A Guide for Auditing HACCP
And Your Other Food Safety Programs

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A lot of effort is put into collecting data for prerequisite programs and the HACCP plan. How much effort do you put into analyzing the data from all these programs? Do you link programs and look for trends or indicators? For example, what type of data do you collect to document the effectiveness of your sanitation program? Do you look for how these results may impact other programs such as your *Salmonella* tests, *E. coli* tests, employee training issues, NRs, consumer complaints, etc. Do you categorize your NRs and look for trends or see if data collected from any of your programs might have predicted the NR?

It is important for each plant to conduct internal audits of how well their HACCP System is working. Your HACCP System includes your HACCP plan as well as your prerequisite and other programs. When the Food Safety and Inspection Service (FSIS) makes a visit to your plant to review and evaluate your HACCP plan, they will look at all your supporting programs, as well as your HACCP plan.

When reassessing your HACCP plan this year, audit your entire food safety system and pay particular attention to validation interactions between your HACCP plan, prerequisite programs, and any other food safety related programs you have in place. These preventive activities will help you insure the safety of your products; better prepare you for the inevitable visit from FSIS to review your food safety programs.

Let's take a step by step look at your HACCP plan. Each HACCP component will be addressed separately. By following the guidelines and answering the questions as they relate to your HACCP plan, you will be able to conduct a systematic audit of your plan. Granted the process is time consuming, but the results are well worth your time. Most of the process in this guideline is the same process FSIS would go through when reviewing your plan.

Hazard Analysis

Before reviewing your hazard analysis, let's review the definitions of a food safety hazard as it is defined in 9 CFR 417.1. **A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.** When reviewing your hazard analysis records determine whether the

analysis considered those properties that have a real chance of occurring in the food or in the processing of the food, and of causing the food to be unsafe. The hazard must be one that would be identified by a reasonable consideration of the food, how it is processed, and where safety issues can arise. The fact that it is possible to imagine a hazard (e.g., a meteor may fall onto the plant) does not mean that the hazard analysis must address that hazard.

In some cases you may wonder whether something is a hazard if it can be controlled with a prerequisite program. USDA held a public hearing in Omaha, Nebraska which involved a lengthy discussion hazards and HACCP prerequisite programs. The "rule of thumb" for whether or not a hazard should be a CCP or if it could be covered by prerequisite programs was discussed. The consensus seemed to be if the hazard was prevented by one prerequisite program it should probably be a CCP.   If the hazard is not reasonably likely to occur due to a series (more than one) of prerequisite programs you have in place, then it would not need to be a CCP. The use of prerequisite programs to control hazards has always been an issue for some time. This "rule of thumb" seemed to be agreeable to most people at the meeting.

Ask yourself the following questions:

1. Do you have a written HACCP plan for each of your products?

2. Does the hazard analysis identify the intended use or the consumers of the finished product?

3. Does your analysis start by identifying all hazards that may occur?

4. Does the hazard analysis identify preventive measures you can apply to the food safety hazards?

5. Does the hazard analysis include a flow chart that describes (diagrams) the steps of each process and production flow in the plant?

6. Does the result of your hazard analysis reveal that one or more food safety hazards are reasonably likely to occur?

7. Have you conducted validation activities to determine whether the HACCP plan will function as intended?

8. Do you have subsequent records that support the adequacy of corrective actions in achieving control at a CCP after a deviation from a critical limit has occurred?

9. Did your records reveal any unforeseen hazards? If so, do you need to include control measures in your HACCP plan to prevent the unforeseen hazards from reoccurring?

Monitoring

You should use the same thought process and methodology as FSIS reviewers when you evaluate your monitoring procedures. In verifying the monitoring requirement, you should answer to the following questions:

1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits?

2. Are the monitoring procedures being performed as described in the HACCP plan?

3. Are the monitoring procedures being performed at the frequencies for the CCPs listed in the HACCP plan?

4. Do your monitoring records of CCPs show conformance with critical limits?

5. How many deviations do you have for each of your CCPs?

6. Did you receive any NRs related to monitoring?

7. Were there any record keeping errors? Were corrective action procedures recorded for record keeping errors?

When conducting your audit, you should:

- Review the HACCP plan to determine whether the HACCP plan design includes the monitoring procedures and frequencies that are used to monitor the critical control points.

- Observe the employee performing the monitoring activities listed in the plan to determine whether the procedures are being executed as written in the HACCP plan. Review records showing the employee responsible for monitoring has been trained. Note what other employees have been trained to perform monitoring activities.

- Based on reviewing the monitoring records or on the basis of observing the establishment performing the monitoring procedures, determine whether the monitoring procedures are being performed at the frequencies specified in the HACCP plan.

Corrective Actions

As a follow-up to your review of monitoring activities, you need to further evaluate any deviations you observed.

Research the answers to the following questions:

1. How many deviations were observed for each CCP over a set period of time (i.e., one month)? For each deviation you found ask:

   i. Did you identify the cause of the deviation(s)?

   ii. Did the corrective action eliminate the cause of the deviation?

   iii. Did the corrective actions ensure that the CCP was brought under control?

   iv. Were measures implemented to prevent recurrence of the deviation?

   v. Did the actions ensure that no product that was injurious to health or otherwise adulterated, as a result of the deviation, enter commerce?

2. Do you see any trends in your deviations? Were more deviations observed at any given time of the day, any particular shift, any particular root cause, product from a specific farm, etc.? When looking for trends, try to trace/link deviation to any records you may have available to you such as product source (farm), equipment malfunction, sanitation, deviations in GMP or prerequisite programs, etc. It is important to look across programs to see if a deviation in one program (i.e., sanitation or other prerequisite programs, receiving records (farm and/or farm service records, etc.) impact CCP deviations, *Salmonella,* or generic *E. coli* testing results. By putting in the effort to link all the records you have, you may be able to make some changes that will improve your overall results. For example, if you have farms which consistently supply you with highly contaminated birds/animals you may want to process those birds/animals last reducing the possibility of cross contaminating less contaminated carcasses with dirty equipment.

3. Did you receive any NRs related to corrective actions? If so, how many? Were any linked?

4. Were there any record keeping errors?

5. If any deviations were due to an unforeseen hazard, was a reassessment done to determine if a critical control point should be added to control the hazard in the future?

Verification

How do you go about auditing the verification requirement? You should use the same thought process and methodology. You should review the HACCP plan, review HACCP records, and observe employees performing verification activities. Review the HACCP plan to determine whether it lists direct observation procedures and frequencies, records review procedures and frequencies, and process monitoring calibration verification procedures and frequencies. Observe all employees performing the verification activities listed in the plan to determine whether the procedures are being executed as written in the HACCP plan. Review the HACCP records or observe the employee performing the verification procedures to determine whether the verification procedures are being performed at the frequencies specified in the HACCP plan. If you have included an alternative generic *E. coli* sampling frequency into the HACCP plan (see 9 CFR 310.25(a)(2)(iv) or 381.94(a)(2)(iv)), you will need to confirm that the alternative is an integral part of the verification procedures for your HACCP plan. If you included product sampling in the HACCP plan, you should observe the employee taking samples and review the results. If you received positive results, you should verify the corrective action requirements of 9 CFR 417.3(b) are met.

The following questions may assist you in your audit of verification activities:

1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?

2. Are process-monitoring instrument calibration activities conducted as per the HACCP plan?

3. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions?

4. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?

5. Does the HACCP plan list product sampling as a verification activity?

6. Are direct observation verification activities conducted as per the HACCP plan?

7. Are the records generated being reviewed?

8. Are pre-shipment sign-off records reviewed periodically?

9. Were any deviations found? If so, were they analyzed for trends? Were they correlated with records from other programs?

NOTE: If a plant only has one employee, it would not be possible for that person to conduct a direct observation of the monitoring activity. In this situation, the HACCP plan would not need to list a direct observation of the monitoring activities. The direct observation ongoing verification activity should be designed for the plant verifier to directly observe the plant employee conducting the monitoring activity. A plant verifier conducting the same activity as the monitor does not meet the regulatory requirement for the direct observation verification activity described in 9 CFR 417.4(a)(ii).

You should document any noncompliance you find and look for correlation with deviations in the HACCP plan and/or other related programs.

Recordkeeping

You will need to verify that you are meeting the recordkeeping requirements. You can do this by reviewing the HACCP plan, hazard analysis, HACCP records, supporting documentation, and decision-making documents. You should review the HACCP plan to verify that it lists the records used to document the monitoring of the CCPs. You should review the HACCP records to verify that the actual values and observations that were obtained during the monitoring activities were recorded. The following questions may be helpful in carrying out this verification task:

1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?

2. Do the records document the monitoring of CCPs and their critical limits?

3. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan?

4. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date the record was made?

5. Are the verification procedures and results of those procedures documented?

6. Is the time recorded when the verification activity was performed?

7. Does the record contain the date the record was made?

8. Are the process-monitoring calibration procedures and results being recorded?

   - Was each entry on the record made at the time the event occurred?

- Does each entry include the time?
- Was each entry on the record signed or initialed by the establishment employee making the entry?

9. If records are maintained on a computer, have appropriate controls been implemented to ensure the integrity of the electronic data and signatures?
   - How do you ensure the integrity of your data?

10. Are records kept for the appropriate length of time?

    - Are the records kept on-site for 6 months?
    - If the records are stored off-site after 6 months, can they be retrieved in 24 hours?

11. Have you reviewed the records associated with the production of the product, prior to shipment?

12. Has the pre-shipment review been signed and dated by the appropriate employee?

Validation

You must have documentation that addresses the requirement in 9 CFR 417.4(a) that "every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis."

You should verify these requirements by reviewing the hazard analysis, supporting documents for the hazard analysis, HACCP plan, decision-making documents associated with the selection and development of the CCPs and critical limits, supporting documentation for the verification procedures and frequencies, and supporting documentation for the monitoring procedures and frequencies. You should have sufficient supporting material should an inspector or FSIS reviewer request supporting documents when he or she questions whether a decision made by the plant is the appropriate one.

When FSIS reviews your validation materials there are three possible outcomes. Those three outcomes are compliance with the requirements, noncompliance with the requirements, and an inability to determine whether there is compliance because more information is needed. The HACCP 01 procedure is documented as performed when the requirements are met. The CSI issues an NR when there is noncompliance with the requirements. A 30-day reassessment letter will be issued to the plant when there is not enough information available to determine whether the HACCP plan complies with 9 CFR 417.

Verify compliance

    You will need to verify these requirements by reviewing the hazard analysis, supporting documents for the hazard analysis, HACCP plan, decision making documents associated with the selection and development of the CCPs and critical limits, supporting documentation for the verification procedures and frequencies, and supporting documentation for the monitoring procedures and frequencies. The following questions may be useful in verifying the recordkeeping requirements:

1. Do you have the supporting documentation for the decisions made in the hazard analysis?

2. Do you have the decision-making documents associated with the selection of each CCP?

3. Do the documents explain why you selected that location for the CCP?

4.   Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?

5. Do you have scientific, technical, or regulatory support for the critical limit?

6. Is the support credible? It should be from a recognized source.

7. Do you have documents supporting the monitoring procedures and frequencies listed in the HACCP plan? As a part of the audit procedure you could perform a monitoring check between the scheduled performances of monitoring procedure. If you find a deviation from the observation or from a records review, you should confirm that a corrective action has been documented.

8. Do you have documents supporting the verification procedures and frequencies listed in the HACCP plan?

9. Do supporting documents support the decisions?

You should document any noncompliance identified.

Reassessment

    The reassessment requirement cannot be randomly verified because reassessment occurs when something triggers it, e.g., a deviation not covered by a specific corrective action or an unforeseen hazard, etc. You are required to document its reassessment when it is triggered by a deviation not covered by a specific corrective action or unforeseen hazard. You should verify that you are meeting the reassessment requirement by reviewing the corrective action records when a deviation not covered by a specific corrective action or unforeseen hazard occurs. When verifying compliance address the following type questions:

1. Was a reassessment conducted as a result of an unforeseen hazard?

2. Do you have supporting documentation for the decisions made during the reassessment?

3. Has a reassessment been conducted to meet the annual reassessment requirement?

4. Did you consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis?

5. Has change occurred that could affect the hazard analysis or HACCP plan?

   a. Did the establishment reassess?
   b. If the reassessment revealed that the HACCP plan no longer meets regulatory requirements, was the HACCP plan modified immediately?

6. If you have failed a *Salmonella* test, was a reassessment conducted?

7. If a reassessment was conducted, did you consider *Salmonella* a food safety hazard reasonably likely to occur in that process?

8. If you did not consider *Salmonella* a food safety hazard reasonably likely to occur, do you have documentation to support this decision?

Other Food Safety Programs
Make a list of all the programs you have in place that could potentially impact the safety of the products you produce. You now need to determine how each of these programs interrelate. For example if you have a program that monitors sanitation effectiveness, results from this program could impact your SSOPs, your *Salmonella* testing program and your generic *E. coli* programs. There could be numerous other programs that could be impacted as well. You challenge is to determine all of these interactions between your various programs. For example, what factors may have caused the ineffective sanitation results you found? Was it due to improper cleaning procedures and/or processing a load of highly contaminated carcasses? You might think what difference does it make? Why should I put in all this effort to determine why it happened when I can just re-clean the area? The reason you want to conduct the analysis to determine the real root cause of the problem. Remember for each corrective action you have to document how you are going to prevent the hazard from reoccurring. This type of analysis will help you search out the REAL root cause of some of your deviations. Some plants who have done this type of analysis have found that when they analyze the average microbial load for birds/animals from their different farms, they can reduce their overall microbial load (*Salmonella,* generic *E. coli*, etc.) by processing the cleanest birds/animals before processing the dirtier birds/animals.