

HAZARD ASSESSMENT AND CRITICAL CONTROL POINT(HACCP)

PRINCIPLE 1 - CONDUCT A HAZARD ANALYSIS

HACCP Principle No. 1 states:

"Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures."

The regulation defines a food safety hazard as "Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption."

A hazard analysis is the identification of any hazardous biological, chemical or physical properties in raw materials and processing steps, and an assessment of their likely occurrence and potential to cause food to be unsafe for consumption. HACCP focuses on significant hazards that are reasonably likely to result in an unacceptable health risk to consumers.

This section will define the hazards and discuss in general where they may occur in meat and poultry production. It will then talk about identifying hazards in your establishment. Finally, this section will explain how you can apply preventive measures to the hazards you have identified, to ensure that the products are safe for consumers. A preventive measure is defined, in the regulation, as "Physical, chemical, or other means that can be used to control an identified food safety hazard."

STEPS IN CONDUCTING A HAZARD ANALYSIS :

To conduct a hazard analysis, you need to do the following:

First - Assure that the prerequisite program-SSOP's and others are in place. Evaluate your operation for hazards.

1. Review the product description developed in Pre-HACCP Step 2 and determine how this information could influence your hazard analysis.

2. Look at all product(s) ingredients and incoming materials for the product(s). You developed this list in Pre-HACCP Step 3.

3. For each processing step identified in the process flow diagram, determine if a biological, chemical or physical hazard(s) could exist at that step.

4. To help identify hazards, you can ask the following questions at each processing step:

Could contaminants reach the product during this processing step? Possibilities include: worker handling, contaminated equipment or materials, cross contamination from raw materials, leaking valves or pipes, dead ends, splashing, etc.

Could any pathogens multiply during this process step to the point where they became a hazard? Consider product temperature, hold time, etc.

Could this step create a situation where an ingredient, work in process, or finished product became contaminated with pathogens? or

Could this step introduce a chemical hazard into the product?

Could this step introduce a physical hazard into the product?

Are the hazards addressed in the SSOP's?

5. Fully describe the hazards identified for each step.

6. For each incoming ingredient and material, indicate if a biological, chemical and/or physical hazard exists.

7. To help identify hazards, you can ask the following questions about each ingredient:

Could this ingredient contain any pathogenic microorganisms, toxins, chemicals or harmful physical objects?

If it became contaminated or were mishandled, could this ingredient support the growth of pathogenic microorganisms?

Are any hazardous chemicals used in growing, harvesting, processing or packaging the ingredient?

Is this ingredient hazardous if used in excessive amounts?

If this ingredient were left out or used in amounts lower than recommended, could it result in microbial growth?

Are any chemical or physical hazards associated with this ingredient?

8. You can ask the following questions about the product/process in general:

Have any livestock entering the slaughter establishment been subjected to hazardous chemicals?

Are any returned/reworked products used as ingredients? If so, could they cause a hazard?

Are preservatives or additives used in the product formulation to kill or inhibit the growth of microorganisms?

Do the amount and type of acid ingredients, and the resulting product pH, affect the growth/survival of microorganisms?

Does the water activity of the finished product affect microbial growth?

Should refrigeration be maintained for products during transit or in storage?

Are any chemical or physical hazards associated with any packaging materials?

9. Fully describe the hazards identified and assess the significance of the hazard based on available scientific and technical literature. This information can be obtained through public libraries, universities, trade associations, in-plant expertise, and/or extension services. This will help you assess the risk, severity, and significance of the hazards identified.

Second - Observe the actual operating practices in your operation
After describing the hazards you've identified with each step, you should:

1. Observe the actual operation in your establishment and be sure that it is the usual process or practice.

2. Observe employee practices where raw or contaminated product could cross contaminate workers' hands, gloves or equipment used for finished/post-process products.

3. Observe product handling past any kill step for potential cross contamination. This includes studying traffic patterns in the establishment.

4. Review any past incidents of physical, biological, or chemical contamination that have occurred to determine the frequency, significance, and nature of the occurrence(s).

Third - Evaluate the likelihood and severity of occurrence of the hazard

The hazard evaluation should be conducted after the list of potential hazards are assembled. During this stage, each hazard is evaluated based on the likely occurrence of the hazard and severity or seriousness of the consequences of exposure to the hazard. The estimate of likelihood of occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature. When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and severity of the potential consequences if the hazard is not properly controlled. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage and the nature of the consumers likely to purchase the product should be considered to determine how each of these factors may enhance or diminish the public health impact of the hazard being considered. The team must determine the influence on food safety of the

manner in which the food is likely to be stored and prepared and whether the food is specifically intended for consumption by a group which may be more susceptible to a particular agent.

A summary of the HACCP team deliberations and the rationale developed during the hazard analysis should be kept for future reference. These documents provide information which will be useful during the periodic review and updating of the hazard analysis and the HACCP plan as well as for conducting a hazard analysis on a similar product.

PREVENTIVE MEASURES

You have identified all significant biological, chemical and physical hazards for each processing step and each ingredient. Now, it is time to identify measures to prevent hazards from compromising the safety of your finished product. You are now ready to fill in the preventive measure(s) column of the Hazard Identification/Preventive Measures Form.

Remember, HACCP defines a preventive measure as "Physical, chemical, or other means that can be used to control an identified food safety hazard."

Some of the measures you can use to prevent chemical hazards are:

Use only approved chemicals.

Have detailed product specifications for chemicals entering your plant.

Maintain letters of guarantee from suppliers.

Inspect trucks used to ship finished product.

Properly label and store all chemicals.

Properly train employees who handle chemicals.

Measures you can take to prevent physical hazards include, but are not limited to:

Make sure your plant specifications for building design and operation are accurate and updated regularly.

Make sure your letters of guarantee for ingredients and product supplies are accurate and updated regularly.

Perform random visual examinations of incoming product and materials.

Use magnets and metal detectors to help find metal fragments that would be a physical hazard.

Use stone traps and bone separators to remove these potential physical hazards.

Keep equipment well maintained.

Train employees to identify potential problems.

Some other examples of preventive measures are:

In beef slaughter a chemical hazard could be the result of animals having high levels of drug residues. A preventive measure would be to reject or cull animals from a supplier on the basis of presentation of residue certification for all line animals presented for slaughter.

In poultry slaughter, the venting, opening and evisceration process could result in a biological hazard from cross contamination by pathogenic microorganisms. Preventive measures for this hazard would be: use Good Manufacturing Practices (GMP's) at all times; properly maintain and operate equipment used to perform these tasks; and rinse food contact surfaces on equipment with chlorinated water between each carcass.

In the grinding step for cooked sausage, a physical hazard could be metal fragments from the grinding equipment. There could be three different preventive measures for this hazard. You could inspect the grinding equipment daily to ensure that it is assembled and operated correctly, is functioning properly, and is not worn or damaged. You could have an employee visually examine the product at the packaging step. Or you could use a metal detector at the packaging step.

In many operations, the packaging step could pose chemical hazards from the packaging materials. A preventive measure could be requiring a letter of guarantee from the supplier assuring that the packaging materials are food grade.

Once you have identified your preventive measures and written them on your form, you are ready to go on to the next step in developing your HACCP plan.

PRINCIPLE 2 - IDENTIFY CRITICAL CONTROL POINTS

HACCP Principle No. 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 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."

So far, in developing your HACCP plan, you have identified biological, chemical, and physical hazards in the raw materials and ingredients you use and in the steps of your process. You've also identified preventive measures for each hazard you identified. With this information, your next step is to identify the points in the process at which the preventive measures can be applied to prevent, eliminate, or reduce the hazard to an acceptable level. Then you can use the CCP Decision Tree or other decision tree, or a logical process to assess each step in the process to determine whether it is a critical control point. The decision tree is applied only upon completion of the hazard identification and assessment. (Many control points may not be critical; often, companies starting out in HACCP identify too many critical control points.)

Fortunately, a great deal of work has already been done for you in identifying CCPs. Many CCPs are already recognized in various food processing and production systems. Some common CCPs are:

Chilling when appropriate.

Cooking that must occur for a specific time and temperature in order to destroy microbiological pathogens.

Product formulation controls, such as addition of culture or adjustment of pH or water activity.

Certain processing procedures, such as filling and sealing cans.

Certain slaughter procedures, such as evisceration or antimicrobial interventions.

These are just a few examples of measures that may be CCPs. There are many more possibilities. Different facilities, preparing the same food, can differ in the number and location of hazards and the points, steps or procedures which are critical control points. This is due, in part, to differences in plant layouts, equipment used, selection and sources of raw materials and ingredients, or the process that is used.

STEPS IN IDENTIFYING CRITICAL CONTROL POINTS

One good tool for identifying Critical Control Points is the CCP Decision Tree. The CCP Decision Tree was developed to help companies separate CCPs from other controls such as SSOP's, GMP's or other operating procedures. You will get the best results if you use the Decision Tree very methodically and use simple, descriptive, and familiar wording. You should apply the Decision Tree at each step in the process where you have identified a hazard.

Determining whether a process step is a CCP is really a basic exercise of answering four questions. To use the Critical Control Point Determination form and the Decision Tree, follow the next six steps:

1. In Column 1 of the Critical Control Point Determination Form, write in each step in the process where you have identified a hazard.

2. In Column 2, write in the identified hazard(s), indicating whether it is biological, chemical or physical. Then take the information you wrote on your Hazard Identification/Preventive Measures form and answer the following questions for each hazard you identified.

3. Question #1 - Do preventive measures exist for the identified hazard? {Note: From a regulatory standpoint, no further action is necessary if the hazard is not reasonably likely to occur.}

If the answer is yes, write YES and proceed to the next question.

If the answer is no, ask the question "Is control at this step necessary for safety?"

If control is not necessary at this step in the process, this process step is not a CCP. Write NO in Column 3 and write how and where this hazard will be controlled. Proceed to the next process step and identified hazard you have entered in Columns 1 and 2.

If control is necessary, in Column 3 explain how the step, process or product will be modified to ensure safety.

Once the step, process, or product has been modified, return to Question #1.

4. Question #2 - Does this step eliminate or reduce the likely occurrence of the hazard(s) to an acceptable level?

If the answer is yes, write YES in Column 4 and identify the step as a CCP in Column 7.

If the answer is no, write NO in Column 4 and proceed to the next question.

5. Question #3 - Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?

If the answer is yes, write YES in Column 5 and proceed to the next question.

If the answer is no, write NO in Column 5, indicating that the step is not a CCP. Then proceed to the next process step and hazard.

6. Question #4 - Will a subsequent step eliminate identified hazard(s) or reduce the likely occurrence to an acceptable level?

If the answer is yes, write YES in Column 6, indicating that the step is not a CCP. Then write down which processing step, which occurs later, will reduce the hazard to acceptable levels. Then proceed to the next process step and hazard.

If the answer is no, write NO in Column 6 and identify the step as a CCP in Column 7.

PRINCIPLE 3 - ESTABLISH CRITICAL LIMITS FOR EACH CRITICAL CONTROL POINT

HACCP Principle No. 3 states:

"Establish critical limits for preventive measures associated with each identified CCP."

The regulation defines 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 observation, such as:

Time/temperature
Humidity
Water activity
pH
Salt concentration
Chlorine level

You will find that many critical limits for your identified CCPs have already been established. You can find these limits in sources such as regulatory requirements, scientific literature, experimental studies, and through consultation with experts.

You may wish to establish critical limits that differ from regulatory requirements. These limits must be based on sound scientific data. However, your critical limits must always assure that the result produces a safe/unadulterated product. In some cases, you will need more than one critical limit to control a particular hazard. For example, the critical limits for cooked beef patties are time/temperature, pattie thickness, and conveyor speed.

STEPS IN ESTABLISHING CRITICAL LIMITS (Using the HACCP Plan Form)

1. For each identified CCP, determine if there is a regulatory critical limit set for ensuring food safety. If so, write that critical limit--or an alternative one if the scientific basis exists to show the value is adequate to ensure food safety--into the critical limit column of your form.

For example, the regulatory critical limit for cooked poultry is 160 degrees F. So, column two of your form would read: "Deep breast muscle temperature of 160 degrees F. as the products exits the fryer/oven/smokehouse."

2. If there are no regulatory critical limits for a CCP, you need to establish critical limits for the CCP that are adequate to maintain control and prevent a food safety hazard. That is the responsibility of each establishment. You may wish to obtain the assistance of outside HACCP experts to help you determine critical limits for your CCPs. Once you have identified critical limits, enter them into the critical limit column of your form.

3. You should also file, for future reference, any documentation such as letters from outside HACCP experts, processing authorities, or scientific reports supporting the critical limits you have identified. This documentation will help validate that the limits have been properly established. In addition, you should keep on file any test results that show your early experience in implementing the HACCP plan, to demonstrate you can implement what is written and make it work.

PRINCIPLE 4 - ESTABLISH MONITORING PROCEDURES

HACCP Principle No. 4 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 whether a CCP is under control and to produce an accurate record for future use in verification.

Monitoring is essential to a HACCP system. Monitoring can warn you if there is a trend towards loss of control, so that you can take action based on an analysis of the variation to bring your process back into control before a critical limit is exceeded. For example, say that an establishment tests the pH of a batch of product at 6 a.m., 7 a.m., and 8 a.m. Each time, the pH is within acceptable limits, but it is steadily climbing toward the high end of the range. This information is showing a trend and the establishment should take action to prevent the pH from exceeding the critical limits.

The monitoring procedures you will establish at CCPs will generally relate to on-line processes. Monitoring may be continuous or non-continuous. Continuous monitoring at a CCP usually is done with measuring equipment, such as automatic time-temperature equipment used at a cooking step. Continuous monitoring is better because it results in a permanent record that you can review and evaluate to ensure that the CCP is under control. However, you should regularly check continuous monitoring equipment for accuracy.

You should use non-continuous monitoring procedures when continuous monitoring is not feasible. Non-continuous monitoring can include: visual examinations; monitoring of ingredient specifications; measurements of pH, water activity (A_w), and product temperatures; attribute sampling; and the like. When you use non-continuous monitoring, you need to ensure that the frequency of monitoring is enough to ensure that the hazard is under control and that the monitoring is performed at random times. For instance, each plant needs to set its own times and frequency for checking the cooking time/temperature of products. This may vary from one establishment to another because of differences in plant size, plant layout, the type of product, the length of time for processing, and the product flow.

Each establishment has the responsibility to establish a frequency that ensures that the CCP is under control. In some cases, you may have to perform tests at a CCP or use statistically based sampling.

Monitoring will go much more smoothly if you:

Clearly identify the employee(s) responsible for monitoring.

Train the employee(s) monitoring the CCPs in the testing procedures, the critical limits established, the methods of recording test results, and actions to be taken when critical limits are exceeded.

Ensure that the employee(s) understand the purpose and importance of monitoring.

You can use the HACCP Plan Form provided or you can develop your own form.

STEPS IN ESTABLISHING MONITORING PROCEDURES

You can identify monitoring procedures for your HACCP plan by doing the following:

1. For each CCP, identify the best monitoring procedure.
2. Determine the frequency of monitoring for each CCP.

3. Determine if the monitoring activity needs to be done randomly to get a good representation of the product throughout the day's production. If it does, decide how the random monitoring will be done.
4. Determine what testing procedures need to be done for each monitoring function. For example, will you need to do a chlorine check or a temperature measurement?
5. Identify and train the employee(s) responsible for monitoring.
6. Make sure that the employee doing the monitoring signs all records and documents associated with CCP monitoring. Also make sure that the monitoring results are documented or recorded at the time the monitoring takes place.
7. Enter the above information in the monitoring column of your form.

PRINCIPLE 5 - ESTABLISH CORRECTIVE ACTIONS

HACCP Principle No. 5 states:

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

The regulation defines corrective action as "Procedures to be followed when a deviation occurs." A deviation is a failure to meet a critical limit.

Since HACCP is a preventive system to correct problems before they affect the safety of the food, you have to plan in advance to correct potential deviations from established critical limits. Once your HACCP plan is in place, any time a critical limit is not met, you will need to take corrective actions. Those corrective actions should include:

1. Determining the disposition of non-complying product;
2. Correcting the cause of the non-compliance to prevent a recurrence;
3. Demonstrating that the CCP is once again under control (This means examining the process or product again at that CCP and getting results that are within the critical limits.);
4. Maintaining records of the corrective actions. Not all deviations can be anticipated, therefore, it is recommend that the statement "other actions as appropriate" be included with the specific corrective action.

Under HACCP, you determine in advance what you will do when a critical limit is not met at a CCP. The employee(s) monitoring CCPs should understand this process and be trained to perform the appropriate corrective actions. It is important that an establishment record all corrective actions and that the employee responsible for taking the corrective actions sign all the documentation. Not all corrective actions can be anticipated. If a corrective action is taken which is not listed in the HACCP plan, this should be recorded on the appropriate document.

In some cases, the product in question will be held for further investigation of the deviation. This investigation may require a thorough record review, product testing, or consultation with a processing authority.

Some examples of corrective actions are:

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

Empower employees to stop the line when a deviation occurs, hold all product not in compliance, and call in the plant's quality control manager, supervisor, other individual who is knowledgeable in HACCP, and/or the responsible establishment official.

Rely on an approved alternate process that can be substituted for the one that is out of control at the specific critical control point. For example, if the in-line eviscerators in a poultry slaughter plant are malfunctioning, evisceration can be done by hand as long as Good Manufacturing Practices (GMPs) are followed.

Regardless of the corrective actions you take, you need to keep records that include:

The deviation that was identified.

The reason for holding the product; the time and date of the hold; the amount of product involved; the disposition and/or release of product; and the individual who made the disposition decision.

Actions to prevent the deviation from recurring. This may involve reassessment and/or revision of the HACCP plan.

You can use the HACCP Plan form provided or you can create your own.

STEPS IN ESTABLISHING CORRECTIVE ACTIONS

1. For each CCP, determine the corrective action to take if the critical limits are exceeded. Determine what should be done with the product if a deviation occurs at this step. You may need more than one corrective action for a CCP.

2. Develop the record form to capture all the necessary information on the deviation, and identify the employee responsible for maintaining and signing the record.

3. Ensure that employees conducting the monitoring at each CCP are fully trained and know the corrective actions to take if a deviation occurs.

4. Enter the appropriate corrective action(s) for each CCP in the corrective action column of the HACCP Plan form and identify the record that will be maintained.

PRINCIPLE 6 - ESTABLISH RECORDKEEPING PROCEDURES

HACCP Principle No. 6 states:

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

Maintaining proper HACCP records is an essential part of the HACCP system. Good HACCP records--meaning that they are accurate and complete--can be very helpful to you for the following reasons:

Records serve as written documentation of your establishment's compliance with its HACCP plan.

Records allow you to trace the history of an ingredient, in-process operations, or a finished product, should problems arise.

Records help you identify trends in a particular operation that could result in a deviation if not corrected.

If you were ever faced with a product recall, HACCP records could help you identify and narrow the scope of such a recall.

Well-maintained records are good evidence in potential legal actions against an establishment.

In accordance with the HACCP principles, your HACCP system should include records for CCPs, establishment of critical limits, handling of deviations, results of verification activities and your HACCP plan including the hazard analysis. For your review, the necessary forms are:

Process Description Form

Product and Ingredients Form - Process Categories and Ingredients

Process Flow Diagram Form

Hazard Analysis/Preventive Measures Form - Hazard Analysis Worksheet

CCP Determination Form - Hazard Analysis Worksheet

HACCP Plan Form - HACCP Worksheet

In many cases, the records you currently maintain may be sufficient to document your HACCP system. Records must contain at least the following information: title and date of record; product identification; critical criteria or limits; a line for the monitor's signature; time of observation, a place for the reviewer's signature; and, an orderly manner for entering the required data.

STEPS IN ESTABLISHING RECORDKEEPING PROCEDURES

1. Review the records you currently maintain and determine which ones adequately address the monitoring of the CCPs you have identified, or develop forms for this information.

2. Develop any forms necessary to fully record corrective actions taken when deviations occur.
3. Develop forms to document your HACCP system. (This will be explained in the next section, on verification).
4. Identify the employees responsible for entering monitoring data into the records and ensure that they understand their roles and responsibilities.
5. Enter the record form name(s) on the appropriate HACCP Plan Form or HACCP Worksheet under column adjacent to the appropriate CCP (see HACCP Plan Form). (Verification will be explained in the next section).
6. Enter the appropriate record form name(s) on the Recordkeeping and Verification Form under the verification procedures column adjacent to the appropriate CCP. (Verification will be explained in the next section).

PRINCIPLE 7 - ESTABLISH VERIFICATION PROCEDURES

HACCP Principle No. 7 states:

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

Verification

After a HACCP plan has been put into place, verification activities occur on an ongoing basis. Verification entails the use of methods, procedures, or tests in addition to those used in monitoring, to determine whether the HACCP system is operating as intended.

Simply stated, you need to verify that your HACCP system is working the way you expected it to work. Several areas are, but are not limited to, the calibration of process monitoring instruments at specified intervals, direct observation of monitoring activities, and corrective actions. These should be included in your HACCP plan in addition to the critical limits, monitoring, and corrective actions and should be defined at each CCP (see example from model). You should also make sure that employees are following your procedures for taking corrective actions when a critical limit is exceeded. Finally, you should routinely check to see that your employees are keeping specific, accurate, and timely HACCP records.

By doing these things, you will evaluate the day-to-day operation of your HACCP system. Don't be surprised if you find that you need to fine-tune your HACCP plan.

Some things you can do to verify your HACCP system are:

- Analytically test or audit your monitoring procedures;
- Calibrate your temperature/test equipment;
- Sample your product, including microbiological sampling;
- Review your monitoring records;
- Review your records of deviations and product dispositions;
- Inspect and audit your establishment's operations;
- Sample for environmental and other concerns.

Validation of a Hazard Analysis Critical Control Point (HACCP) plan is the process by which an establishment demonstrates that what is written in the HACCP plan and implemented in the establishment actually prevents, eliminates, or reduces to a regulated and/or commercially feasible and appropriate level, identified microbiological, chemical, and/or physical hazards. Validation is exclusively the responsibility of the regulated industry. It is the process through which a company assembles data showing that the HACCP plan it will use, will work to control the process and prevent food safety hazards.

Data assembled to validate a HACCP plan may be derived from various sources, including the scientific literature, product testing results, experimental research results, scientifically-based regulatory requirements, official Agency guidelines, computer modeling programs, and data developed by process authorities. Companies have considerable flexibility in assembling data to validate a HACCP plan, both with regard to the sources and the quantity of such data. Data can be derived from a combination of published scientific studies on a specific process that include the results of microbiological testing in conjunction with the results of at least three in-plant validation studies. A combination of the results of process procedures from a processing authority could also be used in conjunction with in-plant testing and letters of guarantee for equipment specifications on the tolerance for detecting physical hazards. However, FSIS believes that validation data for any HACCP plan needs to include results reflecting actual hazard characteristics of product produced using

the HACCP plan. For example, validation data supporting a HACCP plan for slaughter should include some data about the generic E.coli levels in the product. E.coli serves as a useful and effective indicator organism. It's levels can be correlated to the potential presence of other pathogenic organism such as Salmonella. When indicator organism are used, a decrease in the level of the indicator should be correlated to some expected effect on other pathogenic organisms which may be present at much lower levels or be difficult to ascertain. The present regulatory requirements for the production for the production of cooked beef, roast beef, and cooked corned beef (9 CFR 318.17) and for cooked, uncured beef patties (9 CFR 318.23) illustrate scientifically based processing times, temperatures, and conditions for these processes that can serve as a basis for validation. In slaughter operations, data to substantiate the use and efficacy of trisodium phosphate or chlorine in chiller water also illustrate the types of data that can be used to validate critical limits at identified critical control points in a process.

Reassessment

In addition to the on-going validation activities that are conducted, reassessment to determine that HACCP system is adequate should be done by each establishment at least annually.

Reassessment of the HACCP plan is necessary when potential new hazards have been identified that may be introduced into the process or product via emerging pathogens; new ingredients; new, different or additional process steps or procedures; or the introduction of new or different processing equipment.

Reassessment of the HACCP plan and system should also occur when any changes occur in the process, ingredients, raw materials or source of raw materials, formulation, production volume, personnel, packaging, finished product distribution, or any other change that could effect the hazard analysis or that was not included in the original hazard analysis.

The reassessment should be performed by someone who is trained in HACCP. The reassessment should cover a review of the existing HACCP plan and system including the hazard analysis, critical control points, critical limits, monitoring procedures, record keeping, and corrective actions to determine that they still assure process control over food safety hazards.

STEPS IN ESTABLISHING VERIFICATION PROCEDURES

1. Determine the appropriate verification procedure to ensure that each CCP and critical limit is adequately controlled and monitored.
2. For each CCP, determine procedures to ensure that employees are following your established procedures for handling product deviations and for recordkeeping.
3. Identify the frequencies for conducting any verification checks and the records where the results will be recorded.
4. Enter the details on the appropriate verification form for future reference.

VALIDATE YOUR HACCP PLAN

It is very important to validate your HACCP plan. The regulation defines validation as "the scientific and technical process for determining that the CCPs and associated critical limits are adequate and sufficient to control likely hazards." You will probably first want to review your HACCP plan to determine whether the CCPs and critical limits that you established are really the right ones and that you are controlling and monitoring them adequately.

Simply put, when you validate your HACCP plan, you demonstrate what you have written and put into place can actually prevent, eliminate, or reduce the levels of hazards you have identified.

To validate your HACCP plan, you need to assemble information to show that your HACCP plan will work to control the process and to prevent food safety hazards. There are two types of information that you will probably collect. First, you will likely gather supporting scientific information, such as studies that establish the time and temperatures necessary to kill certain harmful bacteria, results of past instances of physical contamination and/or results of test for residues. Second, you may wish to gather practical information, such as test results from products produced under your HACCP plan. An example of a test might be microbiological analysis of your finished, ready-to-eat products or periodic indicator testing to confirm the anti-microbial interventions in slaughter plants are effective. There are many sources of information to validate your HACCP plan, including: the scientific literature, product testing results, experimental research results, scientifically-

based regulatory requirements, official FSIS guidelines, or information developed by process authorities. Remember, the purpose of the validation is to assure that the parameters stipulated in the HACCP system are adequate to ensure process control.

You have a great deal of flexibility in assembling the information to validate your plan, in terms of both source and quantity of information. For example, a slaughter plant should validate that its plan ensures residue control, to prevent volatile levels of chemicals, animal drugs or pesticides in carcasses. A slaughter plant might choose to purchase animals only from suppliers who provide veterinary certifications that the animals have been raised under a program that assures that all animal drugs, pesticides, and other chemicals are properly used. In this situation, the establishment could validate this critical control point with the following information: a copy of the residue prevention program under which the producer is certified; a report of an on-site visit to the feedlot; and results of analysis of carcasses for compounds of concern.

Validation is simpler for HACCP plans for products such as cooked beef, roast beef, or cooked corned beef. Current regulatory requirements for these products include scientifically-based processing times, temperatures, and handling requirements. Your HACCP plan would need only to reflect these regulatory requirements; additional information would be unnecessary. In this case, you could do a minimal number of product analysis to demonstrate that hazards of concern, such as Salmonella, were not found in the products produced under the HACCP plan.

It is important that you reassess your HACCP plan at least once a year. Some changes that will require reassessment are listed below. Changes other than those listed may also compel reassessment.

1. Potential new hazards are identified that may be introduced into the process

for the product.

2. You add new ingredients or change the ingredient supplier.

3. You change the process steps or procedures.

4. You introduce new or different processing equipment.

5. Production volume changes.

6. The end point consumer for the product or the distribution system changes.

7. Personnel changes.

FINISHING YOUR HACCP PLAN

Now you are ready to assemble all your information into one HACCP Plan. It is important for your records that you assemble all your information into a final HACCP plan. To make sure that your HACCP Plan is complete, you may want to check it against the sample checklist provided. The HACCP plan should be reviewed in its entirety and signed and dated by the responsible establishment official/approving employee. All pages of the HACCP plan should be dated and marked with a cross referencing identifier to assure the plan is the most recent. The identifier can be a plan name or number.

Now you are ready to put your HACCP Plan into action and make HACCP a reality in your establishment.

For further detail please contact us:

gsdhillon@aspirebec.com or visit our web site: www.aspirebec.com