What a Preventive Controls Facility Looks Like

FSMA-HARPC vs. HACCP
COMPLIANCE - WHAT'S THE BEST APPROACH?

CCPs

HARPC

GMPs

FDA FOOD SAFETY MODERNIZATION ACT

GLOBAL STANDARD FOR FOOD SAFETY

INTERNATIONAL ALLIANCE

HACCP

SQF INSTITUTE

Food Safety System Certification 22000

GFSi Global Food Safety Initiative
GLOBAL FOOD SUPPLY

THE FOOD SUPPLY NOW IS A GLOBAL ENTERPRISE!
“The Globalization of trade…has increased the chances that the food produced in one place will affect the health and diet of people living in another.”

~Food Safety Magazine (April/May, 2015 Ed.)
• Measures must ensure hazards are **prevented**, or **significantly minimized**

• Preventive controls include:
  – Process controls
  – Food allergen controls
  – Sanitation controls
  – Supply-chain controls
  – Recall plan

• cGMP and hygiene training required as well
• Preventive Controls Qualified Individual (PCQI)
The “HACCP” Rule, aka “HARPC”

- Covers manufacturing, processing, packing, or holding of food
- Exemptions by industry, company size, and activity
- Formal PCQI training
- Regulatory activity has begun!

• Focus on what matters most for food safety!
  - Preventive, not reactive
  - Work in conjunction with and supported by other programs like Good Manufacturing Practices
<table>
<thead>
<tr>
<th>Company Size</th>
<th>Compliance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;500 Employees</td>
<td>Sept. 2016</td>
</tr>
<tr>
<td>&lt;500 Employees</td>
<td>Sept. 2017</td>
</tr>
<tr>
<td>&lt; $1 Million sold or held</td>
<td>Sept. 2018</td>
</tr>
</tbody>
</table>
As appropriate to the facility, the food, and the nature of the control:

- Validation of preventive controls
- Verification of monitoring and corrective actions
- Calibration of process monitoring and verification instruments
- Product testing, environmental monitoring
- Records review
HACCP - Focuses on the Process

- Hazard Analysis
- Critical Control Points (CCPs)
- Critical Limits
- Monitor
- Corrective Action
- Verification & Recordkeeping
PREVENTIVE CONTROLS INCLUDE MORE THAN HACCP

- Hazard Analysis
- Preventive Controls (CCPs, allergen, sanitation, supplier, etc.)
- Parameters & Values
- Monitor
- Corrective Action or Corrections

Verification & Recordkeeping
Food Safety Plan
Including procedures for monitoring, corrective action and verification, as appropriate
<table>
<thead>
<tr>
<th>Element</th>
<th>HACCP Plan</th>
<th>Added in Food Safety Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard analysis</td>
<td>Biological, chemical, physical</td>
<td>Chemical hazards to include radiological; consider economically motivated hazards</td>
</tr>
<tr>
<td>Preventive controls</td>
<td>CCPs for processes</td>
<td>Process CCPs + controls at other points that are not CCPs</td>
</tr>
<tr>
<td>Parameters and values</td>
<td>Critical limits</td>
<td>Parameters and minimum/maximum values (= critical limits for process controls)</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Required for CCPs</td>
<td>Required as appropriate for other preventive controls</td>
</tr>
<tr>
<td>Corrective actions or corrections</td>
<td>Corrective actions</td>
<td>Corrective actions or corrections, as appropriate</td>
</tr>
<tr>
<td>Verification</td>
<td>For process controls</td>
<td>As appropriate for all preventive controls; supplier verification required when supplier controls a hazard</td>
</tr>
<tr>
<td>Records</td>
<td>For process controls</td>
<td>As appropriate for all preventive controls</td>
</tr>
<tr>
<td>Recall plan</td>
<td>Not required in the plan</td>
<td>Required when a hazard requiring a preventive control is identified</td>
</tr>
</tbody>
</table>
Preventive Controls = CCPs + Some PRPs

HACCP VS. PREVENTIVE CONTROLS

HACCP

PRPs

Basic GMP
New additions ("HACCP +")
- Focus on allergen cross-contamination
- Microbiological risk / environmental contamination
- Radiological hazards (if present)
- Economically motivated hazards

Identifying preventive controls, not just CCPs
FOOD SAFETY PLAN: THE PROCESS

Flow Diagram – Process Steps
Ingredients list

Hazard Analysis

Preventive Controls

CCPs

If present, they are a “process preventive control”
## HAZARD ANALYSIS - COMBINED APPROACH

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

<table>
<thead>
<tr>
<th>PRODUCT:</th>
<th>PLANT NAME:</th>
<th>ADDRESS:</th>
<th>PAGE 1 of X</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISSUE DATE</td>
<td>mm/dd/yy</td>
<td>SUPERSEDES</td>
<td>mm/dd/yy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Process Control</th>
<th>Hazard(s)</th>
<th>Critical Limits</th>
<th>Monitoring</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>What</td>
<td>How</td>
<td>Frequency</td>
<td>Who</td>
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</tr>
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</table>
## Process Preventive Controls

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<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 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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cook</strong></td>
<td>Survival of vegetative pathogens such as <em>Salmonella</em></td>
<td>Yes</td>
<td>X</td>
<td>Thorough cooking is required to kill vegetative pathogens</td>
<td>X</td>
</tr>
</tbody>
</table>

### Process Control Form

<table>
<thead>
<tr>
<th>Process Control</th>
<th>Hazard(s)</th>
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<th>Corrective Action</th>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CRITICAL LIMIT DEFINITION

HACCP:

- A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. (NACMCF, 1997)

- A criterion which separates acceptability from unacceptability (Codex Alimentarius)
PC Rule:

- The maximum or minimum value, or combination of values, to which any biological, chemical or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.
  - Derived from 21 CFR 117.135(c)(1)(ii)
<table>
<thead>
<tr>
<th>Information Source</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td>Hazard Guides; guidelines, tolerances and action levels; Food Code; Pasteurized Milk Ordinance (PMO); Acidified Foods regulations</td>
</tr>
<tr>
<td>Other regulatory guidelines</td>
<td>State and local regulations, tolerances and action levels; USDA regulations, tolerances and action levels</td>
</tr>
<tr>
<td>Experts (internal and external)</td>
<td>Process authorities, university food scientists/microbiologists, consultants, equipment manufacturers, sanitarians, trade associations</td>
</tr>
<tr>
<td>Scientific studies</td>
<td>In-house experiments, 3rd party challenge studies (universities or contract labs)</td>
</tr>
<tr>
<td>Scientific literature</td>
<td>Peer reviewed journals, food science texts, microbiology texts, Food Safety Preventive Controls Alliance information</td>
</tr>
</tbody>
</table>
ELEMENTS OF MONITORING

ELEMENTS:
1. **What** to monitor
2. **How** to monitor
3. Frequency to monitor
4. **Who** will monitor

"Qualified Individual"

WHAT:
- “on and functioning” (metal detector)
- “in place and intact” (screen)
- “presence of supplier guarantee” (Load basis)

HOW:
- In-line analyzer
- “Real time” laboratory analysis
- Visual checks
- On-line measurements
**Corrective action**
- Procedures that must be taken if preventive controls are not properly implemented.
  - from 21 CFR 117.150(a)(1)
  - Example: piece of equipment is consistently found dirty on pre-op, or individual consistently not cleaning equipment adequately.

**Correction**
- An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).
  - 21 CFR 117.3
  - Example: During pre-op inspection a piece of equipment is found to be a little dirty.
Two Main Requirements:

1. Preventing allergen cross-contact
   - Clean shared equipment – potential sanitation controls
   - Properly manage rework
   - Avoid in-process or post-process allergen cross-contact

2. Accurate allergen labeling of finished food
   - Ensure labels are correct – potential supply-chain program
   - Ensure the correct label or package is used

• Human error can be involved – training is essential!
*Ensure all allergens are identified in compliance with appropriate law:

**FALCPA* Required Food Allergen Labeling**

- Milk
- Egg
- Peanut
- Tree nuts (species specific)
- Fish (species specific)
- Crustacean shellfish (species specific)
- Wheat
- Soy

* Food Allergen Labeling and Consumer Protection Act

Photo Sources: Microsoft Clip Art and KMI Swanson (soybeans)
**ALLERGEN CONTROL FORMS**

E.G. Food Company Example

<table>
<thead>
<tr>
<th>Allergen Control</th>
<th>Hazard(s)</th>
<th>Criterion</th>
<th>What</th>
<th>How</th>
<th>Frequency</th>
<th>Corrective Action</th>
<th>Verification</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergic packaging (labeled carton)</td>
<td>Undeclared allergens – egg, milk, soy (wheat in biscuit only)</td>
<td>All finished product labels must declare the allergens present in the formulation listing</td>
<td>Visual check of carton</td>
<td>Before release to production</td>
<td>Label coordinator</td>
<td>Review of Label verification, Corrective Action and Verification records within 7 working days</td>
<td>Allergen Label Verification listing; Allergen Label Verification log; Corrective Action records;</td>
<td></td>
</tr>
</tbody>
</table>

Accurate Labeling – upon receipt of packaging materials

Accurate Labeling – finished goods at consumer level
Relevant Hazards and Conditions

- Environmental pathogens when RTE product is exposed to the environment prior to packaging
  - E.g., *Salmonella* and *L. monocytogenes*

- Pathogens transferred through cross-contamination
  - E.g., from insanitary objects or employees handling raw and processed product

- Food allergen cross-contact
  - Unintended milk, soy, egg, fish, crustacean shellfish, wheat, peanut or tree nut cross-contact
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<th>Ingredient/Processing Step</th>
<th>(2) Identify potential food safety hazards introduced, controlled or enhanced at this step</th>
<th>(3) Do any potential food safety hazards require a preventive control?</th>
<th>(4) Justify your decision for column 3</th>
<th>(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <em>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</em></th>
<th>(6) Is the preventive control applied at this step?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assemble, wrap</td>
<td>Introduction of environmental pathogens such as <em>L. monocytogenes</em></td>
<td><strong>X</strong></td>
<td>Recontamination may occur if sanitation control is not in place.</td>
<td><strong>Sanitation Controls</strong> – prevent recontamination</td>
<td><strong>X</strong></td>
</tr>
<tr>
<td>C</td>
<td>Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit</td>
<td><strong>X</strong></td>
<td>Biscuits could introduce wheat allergen to other products without control</td>
<td><strong>Sanitation and Allergen Controls</strong> – prevent cross-contact</td>
<td><strong>X</strong></td>
</tr>
</tbody>
</table>
Procedures, practices and processes for:

• Cleanliness of food-contact surfaces
• Prevention of allergen cross-contact and cross-contamination
• From insanitary objects and personnel to food, food packaging material, other food contact surfaces
• From raw product to processed products

* When hazard analysis identifies a hazard requiring a preventive control
Environmental Monitoring

• If applicable, required to verify the effectiveness of preventive controls for environmental pathogens
  – E.g., facilities where *ready-to-eat* product is exposed to the environment
• Must be tailored to each facility
• A useful program diligently *tries to find* the organism and addresses issues identified!

*Ready-to-eat food (RTE food)* means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.
Risk-Based on Hazard Analysis:

- The hazard analysis identifies hazards requiring a supply-chain-applied control

- An ingredient may not have a hazard requiring a preventive control; e.g., vinegar

- A hazard requiring a preventive control that is associated with an ingredient or raw material may not require a supply-chain program; e.g.,
  - Pathogens that will receive a validated kill step in your facility
WHO CONTROLS THE HAZARD?

- **Supplier**
  - Manufacturer, processor
  - Raise the animal
  - Grow the food

- **Receiving Facility**
  - Manufacturer, processor

- **Customer**
  - Manufacturer, processor or preparer
SUPPLY-CHAIN PROGRAM GENERAL REQUIREMENTS

Use approved suppliers

Determine supplier verification activities

Conduct supplier verification activities

Document supplier verification activities

When applicable, verify a supply-chain-applied control applied by an entity other than your supplier
ONSITE AUDIT REQUIREMENTS

- For serious hazards requiring a supply-chain-applied control (refer to Reportable Food Registry for what a serious hazard would be)
  - Documented onsite audit before using the raw material
  - At least annually after the initial audit

- Must use a qualified auditor

- Review supplier’s written HACCP or other Food Safety Plan and implementation documents for hazard identified in your hazard analysis
Recall Plan Requirements

- Required for any food with a hazard requiring a preventive control
- Must be written
- Must describe steps to take and assign responsibility to:
  - Notify direct customers and consignees
  - Notify the public, when appropriate
  - Conduct effectiveness checks
  - Execute disposition of food
What Records Are Required?

Food Safety Plan

- Hazard analysis
- Preventive controls
  - Process preventive controls
  - Allergen preventive controls
  - Sanitation preventive controls
- Supply-chain program requirements
- Recall plan
- Monitoring procedures
- Corrective action procedures
- Verification procedures
The Food Safety Plan must be signed and dated by owner, operator or agent-in-charge **of the facility**
- Upon initial completion
- After modifications are made

Intent is to keep management informed of changes

Also indicates support, commitment to company employees and others
FROM PCQI - BASIC INFORMATION ON RECORDS

- Name of record
- Name and location of facility (address is usually expected – see 117.305)
- Date and, when appropriate, time of activity documented
- Actual measurement or observation taken, as applicable
  - True record – not copied over from temporary notes
- Product identification, if applicable
- Signature or initials of the person performing the monitoring activity
- Signature or initials of the person reviewing the record, and date of the review
• Determine where you fit in
• Get training, and train your staff
  – PCQI, GFSI, HACCP training
• Evaluate current programs
• Develop your checklist and act on it
• Contact us for help!