document applicable controls based on risk
- Again, approve suppliers before use

- Import documentation format will change
  - To import, obtain a Dunn & Bradstreet DUNS number (importer of record)
Supply Chain - Some Notable Items

- GAP or GFSI are not a FSMA equivalent.
- If a “hazard requiring a PC” is controlled by your supplier, on-site audit is required.
- Items for R&D not applicable.
- Importers are deemed in compliance with most of FSVP when they:
  - Comply with PC supply-chain provisions
  - Implement preventive controls under PC regulation for hazards in food they import
  - Are not required to implement a preventive control under certain PC provisions (food cannot be consumed without further control, or there is a documented control later in the supply chain)
## Managing Supplier Documents

### Supply Chain Documentation

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Item Supplied</th>
<th>FSMA Rule</th>
<th>Compliance Date</th>
<th>Exemptions</th>
<th>Identified Hazards Requiring a PC</th>
<th>Control</th>
<th>Required Document</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanutco</td>
<td>Peanuts - Roasted</td>
<td>Preventive Controls</td>
<td>September-17</td>
<td>None</td>
<td>Salmonella, aflatoxin</td>
<td>Supplier pasteurization, CoA, lab analysis</td>
<td>FSMA compliance audit</td>
<td>3/17/2017</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Validation of roasting process</td>
<td></td>
<td>3/1/2016</td>
</tr>
<tr>
<td>Nutty Neighbors</td>
<td>Peanuts - Raw in shell</td>
<td>Produce Safety</td>
<td>September-19</td>
<td>Very Small</td>
<td>Salmonella, aflatoxin</td>
<td>Pasteurized here or by customer, CoA, lab analysis</td>
<td>Letter of guarantee - FSMA PS compliance</td>
<td>11/15/2018</td>
</tr>
<tr>
<td>Maritime Bliss</td>
<td>Salt</td>
<td>Preventive Controls</td>
<td>September-16</td>
<td>None</td>
<td>None</td>
<td>N/A</td>
<td>Attestation - very small supplier</td>
<td>11/15/2018</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Letter of guarantee</td>
<td></td>
<td>5/1/2016</td>
</tr>
</tbody>
</table>

### Customer

<table>
<thead>
<tr>
<th>Customer</th>
<th>Item Purchased</th>
<th>FSMA Rule</th>
<th>Compliance Date</th>
<th>Exemptions</th>
<th>Identified Hazards Requiring a PC</th>
<th>Control</th>
<th>Required Document</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs. Peanut</td>
<td>Raw peanuts</td>
<td>Preventive Controls</td>
<td>September-18</td>
<td>None</td>
<td>Salmonella</td>
<td>Pasteurization of nuts</td>
<td>Letter of attestation - pasteurization of nuts</td>
<td>3/17/2019</td>
</tr>
</tbody>
</table>

Today's Date: 4/18/2016
Today's Date + 60 Days: 6/17/2016
Pulling it together: Create A To-Do List

- Review the requirements
- Document actions to take
- The list is a communication tool
  - Identify resource needs
  - Hours to implement
  - Hours to maintain
  - Capital improvements
- Track & manage work
- Communicate at-risk items
- Celebrate wins!
# Project Management

<table>
<thead>
<tr>
<th>Item</th>
<th>Hours to Implement</th>
<th>Hours/Month Maintenance</th>
<th>Responsible</th>
<th>Due</th>
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<tbody>
<tr>
<td>PCQI Training</td>
<td>24</td>
<td>N/A</td>
<td>Tom &amp; Selina</td>
<td>May 2016</td>
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<tr>
<td>Hazard Analysis Update</td>
<td>10</td>
<td>N/A</td>
<td>Food Safety Team</td>
<td>July 2016</td>
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<tr>
<td>New Records Reviews</td>
<td>8</td>
<td>4-8</td>
<td>Tom, Selina, Jake</td>
<td>Sept 2016</td>
</tr>
<tr>
<td>Supply chain program</td>
<td>40</td>
<td>5</td>
<td>Tom, Denice</td>
<td>Dec 2016</td>
</tr>
</tbody>
</table>
FDA Guidance

Being prepared for release:
- Hazard analysis and preventive controls
- Environmental monitoring
- Food allergen controls
- Validation of process controls
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.

FDA & FSPCA TANs are available.
In Summary: Your To-Do List

- Determine where you fall & note compliance dates
- Establish training programs & begin to execute
  - PCQI
- Evaluate current GMP programs & update
- Update Hazard analysis, Determine & Document Control Points
  - Determine validations, monitoring, verification, corrective actions
- Document supplier controls based on hazard analysis
- Project management
A Few More Things

- Add facility address to documents
- Ensure HACCP plan is signed by site “agent in charge”
- Review & document retention of records
  - Equipment adequacy
  - Previous versions of documents
  - Pesticide labels
  - Others required by rule
Thank You!

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