Validation and Verification Basics for a HACCP System

Presented by Stephens Guidry, SGS North America
Brief history of SGS in Florida citrus feed industry

- With more than 1,650 offices/laboratories worldwide and over 80,000 employees, SGS is one of the largest independent inspection, testing, and certification companies in the world.

- SGS international headquarters is located in Geneva, Switzerland.
Brief history of SGS in Florida citrus feed industry

- **SGS North America** corporate headquarters is located in Rutherford, NJ and oversees the operation of multiple companies dedicated to providing expert independent services to a wide variety of industries. Areas of SGS expertise based in North America include, but are not limited to:

- Traditional agricultural operations (inspection, testing, and certification of products ranging from raw agricultural materials to ready to eat finished products)
- Certification of facilities to international and local standards including ISO, HACCP, JPA, Identity Preserved Systems, etc.
- Minerals and chemicals (inspection and testing)
- Petroleum Industry (inspection and testing)
Brief history of SGS in Florida citrus feed industry

- Approximately 15 years ago, following a rash of animal feed safety incidents, EU nations (a large market for Florida citrus pulp pellets) began a major push to insure the safety of imported animal feed ingredients.

- Feed ingredient suppliers which were not certified to one of the EU recognized feed safety systems such as GMP+ International (formally PDV), Coceral, Fami QS, Ovocom, etc ran the risk of having their product placed on hold upon arrival at the discharge port until sampling and testing confirmed EU compliance for the ingredient.

- HACCP programs for the juice side had been in place for years and, in general, were mature systems. However, the same could not be said for the feed mill side of the industry.
Brief history of SGS in Florida citrus feed industry

- In addition to compliance to the EU requirements, the industry must also take into consideration the developing requirements for The Food Safety Modernization Act (FSMA)
OVERVIEW

To provide a basic understanding of the differences of three interrelated elements of a typical HACCP plan which are commonly confused:

1. Monitoring
2. Verification
3. Validation
WHY USE HACCP?

- HACCP is a tool that allows companies to examine their entire process to determine if they can produce a safe and compliant product for their intended market.

- Fully implemented HACCP plans allow companies to monitor the production process to assure compliance to established requirements.

- In many cases use of HACCP is driven by legislative requirements.
DEFINITION OF HACCP

HACCP =
- Hazard
- Analysis
- Critical
- Control
- Points
SEVEN PRINCIPLES OF HACCP

1. Conduct a hazard analysis
2. Determine Critical Control Points
3. Establish critical limits
4. Establish monitoring programs
5. Establish corrective actions
6. Establish verification procedures
7. Establish record keeping and documentation procedures
12 STEPS OF HACCP

1. HACCP team
2. Product identification
3. Intended use for your product
4. Diagram the process (theoretical)
5. Confirmation of flow diagram (actual)
6. Identify potential hazards for each step of process and conduct a hazard analysis
12 STEPS OF HACCP

7. CCP determination
8. Critical limit determination
9. Create a monitoring system
10. Corrective action procedure
11. Verification procedures
12. Documentation and record keeping
WORKING PERSON’S DEFINITION OF HACCP

- Hard
- Agonizing
- Confusing
- Complicated
- Paperwork
KEY DEFINITIONS

Monitoring

- Conducting a planned sequence of observations or measurements to control defined parameters
- Used to assess if the CCP, CP, or pre-requisite program is under control
- For process or pre-requisite program deviations, recording of the corrective and preventative actions must occur
- Producing an accurate record of the monitoring activity
EXAMPLE OF MONITORING

- A temperature reading, taken with a properly calibrated thermometer, must be obtained from the center of the flow of the product at a specified location every 15 minutes by a trained employee with results recorded on the specified form.

- Monitoring is a real time activity.
Verification

- Verification is the act of reviewing the monitoring documentation to determine if the monitoring tasks as set forth in the HACCP plan are being followed.

- Two types of verification:
  1. **Record verification**: A documented review of a specified time period of production records generated by the trained monitoring employee. This is not a real-time activity.
  2. **On-site verification**: Real-time observations and interviews of monitoring personnel to ensure compliance with monitoring and recording requirements. Interviews should include an evaluation of the employees knowledge of corrective action procedures in the event of a deviation in their respective area.
EXAMPLE OF RECORD VERIFICATION

- A documented examination, by a trained reviewer, of a 24 hour temperature log for the following:
  - Measurements were taken by trained employees using properly calibrated equipment
  - Temperature guidelines have been met
  - All required records have been filled out completely and are traceable to the trained employee
  - In the event of a deviation, specified corrective actions have been implemented and documented
KEY DEFINITIONS

Validation

- Validation is confirming that the elements of the HACCP system are effective in controlling biological, chemical, and physical hazards.

- **Question**: Why don’t you see validation listed in the 7 HACCP Steps?
  
  **Answer**: Validation is an element of verification (HACCP Step 6) which makes use of the many elements to determine if the HACCP plan is adequately controlling the hazards determined by the facility's risk assessment.

- Validation is normally performed by the trained HACCP team in house and/or thru the use of qualified consultants.
VALIDATION

- All HACCP systems require initial validation prior to implementation, as well as periodic validation (usually annually at a minimum)

- The HACCP system must be revalidated after changes in the process or equipment
In order to ensure a complete validation of the existing or new HACCP plan, the following elements, at a minimum, should be taken into account during the review:

- **Hazard analysis**
  - Does the current hazard cover all the risks you have determined for your process?

- **Flow/process diagrams**
  - Physically verify existing diagrams

- **CCPs**
  - Are CCPs clearly identified within the system

- **Critical Limits**
  - Are limits clearly specified with corrective action procedures in place to address deviations?
KEY ELEMENTS OF VALIDATION

- Monitoring activities
  - Are monitoring activities consistently being carried out in accordance with the requirements of the plan?
  - Are verification activities being carried out in accordance with the requirements of the plan?

- Review of deviations
  - Are all deviations being handled in accordance with the prescribed corrective action plans?
  - Is documentation present to confirm compliance with the prescribed corrective action plan?

- Complaints
  - Have customer complaints been examined to determine if changes in the current process are required?
KEY ELEMENTS OF VALIDATION

- Changes in legislation
  - Is your plan in compliance with current legislation?

- New scientific data
  - Has new scientific data been released which may require changes to your plan?

- Results of internal and external audits
  - Have audits revealed non-compliances to your system?
  - Are the non-compliances isolated instances or systematic problems?
DURING THE AUDIT

What does an auditor want to see during a HACCP audit?

- Honest
- Accurate
- Complete
- Concise
- Paperwork
REFERENCES

- University of Florida, IFAS Extension: Hazard Analysis Critical Control Points (HACCP)
- Codex Alimentarius: Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application
- Food Safety and Inspection Service: Hazard Analysis and Critical Control Point (HACCP) Systems
- NACMCF: HACCP Principals and Application Guidelines
- Government of Saskatchewan: Monitoring, Verification, and Validation (Sept 2012)
Thank you!

Questions?

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