HACCP

(Hazard Analysis Critical Control Point)

HACCP Plan

The Hazard Analysis and Critical Control Point (HACCP) System is a logical, scientific, and systematic approach to identifying and controlling food safety problems in food production. The companies HACCP system establishes controls in the production process to prevent, eliminate, or reduce to acceptable levels biological, physical, or chemical hazards which have been identified. Each company must have a HAACP plan in place prior to distribution of products.

There are seven HACCP principles that must be applied when writing a HACCP plan.

1. Conduct a hazard analysis
2. Identify critical control points
3. Establish critical limits for each critical control point.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish recordkeeping procedures.
7. Establish verification procedures.

We are reviewing the USDA, FSIS HACCP regulations in detail. These regulations are based on the seven HACCP principles that are listed above. We will begin with regulation 417.1 which covers the definitions of terms used in this section of the regulations.

§417.1 Definitions.

For purposes of this part, the following definitions shall apply:

1. **Corrective action. Procedures to be followed when a deviation occurs.**
2. **Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.**
3. **Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.**
4. **Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.**
5. **HACCP System. The HACCP plans in operation, including the HACCP plan itself.**
6. **Hazard. SEE Food Safety Hazard.**

7. **Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.**

8. **Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.**

9. **Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.**

Principle 1-Conduct a Hazard Analysis

HACCP Principle 1 states:

"Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures". A food safety hazard is defined as "a biological, physical, or chemical property that may cause a food to be unsafe for human consumption".

§417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis.

(1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

(i) Natural toxins;
(ii) Microbiological contamination;
(iii) Chemical contamination;
(iv) Pesticides;
(v) Drug residues;
(vi) Zoonotic diseases;
(vii) Decomposition;
(viii) Parasites;
(ix) Unapproved use of direct or indirect food or color additives; and
(x) Physical hazards.

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(b) The HACCP plan.

(1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter--all species.
(ii) Raw product--ground.
(iii) Raw product--not ground.
(iv) Thermally processed--commercially sterile.
(v) Not heat treated--shelf stable.
(vi) Heat treated--shelf stable.
(vii) Fully cooked--not shelf stable.
(viii) Heat treated but not fully cooked--not shelf stable.
(ix) Product with secondary inhibitors--not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and
(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
(5) Include all corrective actions that have been developed in accordance with Sec. 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of this part.

(d) Signing and dating the HACCP plan.

(1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

- **(i) Upon initial acceptance;**
- **(ii) Upon any modification; and**
- **(iii) At least annually, upon reassessment, as required under Sec. 417.4(a)(3) of this part.**

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

Each step in the process flow chart must be evaluated to determine if a biological, physical, or chemical hazard exists or may be introduced at that step and if preventive measures are available. Hazards that are low risk and not likely to occur should be listed on the hazard analysis and the reason that no further consideration is needed should be stated. These determinations should be based on incidence evaluation and/or scientific data.

Biological Hazards

Biological hazards are living organisms, including microorganisms that can put human health at risk. These hazards include bacteria, parasites, protozoa, viruses to mention a few.

The numbers and types of bacteria vary from one food or animal species to another, from one geographic region to another, and with production and slaughter methods. During production, processing, transportation, preparation, storage, and service, any food may be exposed to bacterial contamination. The most common biological hazards in meat and poultry are microbiological; however biological hazards may also be due to parasites or zoonotic disease processes.

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Some of the major pathogenic bacteria organisms that can cause food borne illness are: *Campylobacter*, *Salmonella, Clostridium perfringens, Listeria monocytogenes, Staphylococcus aureue, Clostridum botulinum,* and *Escherichia coli O157:H7.*

Physical Hazards

A physical hazard is any physical material not normally found in a food that causes illness or injury to the individual using the product. Physical hazards include a variety of foreign materials or objects, such as glass, metal, and plastic. Foreign objects that cannot cause illness or injury are not hazards, even though they may not be aesthetically pleasing to the customer.

A number of situations can result in physical hazards in finished product and can include, but not limited to:

1. Contaminated raw materials

2. Poorly designed or poorly maintained facilities and equipment. An example may be paint chips falling from overhead structures onto exposed product or pieces of metal from worn or improperly maintained equipment entering product.

3. The SSOP's can be used to identify and control cross-contamination due to employee practices. An example may be a procedure to recondition product that has fallen on the floor.

Chemical Hazards

Chemical hazards fall into two categories and may also cause food borne illnesses.

1. Naturally occurring poisons or deleterious substances are those that are natural constituents of foods and are not the result of environmental, agricultural, industrial, or other contamination. Examples include aflatoxins, mycotoxins, and shellfish toxins.

2. Added poisonous or deleterious substances are those that are intentionally or unintentionally added to foods at some point in growing, harvesting, storage, processing, packing, or distribution. This group of chemicals can include pesticides, fungicides, insecticides, fertilizers, and antibiotics, as well as direct and indirect food additives. This group can also include chemicals such as lubricants, cleaners, paints, and coatings.

To identify any chemical hazards, establishment management needs to determine any chemical residues that might be in the animal.

1. Types of drugs and pesticides routinely used in raising the animals that are used as sources of the meat and poultry ingredients.

2. Feeds and supplements fed to the animals.

3. Environmental contaminants the animals may have come into contact with, both naturally occurring contaminants and added contaminants.

4. Pesticides used on plants that may end up as residues in the animal.
5. The source of the water the animals were allowed to drink.

The following preventive measures can be taken:

1. Require written assurances from suppliers for each lot of animals, stating that the animals are free of illegal residues.
2. Set a maximum allowable residue limit for specific drugs, pesticides, and environmental contaminants in animal urine or tissues to ensure lawful tolerances are met.
3. Ensure that trucks used to ship the animals do not have chemical hazards that could contaminate the animals.

Most establishments use chemicals during processing and to keep their operations sanitary. Chemical hazards can occur at any point.

1. Prior to and upon receiving chemicals.
2. Wherever the chemical is used in the establishment.
3. Storage
4. Use of cleaning agents, sanitizers, lubricants, or other maintenance chemicals.
5. Prior to shipping finished product or in trucks used to ship finished product.

Identify Critical Control Points

Principle 2 states:

"Identify the Critical Control Points (CCPs) in the process"

A Critical Control Point (CCP) is defined as "a point, step, or procedure in the food process at which control can be applied and, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels".

The Team must identify preventive measures, if they exist, for each hazard identified. The next step is to identify points in the process at which CCP's can be established to prevent, eliminate, or reduce the hazard. There may be control points that are not critical and therefore the establishment may identify too many CCPs.

Some common CCPs may be:

1. Chilling, when appropriate.
2. Certain slaughter procedures, such as zero tolerance.

3. Product formulations.
4. Cooking temperatures and time.

Establishing critical limits

Each CCP must have critical limits established that are designed to maintain control and prevent a food safety hazard. Regulatory limits may be used, or scientific reports or history may be used to establish critical limits. The supporting documentation will aid in validating that the limits have been properly set.

Principle 3-Establish Critical Limits for Each Critical Control Point

This principle states:

Establish critical limits for preventive measures associated with each identified CCP

The USDA regulations define critical limit as "the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard".

Critical limits are expressed as numbers or specific parameters based on visual observations. As an example:

1. Time and/or temperature
2. Humidity
3. Water activity
4. pH
5. Chlorine level
6. Zero tolerance

Many critical limits for CCP's have been established through regulatory requirements, scientific literature, or other studies.

Critical limits not based on regulatory requirements must be based on sound scientific data and ensure that the process produces safe/unadulterated product. More than one critical limit may be needed for some CCP's. As an example; a chemical intervention on carcasses may require that the mixture, delivery pressure, and time all be set in a critical limit.

For each identified CCP, the Team must establish critical limits that are adequate to control and prevent food safety hazards. All documentation such as scientific reports or other information supporting the critical limits must be on file in the plant. This documentation will help validate that the limits have been properly set. The Team may choose to set operating limits that are more restrictive than the critical limit.

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Principle 4-Establish Monitoring Procedures

This principle states:

"Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control".

Monitoring is a planned sequence of observations or measurements to assess if a CCP is under control and to produce an accurate record for future use in verification.

Monitoring is essential to the HACCP system. Monitoring can identify trends indicating that there may be a loss of control if no action is taken.

Monitoring may be continuous or noncontinuous. Continuous is done with measuring equipment such as automatic time/temperature devices used in cooking. Continuous monitoring is the better choice since it provides a permanent record that can be evaluated to ensure the CCP is under control. If a continuous device is used it must be calibrated for accuracy. Noncontinuous monitoring should be used only when continuous monitoring is not feasible. Noncontinuous monitoring can include visual examinations, measuring pH or water activity (Aw), product temperatures, or sampling. The frequency of monitoring must be set to ensure that the hazard is under control and the monitoring is performed at a random time. As an example; the Team may set the monitoring frequency to monitor zero tolerance on carcasses base on plant size, plant layout, product flow, and the number of animals slaughtered.

The Team must train identified employees that will be conducting the monitoring. The training must include the method of monitoring, critical limits, documentation of results, and action to be taken if a deviation of critical limits occurs.

The Team should identify procedures for monitoring the CCP critical limits. This procedure can include:

1. Identify the best monitoring procedures
2. Determine the frequency of monitoring.
3. Determine if the monitoring can or should be done randomly and if a random monitoring can be conduct, set the procedures.
4. Determine testing procedures that need to be done for each monitoring activity.
5. Identify and train employees responsible for monitoring.
6. Make sure that records are available for employees conducting the monitoring to document results, initial the entry, and enter time of the event.

Principle 5-Establish Corrective Actions

Principle 5 states:

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"Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit".

A corrective action is defined as "procedures to be followed when a deviation of a critical limit occurs".

§417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with Sec. 417.4(a) (2) (iii) and the recordkeeping requirements of Sec. 417.5 of this part.

Remember, HACCP is a preventive system that identifies and corrects problems before they affect the safety of the food. Therefore, HACCP Teams must plan in advance in the event of deviation of a critical limit. Corrective actions must be taken for all deviations of critical limits. Corrective actions must include:

1. The cause of the deviation is identified and eliminated.
2. The CCP will be under control when the corrective action is taken.

3. Measures to prevent recurrence are taken.

4. No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

All corrective actions taken must be documented at the time and the employee making the entry must also initial, date, and enter the time of the event on the record. It is imperative that employees are properly trained on corrective actions to be taken in case there is a deviation of a critical limit. Since it is impossible to anticipate all corrective actions, the Team can list the regulatory requirements for corrective action in the HACCP plan and then demonstrate in the records system that all parts of corrective action were taken.

Some examples of corrective action are:

1. Immediately adjust the process and hold product for further evaluation and/or disposition.

2. Allow employees to stop the process when a deviation occurs, hold product, request assistance from quality assurance, supervisors or other management.

3. Have an approved alternate process in place that can be substituted for the one the one that is out of control.

The HACCP Team must establish a corrective action to be taken if a deviation of a critical limit occurs, what will be done with the product involved, develop a record to document all of the information and that the employee taking the action can initial, and record the time and date. In addition, ensure that employees responsible for conducting the monitoring are trained and know the corrective action to take if a deviation occurs.

Principle 6-Establish Recordkeeping Procedures

Principle 6 states:

"Establish effective recordkeeping procedures that document the HACCP system".

§417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's

(b) HACCP plan:

(1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention.

(1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

Proper recordkeeping is essential in a HACCP system. Accurate and complete records demonstrate that:

1. The establishment is in compliance with its HACCP plan
2. Allow the establishment to trace the history of ingredients, in-process operations, or finished products if problems arise.
3. Identify trends in operations that could result in a deviation if corrective action is not taken.
4. Identify specific products involved if a deviation occurs.

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The HACCP system should include records for CCP's, critical limits, handling of deviations, results of verification activities, the HACCP plan, hazard analysis, and all supporting documentation. Records must contain the following: title and date of record; product identification; critical limits, monitor' and reviewer's signature.

Principle 7-Establish Verification Procedures

Principle 7 states:

"Establish procedures to verify that the HACCP system is working correctly"

§417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;
(ii) Direct observations of monitoring activities and corrective actions; and
(iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with Sec. 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of Sec. 417.2(c) of this part.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes

in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Once the HACCP system has been established and implemented, verification activities occur on an ongoing basis. Verification is the methods, procedures, or tests in addition to the monitoring, to determine if the HACCP system is operating as intended. More simply, the establishment must verify that the system is working the way it was expect to work. Verification must include:

1. Calibration of monitoring instruments.
2. Direct observation of monitoring being performed
3. Review of records.

The Team must establish verification procedures, frequencies of the conducting the verification procedures, as well as recordkeeping to record all results of verification.

In addition to the on-going verification activities that are conducted, reassessment to determine that the HACCP system is adequate must be conducted by the establishment at least annually. Reassessment is necessary when potential new hazards have been identified and may be introduced into the process by new ingredients, new or different process steps or procedures, or new processing equipment. Reassessment should also be completed when there are changes in the process, ingredients, raw materials or sources of raw materials, formulation, production volume, packaging, or any other changes that could affect the hazard analysis or was not included in the original hazard analysis. The reassessment must cover the entire the entire HACCP system.

Validation of the HACCP plan is important. Validation is the scientific and technical process for determining that the CCP's and critical limits are adequate and sufficient to control the identified hazards. Another way of saying it is, the validation activity is when the establishment validates that the plan they have developed and implemented actually prevents, eliminates or reduces the levels of hazards that have been identified.

Inadequate HACCP Systems

§ 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;
(b) Establishment personnel are not performing tasks specified in the HACCP plan;
(c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;
(d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or
(e) Adulterated product is produced or shipped.

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Training

§417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with Sec. 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with Sec. 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Government inspection verification

Up to this point we have discussed what establishments are responsible for under the HACCP regulatory requirements. Establishments are responsible for conducting hazard analysis, developing CCP's and critical limits, monitoring procedures, corrective actions, recordkeeping, and verification. As you noticed there are specific roles for many establishment employees. Likewise, there are specific roles for government inspection personnel.

It is now time to discuss the role of the government inspection personnel. Inspection personnel's role is to verify the HACCP systems that the establishment has developed are functioning as intended. There are different ways to conduct the verification of HACCP systems.

The discussion of this part needs to begin with some basic requirements. The USDA has included in the regulation the role of inspection personnel. Inspection's role is to determine the adequacy of the HACCP plan (s) and that the plan meets regulatory requirements of CFR 417 and other applicable regulations.

§417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions utaken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

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(g) Sample collection and analysis to determine the product meets all safety standards; and
(h) On-site observations and record review.

There are many questions that should and could be asked during a review of an establishments HACCP system and prior to its implementation by the establishment. By conducting a systematic verification of the HACCP system, initially or any time there has been a reassessment resulting in a modification, all basic and requirements can be reviewed and a determination can be made as to the adequacy of the HACCP plan.

1. Did the establishment develop a product description and flow chart?
2. Did the flow chart include all steps of the process?
3. Did the establishment develop and conduct a hazard analysis that included all steps identified in the flow chart?
4. Did the hazard analysis identify hazards reasonably likely to occur in the process?
5. Did the establishment determine and develop CCP's to control all hazards identified in the hazard analysis?
6. Did the establishment determine and develop Critical Limits for every identified CCP that when implemented eliminates, prevents, or reduces hazards to an acceptable level?
7. Did the establishment develop monitoring procedures?
8. Did the establishment develop corrective actions in the event a deviation occurs?
9. Did the establishment develop a recordkeeping system?
10. Did the establishment develop verification procedures?
11. Does the establishment have on file supporting documentation to support all decision made?
12. Did a person with authority to make decisions for the establishment sign and date the plan?

If inspection personnel discover a problem with the basic requirements, then they must document that problem and not allow the establishment to implement the plan until the problem is corrected. However, once the determination that the HACCP plan meets basic requirements is made, the plant is allowed to implement it. Inspection personnel continue to verify the plan after it has been implemented.

Inspection personnel must conduct daily on-going verification that the HACCP plan is being implemented as designed. A systematic approach should be developed to conduct the on-going verification.

The on-going verification can be accomplished by observing the monitoring or verification activities, by reviewing records or a mixture of both at all CCP's. By observing the monitoring or verification activity an inspector can determine if the establishment employees are conducting the procedures correctly, getting accurate results, taking corrective action when a deviation occurs, recording the results as required, and are signing the pre-shipment review record for each lot of product. By reviewing records the inspector can determine if the establishment is completing the records accurately with all pertinent information being completed.

If inspectors identify problems during any on-going verification procedure, they must document the problem and require the establishment to take appropriate corrective action. When product is involved inspection personnel must detain/retain the product until it has been determined that product is safe for human consumption.