Verification and Validation of HACCP Plans in U.S. Meat Processing Facilities

Introduction

HACCP (Hazard Analysis and Critical Control Points) is a systematic method for assuring food safety based on seven principles for development and implementation. Principle number 6 of HACCP is verification. Verification is a check in the system to assure that the controls are using the best scientific approach and that the procedures defined by the HACCP plan are being followed. In other words, “Do we say what we do?, and “Do we do what we say?” For the meat industry, the activities for Principle 6 of HACCP usually include verification tasks, validation studies, and reassessment for regulatory purposes.

Verification

Webster defines verification as “To establish the truth, accuracy, or reality of.” The National Academy Committee on Microbiological Criteria further defines verification for HACCP for Foods (NACMCF, 1997) as “Those activities other than monitoring that determine the validity of and compliance with the HACCP plan.” Several tasks should be identified as verification activities for the HACCP system. These include verification of prerequisite programs, verification of the critical control points, and verification of the overall HACCP plan. In addition, the regulations in 9 CFR 417 identifies verification activities that which will be performed by the USDA inspectors. Companies may also consider involving outside experts in an audit or may send personnel to suppliers of food ingredients to verify HACCP and food safety plans.

Validation

Validation is also part of Principle 6, Establish Verification Procedures. Validation is defined as “to support or corroborate on a sound or authoritative basis” or to “establish validity of the HACCP plan by supplying factual proof.” Within HACCP, validation is “the element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards” (NACFMF, 1997).

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Table 1. Examples of Frequency of Verification Activities. Adapted from NAMCF 1997 Regulatory Verification.
Validation can be accomplished by conducting in-plant studies, providing literature citations, and conducting pathogen inoculation studies in controlled laboratory settings.

**Reassessment**

Under USDA regulations, reassessment is also a term that is used in reference to the activities for HACCP Principle 6. Reassessment is a thorough review of the hazard analysis to address specific hazards and to determine if the hazards are controlled by the HACCP plan. Reassessment asks the question “Is the HACCP Plan STILL Controlling Hazards?” Reassessment is required in the regulations for meat and poultry HACCP plans (9 CFR 417) and is required to occur at least once a year and whenever an unforeseen hazard is found. An unforeseen hazard may be a pathogen identified as an adulterant that is found in the final product.

**Verification of Prerequisite Programs**

Sanitation standard operating procedures (SSOP) and good manufacturing practices (GMPs) are important building blocks for the HACCP plan. Verification of these programs will ensure the plant operating conditions used to establish the HACCP plan are still effective. Sanitation Standard Operating Procedures are required for Meat and Poultry operations under Federal Meat Inspection (9 CFR 416) or State Meat Inspection programs and verification is required under the regulations. Good Manufacturing Practices are programs implemented by the plant and include many of the routine operations in the food production facility and are specified in the regulations for meat and poultry operations.

Under the SSOP regulations the verification activities for the plant are described as maintenance of the SSOP’s in 9 CFR 416.14 and Verification by meat inspection (FSIS, Food Safety and Inspection Service, USDA) is detailed in 416.17. The plant personnel should 1) review the written plan and its application to the current facility and operations, 2) review sanitation procedures and the frequency procedures are performed, 3) perform direct observation of the sanitation SOP’s, and 4) audit the sanitation records. In addition, microbial testing or rapid sanitation checks of equipment and direct food contact surfaces can be used to demonstrate the effectiveness of the sanitation program. The FSIS inspector performs verification by 1) reviewing the sanitation SOP’s, 2) reviewing the daily records, 3) direct observation of the procedures, and 4) direct observation or testing of equipment and facilities to assess sanitary conditions.

Good Manufacturing Practices are not specified in the meat and poultry regulations. Some elements of GMPs, however, are included in the sanitation regulations (9 CFR 416). Because of this, GMPs may vary among meat and poultry processing facilities. The following elements of a GMP program should be addressed within the plant:

1. personnel
2. building and facilities
3. plant and grounds
4. sanitary operations
5. sanitary facilities and control
6. equipment and utensils
7. processes and controls
8. warehousing and distribution

Verification of GMPs should be conducted annually and may include review of written documents, monitoring, and reports or records associated with GMP programs. When reviewing the plant GMPs, the review should ensure that potential food safety hazards are not addressed by GMPs, rather than they are addressed in the HACCP plan and controlled by appropriate CCP’s.

**Verification of the HACCP Plan**

Verification should also consist of:

1. making sure that all parts of the HACCP plan are present
2. the plan is scientifically correct
3. it reflects the current formulation and manufacturing conditions
4. it has been updated to reflect any changes in the food system that would affect safety.

Records that should be reviewed include:

1. the flow diagram
2. the list of ingredients
Changes in any one of these components may affect the hazard analysis and could impact the occurrence or severity of a potential hazard that should be addressed in the HACCP plan.

Several components of the HACCP plan are required by the regulations for meat and poultry plants. Plants should verify that the HACCP plan includes:

1. the written hazard analysis
2. documents associated with selection and development of CCPs
3. Critical Limits, 4) monitoring procedures and frequency
4. verification procedures and frequency.

Supporting documentation is required for each of these HACCP records. and may include:

1. scientific literature citations
2. plant historical records, and/or
3. data from in-plant studies.

Supporting documentation will help assure that the plan is scientifically correct.

The HACCP plan needs to reflect current plant operations. When new products are produced or current products are improved by changing processing procedures, new equipment and/or new processing steps are usually added. Some production changes may only improve the efficiency of production or the quality of the product, however, some changes may affect food safety. A change may introduce or enhance a hazard that needs to be addressed in the HACCP plan. More than likely, a change may result in improvement of food safety by reducing or controlling a potential hazard. Changes that may affect food safety hazards include:

1. new ingredient suppliers
2. a change in the packaging equipment
3. formulation changes in non-meat ingredients, or
4. utilizing new sanitation and cleaning chemicals.

Each change should be evaluated in a hazard analysis to ensure that food safety hazards are controlled.

**Verification of CCPs and Monitoring**

Verification should also identify several activities that are conducted daily or more frequently for each Critical Control Point (CCP) in the HACCP plan. The HACCP plan depends on accurately applying the critical limit for the CCP identified, including accuracy in measurement and completeness in records. Daily verification includes: 1) record review, 2) review of corrective actions, and 3) calibration of instruments. Additionally, the plan should operate effectively in the production system.

Verification of the records at each CCP is conducted to assure the following:

- The record was recorded according to the frequency identified in the monitoring procedures and by the person identified in the HACCP plan.
- The record form was prepared correctly, i.e. no ditto marks, actual temperatures and times are recorded, and signatures are present.
- All monitoring periods during production were included.
- All critical limits were met.
- Any deviation from the critical limit is identified and a corrective action was indicated.

Verification of CCP records in meat and poultry processing plants is required by regulations (9 CFR 4172(a)(2)) and requires the reviewer to sign and date the record. In addition, the regulation (9 CFR 4175(a)(3)(c)) requires that the monitoring records and corrective action records be reviewed prior to shipping product. This is commonly known as pre-shipment review. Regulations allow processors flexibility on when and how to perform the pre-shipment review. Many processors meet this requirement by performing a pre-shipment review for each lot of product produced.
Verification of Deviations

Deviation in a critical limit for a CCP could result in a potential hazard and, therefore, the proper corrective action is essential. Verification should assure that for each deviation a corrective action is recorded and information about the deviation is recorded. The corrective action should 1) be conducted as identified in the HACCP plan, 2) document how product was identified and the disposition of the product, 3) report the individuals responsible for the corrective action, and 4) be properly prepared, signed, and dated. In addition, appropriate personnel may need to provide justification for the corrective action taken. Since corrective actions generally occur infrequently, the corrective actions for a CCP also need to be reviewed over an extended time period to identify any trends or problems in the process.

Calibration

Calibration is another task that ensures critical limits for CCP’s are met. The most common calibration is for thermometers. If equipment is out of calibration, it needs to be replaced or adjusted. Records will need to be verified for equipment that is outside of calibration limits if the equipment has been used to measure critical limits. The review of the records should focus on the possibility that the measurement of a critical limit resulted in a deviation of the critical limit and a potential food safety hazard occurred. Therefore, frequent calibration is encouraged to minimize the amount of product that would need to be reviewed.

Periodic Verification of the HACCP Plan

Periodic verification of the HACCP plan by outside individuals or HACCP team members not involved in the daily collection of data will help to ensure that the HACCP plan is controlling the identified hazards adequately. The frequency and the method will be specified in the HACCP plan. For example, the HACCP plan may indicate that a member of the HACCP team will measure a critical limit as a check of the operator that would normally measure the critical limit that is indicated in the monitoring procedures of the HACCP plan. Observation of the monitoring procedures for a critical limit in a HACCP plan is another example. Table 1 provides examples of verification activities and the frequency of verification for those activities. A record of the verification is required by the regulations.

FSIS will also verify adequacy of HACCP plans. According to 9 CFR 417.8, agency verification will include 1) reviewing the HACCP plan, 2) reviewing the CCP records, 3) reviewing and determining the adequacy of corrective actions, 4) reviewing critical limits, 5) reviewing other records pertaining to the HACCP plan, 6) direct observation or measurement at a CCP sample collection and analysis to determine if the product meets all safety standards, and 7) on-site observations and record review.

Validation

Validation is the portion of verification that collects or evaluates scientific information or literature to determine if a HACCP plan is controlling the identified hazards, with specific emphasis on CCPs and associated critical limits. Validation is usually conducted after initial development of the HACCP plan and on a periodic basis after development of the HACCP plan. Initial validation can be conducted during the first few weeks of processing under the HACCP plan. Periodic validation needs to occur annually, or more frequently, depending on the needs and changes in the processing operation. Validation may include: 1) hazard analysis justification, 2) support for hazard identification and CCP location, and 3) support of critical limits and monitoring activities.

Initial Validation

Initial validation of the HACCP plan will determine that 1) the plan is scientifically and technically sound, 2) all hazards have been identified, and 3) identified hazards will be effectively controlled if the HACCP plan is properly implemented. Simply put, validation of the HACCP plan will assure that the plan will prevent, eliminate or reduce the level of hazards identified by the hazard analysis. A HACCP team may rely on expert advice, scientific studies, scientifically based regulatory requirements or in plant measurements or studies for the initial validation of the HACCP plan. For example, processors that prepare cooked roast beef will be able to refer to the stabilization guidelines by USDA for control of Salmonella as verification of their cooking process.
Ongoing Validation

In addition to initial validation, the HACCP team will need to conduct periodic validations of the HACCP plan as needed. USDA regulations for meat and poultry products (9 CFR 417.4(a)(3)) require an annual reassessment or validation of the HACCP plan. In addition validations should be conducted when there is an unforeseen failure. For example, ongoing validation needs to occur if a new hazard is recognized or if a significant product or process change occurs.

Validation Studies

Validation of a CCP may require an in-plant study to ensure that a critical limit that is supported by literature or advised by a processing authority is controlling the identified hazards under the operating conditions of the plant. In-plant studies for microorganisms usually rely on indicator organisms to complete the study. The studies should be statistically designed to answer the question and an appropriate number of samples need to be collected to demonstrate any differences. The number of samples and design will vary for each situation and experts should be consulted. Studies involving the detection of pathogenic microorganisms usually require inoculation of the products and should only be conducted in controlled laboratory settings.

Verification Records

The HACCP team should record all verification and validation activities. In addition to documentation of the verification activity, a change page for the HACCP document should be included. A change page should include: 1) the change, 2) why it was made, 3) who made the change, 4) when it was implemented, and 5) supporting documentation. Regulatory requirements 9CFR 417.4(a)(3) for meat and poultry plants indicate that “The responsible establishment official has signed and dated the HACCP plan at least annually thereafter upon required plan reassessment.”

Summary

Principle 6, HACCP Verification consists of two primary activities, 1) verifying that the HACCP plan is functioning as designed and 2) validation that the HACCP plan is designed using sound scientific and technical principles. Verification and validation activities are required under HACCP regulations for meat and poultry operations and some verification activities are conducted by USDA inspectors. Verification should address 1) pre-requisite programs, 2) CCP’s, 3) calibration, and 4) the HACCP plan. Validation should be conducted initially and on a periodic basis after implementation.

References


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