HACCP Today:

Critical Controls Concepts

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Jeff Chilton, VP of Professional Services
Alchemy Systems

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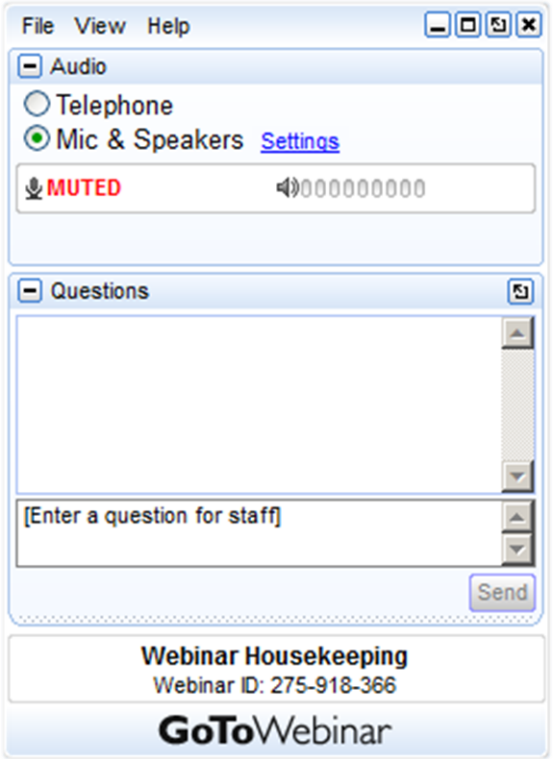

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Today's Speaker

Jeff Chilton
VP of Professional Services

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AGENDA

- Why HACCP?
- HACCP Fundamentals
- HACCP Compliance Tips
- Common HACCP Mistakes
- Measuring HACCP Effectiveness
- HACCP Reassessments
- HACCP Resources
- Questions

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Why HACCP?

- **HACCP is**
  - **Your process control system** to assure no foodborne illness outbreaks occur from your facility
  - **Your insurance policy** to protect your business, brand, and consumers
- **HACCP is**
  - Necessary to meet regulatory requirements and customer/audit expectations
  - Endorsed by CODEX, NACMCF, and GFSI
  - Mandated for USDA & FDA regulatory requirements

HACCP FUNDAMENTALS

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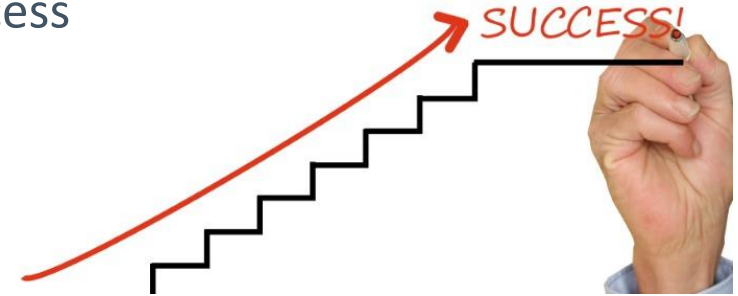
2 Pillars of HACCP Success

1. **Management Commitment & Support (Top -> Down approach)**
   - Dedicated resources and budget for employee training and capital expenditures

2. **Effective Prerequisite Programs, Monitoring, and Record-Keeping for:**
   - Calibration
   - Foreign Material Control
   - GMP's
   - Maintenance
   - Pest Control
   - Product Labeling
   - Sanitation
   - Storage/Transport
   - Supplier Approval
   - Training
   - Waste Disposal
   - Water Pot-ability

5 Preliminary Steps to HACCP

1. Assemble the HACCP Team
2. Describe the food and it's distribution
3. Describe the intended use and consumers
4. Develop the Flow Diagram of the process
5. Verify the Flow Diagram of the process



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7 Principles of HACCP

1. Conduct a Hazard Analysis
2. Determine the Critical Control Points (CCP's)
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Verification Procedures
7. Establish Record-keeping Procedures

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HACCP COMPLIANCE TIPS

Monitoring

- Understand why you are monitoring
- Identify the best monitoring procedure and determine frequency
- Clearly identify employees that will perform monitoring
- Train the employees on testing procedures, critical limits, how to record results, and corrective actions
- Review how to record the information to assure records are complete, accurate and timely
- Sign-off on records

Corrective Action (FSIS Regulation 9 CFR 417.3)

Records MUST document:

- The cause of the deviation is identified and eliminated
- The CCP will be under control after the corrective action is taken
- Measures to prevent recurrence are established
- No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce

Types of Verification – Know the Difference!

- 3 Types of CCP Verification are required by 9 CFR 417.4
    1. Direct Observation of Monitoring
    2. Record Review
    3. Calibration of Monitoring Instruments
- Verification of the overall HACCP System, at least annually
- Validation of critical limits, critical operational parameters, and HACCP System
- Regulatory verification

Record Keeping

- It is imperative that HACCP records are complete, accurate and timely!
  - Correct dates
  - Actual times are recorded
  - There are no missed monitoring checks
  - Critical limits are achieved
  - Records are reviewed
- Count on HACCP records to prove your products are safe
- HACCP records demonstrate compliance to regulations
- Remember, HACCP Records are legal documents

COMMON HACCP MISTAKES

Common HACCP Mistakes

- Not including all process steps in flow charts, including rework, returned product, water, air & gasses
- Not correlating Hazard Analysis Worksheet steps with your flow chart steps
- Not identifying or specifying the correct biological, physical, or chemical hazards specific to the type of pathogens or foreign materials of concern
- Too many or too few Critical Control Points (CCP's) identified

Common HACCP Mistakes

- Not fully defining CCP Procedures in HACCP plan summaries
- Insufficient records - not complete, accurate, or timely
- Not completing your HACCP plan reassessments when necessary
- An improperly documented HACCP plan validation

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MEASURING HACCP EFFECTIVENESS

HACCP Metrics Overview

- Suppliers should set objectives for their food safety and quality systems with measurable metrics and specific goals

- Objectives should be routinely measured against goals to assess the performance of the food safety and quality systems
  - Recommended monthly or quarterly, but no less than annually

- Results and trends should be analyzed to identify continuous improvement opportunities for the food safety and quality management system

HACCP Metrics

- **Recalls** – zero tolerance goal!
- **Audit results** – passing within top two scoring tiers
- **External and internal audit non-conformances identified** – quantity and trends
- **Customer Complaints** – based on % targeted improvement over baseline results
- **Non-Conforming Product** - # incidents and based on % targeted improvement over baseline results
- **CCP Deviation History** - # of deviations

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HACCP Metrics

- **USDA NR's Non-Compliance Records** – quantity and % targeted improvement over baseline results
- **Vendor Non-Conformances** - # of incidents, trend analysis and % targeted improvement over baseline results
- **SSOP Results** – number of pre-operational and operational sanitation deficiencies, based on % targeted improvement over baseline results
- **Microbiological Results** – finished product testing % compliance within specification; food contact surface and environmental testing & compliance with goals
- **Corrective Action Results** - # incidents and effectiveness evaluation to prevent recurring deficiencies

HACCP Management Reviews

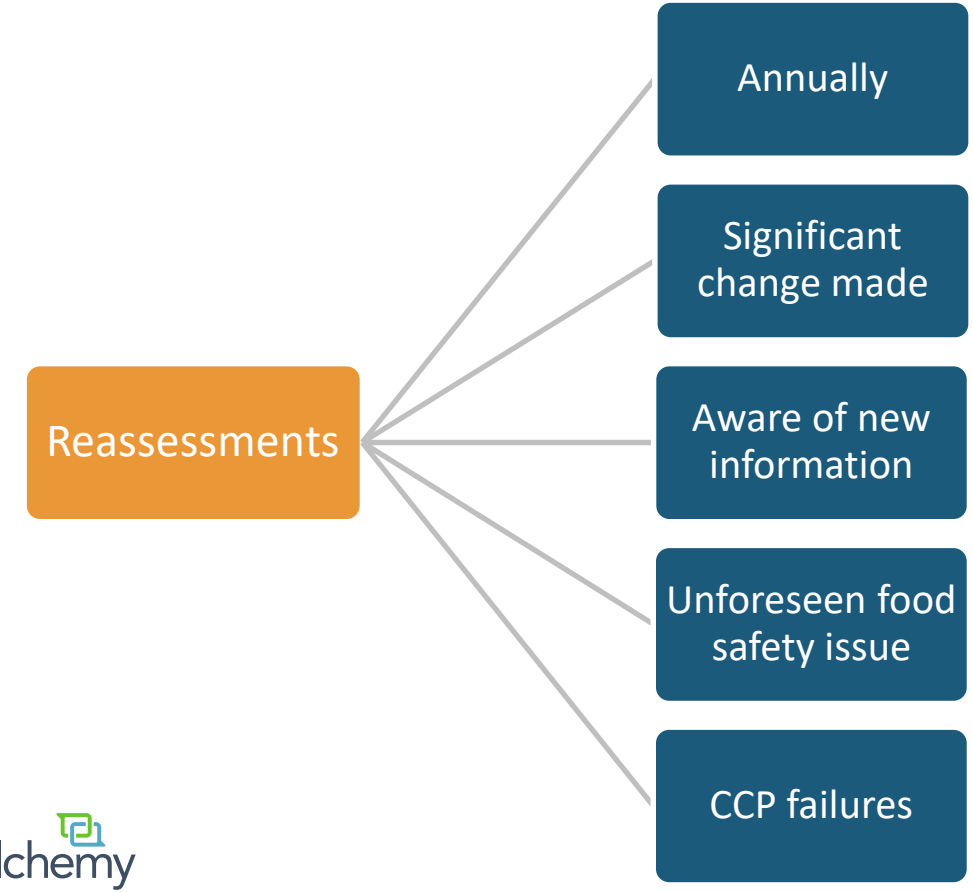
- Management reviews of the results should be completed at least quarterly
- HACCP team and senior management should participate in the reviews
- Consider inputs of results and necessary outputs to address problem areas and drive continuous improvements

Food Safety & Quality System Automation

- QA departments manage huge volumes of information related to supply chain management, written programs, records, and microbiological results
- Paper records can be replaced with electronic records
- It is highly recommended that you electronically automate food safety and quality systems with software that manages the processes, such as Safety Chain, Safe Food 360, TraceGains and Intelex
- Trend analysis of results can be completed to drive continuous improvement

HACCP REASSESSMENTS

HACCP Reassessment Overview



- Perform before a change is operative and within 90 days of a new plan
- Revise the HACCP Plan if a significant change is made or document basis for no revision
- Performed by a HACCP trained individual
- USDA or FDA determines if it is necessary to respond to new hazards or developments

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Annual HACCP Reassessments Should Assess:

- Written HACCP Plan
- HACCP Records
- SSOP and SSOP Records
- CCP Verification Audits
- Pre-op and Operational Sanitation Audits
- Prerequisite Programs
- Microbiological Results
- Annual HACCP Plan Reassessment Checklist
- Reassessment Report and Validation Reference Report
- HACCP Plan Reassessment Validation Worksheet

Types of HACCP Plan Validation

- **Element 1**
  - External Validation (Scientific Supporting Documentation) that support the hazards, CCP's, and critical limits selected
    - Regulatory requirements
    - Regulatory guidelines
    - Scientific studies
  - Note: If used, it is imperative your products and processes exactly match the parameters of the references cited (temp, time, PSI, pH, Aw, etc.)

- **Element 2**
  - Internal Validation (Initial Validation)
    - For USDA regulated facilities and as a best practice
    - Plant studies or laboratory challenge studies that demonstrate adequate control based on your specific critical operational parameters (Combase, plant trial validations, challenge studies)

HACCP Reassessments

- **Do**
  - Review the written HACCP plan and SSOP
  - Review 60 days of HACCP records
    - SSOP and SSOP Records
    - CCP Verification Audits
    - Pre-op and Operational Sanitation Audits
    - Prerequisite Programs
    - Microbiological results
- **Don’t**
  - Just changed the date on a cover page and re-sign it
  - Forget to verify the flow chart

HACCP RESOURCES

NEW! Basic HACCP eLearning Course

- Accredited by the International HACCP Alliance
- Receive a certificate of completion
- Teaches you how to develop & implement an effective Food Safety Plan based on CODEX HACCP specifications, which is required by the four major GFSI schemes
  - **SQF, BRC, FSSC 22000, and IFS**

Learn more at: https://academy.alchemysystems.com/basic-haccp-course/

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