

7. DEVELOPMENT OF HACCP WORKSHEET AND PLAN FORM

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Hazard Analysis and Critical Control Point (HACCP) is a food safety management system, in which all types of food safety hazards in a food production unit are identified, monitored, controlled and recorded. This is achieved by systematic implementation of seven principles of HACCP. Hazard analysis worksheet is a tool used to evaluate all hazards in each processing step and to check whether that processing step is a Critical Control Point (CCP). Once CCP's are determined, HACCP plan form is used for effectively manage and control all identified CCP's.

Hazard-Analysis Worksheet

A hazard-analysis worksheet can be used to organize and document the considerations in identifying food-safety hazards. The worksheet addresses the first two principles of HACCP. Although there is no specific or required form, the worksheet should document specific information as required by FDA (Food and Drug Administration, USA). The first two principles of HACCP is being taken care by HACCP worksheet. A typical worksheet is depicted in Annex 1. Each worksheet should bear the name and address of the production unit, name of the product, intended use of the product and target consumers and method of storage and distribution. Obviously separate worksheet is required for each class of products.

Description of Fishery Products/Intended Use

The HACCP team look at all the fishery products produced in the facility and decide which products to be included in the HACCP Plan. Once the products are identified, the team has to prepare its description, which include details such as composition, structure and physical characteristics, processing method, packaging, conditions for storage and distribution, shelf life, instructions for use and microbiological and/or chemical criteria (if any) of the product. The HACCP team also has to state the intended use for the product which describes, target consumers, anticipated preparation and use of the product by consumers, special considerations if any (for example if the product is to be used in institutions or by traveler, etc. or are these dangers in use for any vulnerable groups in the population who might obtains the product) and specific requirements imposed by the importer or importing country. Examples of Product description and intended use of the product are given below.

PRODUCT DESCRIPTION OF FROZEN RAW SHRIMP

1.	Species	1. Penaeus indicus (white/NARAN) 2. Penaeus monodon (Tiger) 3. Metapenaeus monoceros (Choodan)
2.	Type	1. Head on (whole) 2. Headless (HL) 3. Peeled and Deveined (PD) 4. PD Tailon 5. Peeled and undeveined (PUD) 6. PUD Tailon 7. Butterfly
3.	Count	
4.	Freezing Method	IQF / Block Frozen
5.	Packaging	Packed in LDPE bags or laminated duplex cartons which are packed in 5 or 7 PL paper board master carton
6.	Storing	Stored at a temperature -18°C or below
7.	Instructions for use	To be fully cooked before use or further processed in a product
8.	Shipment/Transport	Refrigerated containers at a temperature -18°C or below

INTENDED USE OF THE PRODUCT

1.	Name of the product	Frozen raw shrimp
2.	Consumer	General public / and processing facility
3.	Anticipated use of the product	Fully cooked before consumption
4.	Special considerations	NIL

Fig 1 depicts a model of HACCP worksheet followed by Indian seafood industry. This model is adapted from USFDA. Each processing step should be listed serially in Column 1 as given in the verified process flow diagram.

All the identified hazards – biological, chemical and physical – for each processing step are listed in Column 2. Our assessment of each hazard, based on the evaluation of its significance and severity should be entered in Column 3. Your decision in column 3 should be logically and clearly justified in Column 4. The possible preventive or control measures for each hazard are listed in column 5.

Control or Preventive Measures

Control measures are actions and activities that can be used to prevent or eliminate a food-safety hazard or reduce it to an acceptable level. Control measures for various hazards

can be obtained from standard literature, hazard guides, labels etc. Examples of control measures are listed below:

A. Control measures for biological hazards

Bacteria and other pathogenic micro organisms

Control of time and temperature (Minimum storage time and adequate maintenance of temperature by icing, refrigeration etc will minimize the growth of harmful bacteria)

Retorting, Cooking, frying, drying (high temperature exposure for the required time / removal of moisture to attain required water activity, will kill bacterial population)

Quick Freezing, Chilling, Cooling (will minimize / prevent the growth of bacteria)

Fermentation, pickling or addition of preservatives etc (These will prevent the growth of some bacteria)

Source control (These controls assumes importance, when a particular hazard cannot be controlled by any processing activities. For example in the case of block frozen shrimps, salmonella can be controlled by developing suitable standard operating procedures to ensure that no contamination occur while harvesting and handling)

B. Control measures for Chemical hazards

1. Source control (Antibiotics can be controlled by harvesting them from farms which practices approved standard operation procedures for application of antibiotics or by using only permitted antibiotics. These can be verified by auditing the farm facilities during the time of application of antibiotics. This is supplemented with supplier guarantee declaration and third party testing).
2. Production control (eg., Use and application of chemicals under expert guidance).
3. Labeling control (eg., finished product properly labeled with ingredients and known allergens).

C. Control measures for Physical Hazards

1. Source control (eg., vendor certification and raw-material testing).
2. Production control (eg., use of magnets, metal detectors, sifter screens, destoners, clarifiers, air tumblers, x-ray equipment, and visual inspection).

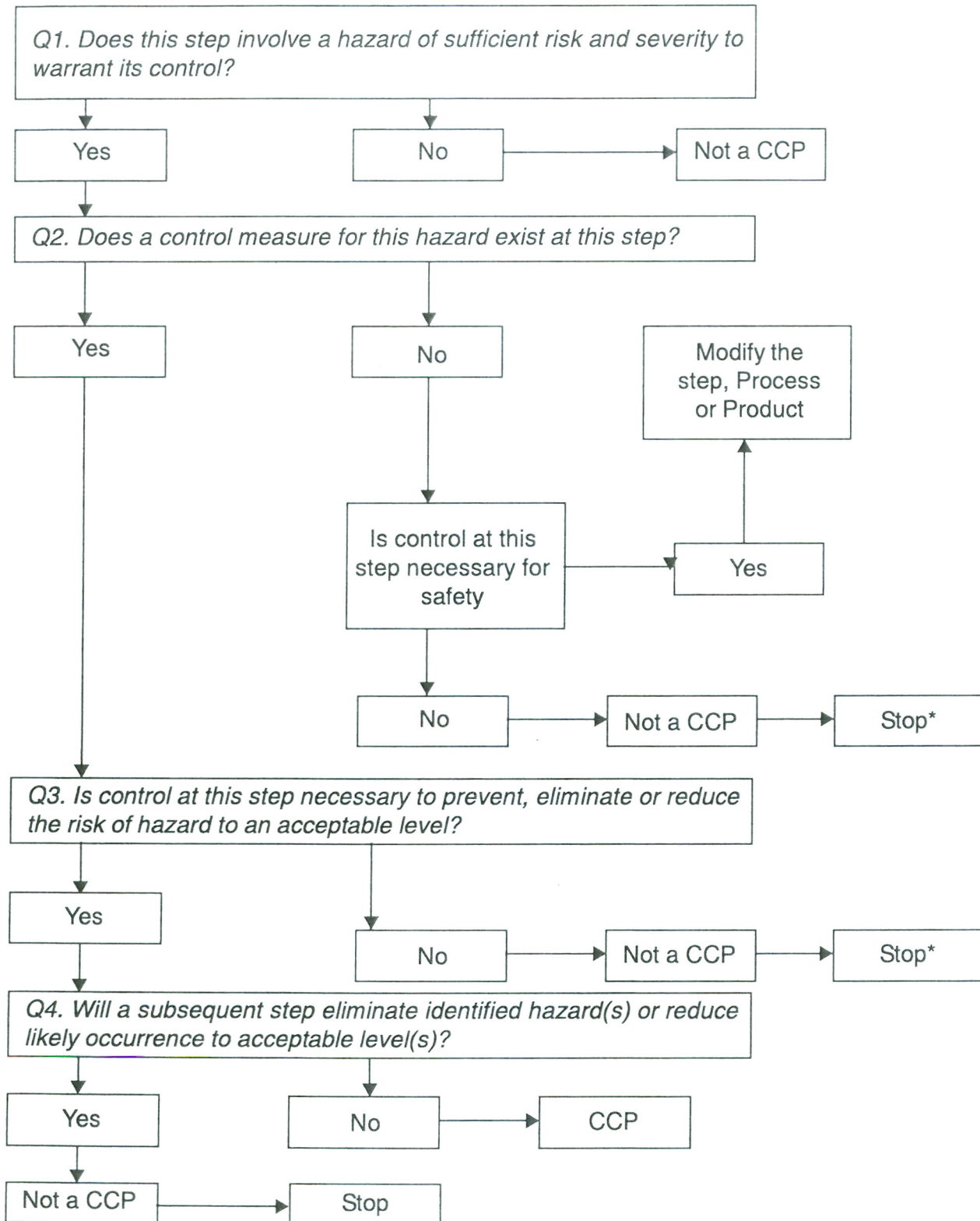
Determination the Critical Control Points

The next important step is to ascertain whether the processing step in question is a Critical Control Point (CCP). This has to be entered in (Col no 6) of the worksheet. For each significant hazard, there should be a CCP in which the hazard in question is totally eliminated or brought below the permitted limit. The determination of CCP is facilitated by the applying the decision tree developed by Codex Alimentarius Commission. (Fig 5.) A CCP is defined as that processing step, which effectively prevents and eliminates a food safety hazard or reduce it to an acceptable level. CCPs are product and process specific and CCP seen in one processing unit may not be applicable to another.

Description of CCP Decision Tree

CCP decision tree is a tool developed by Codex Alimentarius Commission, which can be employed to determine whether a particular processing step is a CCP. The decision tree consists of a series of questions the processor has to answer. Based on the answers, we will be guided to other related questions and determine whether the activity is a CCP. If properly used, the decision tree can be a useful tool for identifying CCP's. But as FDA says, the CCP decision tree is not a substitute for the expert knowledge, since complete reliance on the decision tree might lead to false conclusions.

CODEX CCP DECISION TREE



Let us take an example of peeled and cooked prawn. The flow chart of the product is given in fig 6

Question 1. Does a control measure(s) exist at this step or subsequent steps in

the process flow for the identified hazard?

If your answer is yes, proceed to Question 2. If you cannot identify a control measure in the process for the hazard, select No for the answer.

If No is selected, then ask: Is control at this step necessary for safety?

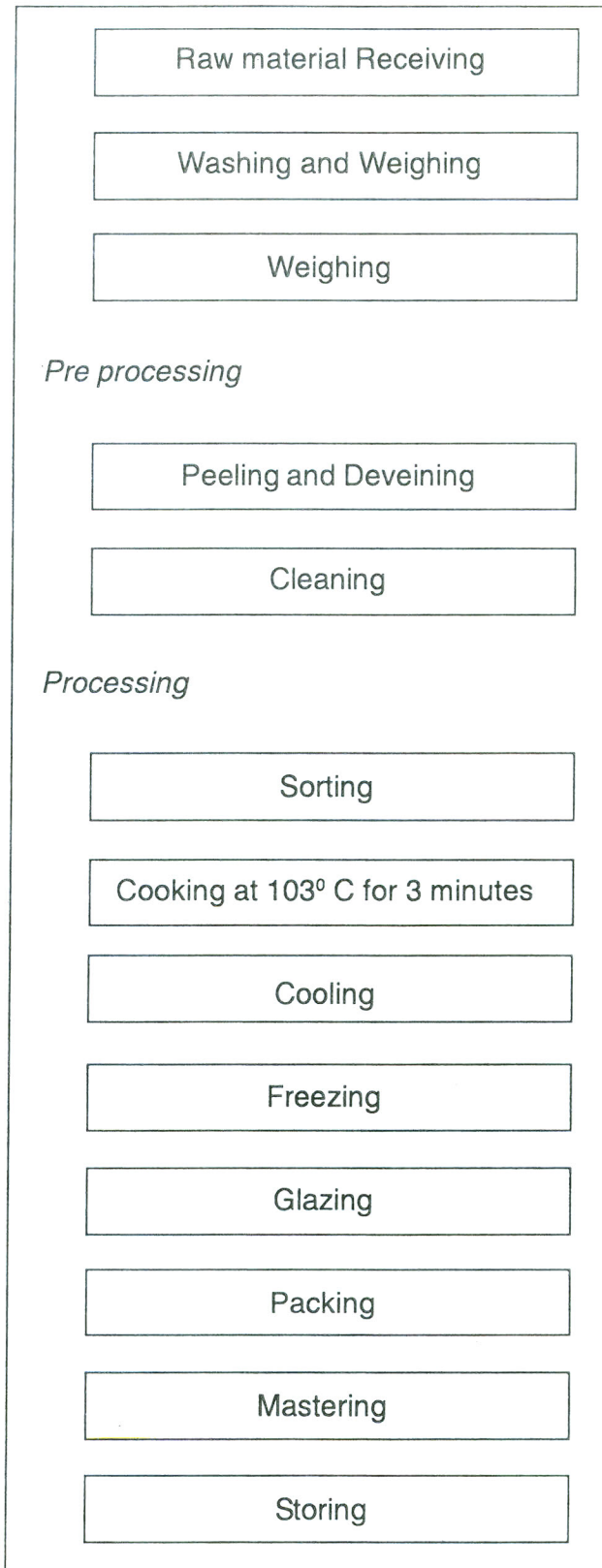
If you have no as the answer here also, then this step is not a CCP for that hazard. Move to the next processing step.

But If the answer is yes, then you have identified a significant hazard that is not being controlled. That means, your process or product must be redesigned to include a control measure.

Question 2. Does this step eliminate or reduce the likely occurrence of a significant hazard to an acceptable level?

To answer this question, consider whether this is the **best** step control the hazard? If the answer is yes, then the step is a CCP. Move to the next food-safety hazard.

If the answer is no, Proceed to Question 3.



Question 3. Could contamination with an identified hazard or hazards occur in excess of acceptable levels, or could these increase to unacceptable levels?

The question refers whether contamination that already exists increases at this step. If the answer is no, then the step is not a CCP for that hazard. Move to the next hazard at that step or the next step with a food-safety hazard.

If the answer is yes, then proceed to the fourth question.

Question 4. Will a subsequent step eliminate the identified hazard or hazards or reduce the likely occurrence to an acceptable level?

If you answer no, then this step is a CCP. If you answer yes, then this step is not a CCP for this hazard. In this case, be sure the hazard is controlled by a subsequent processing step.

HACCP Plan Form

HACCP plan form is tool which helps to manage each CCPs. The planform will address the last five principles of HACCP. A typical planform is given in fig 7.

Like in the worksheet, each planform should bear the name and address of the production unit, name of the product, intended use of the product and target consumers and method of storage and distribution.

The planform will help you to 1) set critical limits 2) establish monitoring procedures 3) determine corrective actions and 4) design records (to positively document that the process is in control) for identified hazards in each CCP.

The plan form has ten columns. The Column 1 in the HACCP Plan form contains the CCP's , which are identified using HACCP worksheet. Column 2 lists the hazards and critical limits are listed in column 3. Columns 4 to7 are meant for entering monitoring procedures, in which details of what to be monitored, how the monitoring is done, frequency of monitoring and the persons responsible for monitoring are entered. Column 8 details the corrective actions to be taken in case of any deviation. Column 9 lists the various verification procedures required to validate our HACCP plan and column 10 details the relevant records which are to be maintained.

Critical Limit

A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food-safety hazard.

A critical limit represents the boundaries that are used to ensure that an operation produces safe products. Each CCP must have one or more critical limits for each food-safety hazard. When the process deviates from the critical limit, a corrective action must be taken to ensure food safety.

HACCP PLAN FORM

Name of the firm :
Address :

Product Description	:	
Method of Distribution and storage	:	
Intended use and Consumer	:	

HAZARD PLAN FORM									
1	2	3	4	5	6	7	8	9	10
Critical Control Point (CCP)	Significant Hazard	Critical Limits	Monitoring				Corrective Action (s)	Records	verification
			What	How	Frequency	Who			

How to establish Critical Limits:

Critical limit for the operation may not be available readymade. They have to be fixed by conducting tests and validating them with competent laboratories. These tests may be designed and conducted in association with reputed laboratories or by consulting scientific publications, regulatory guidelines, in house experiments etc.

General source	Examples
Scientific publications	Journal articles, food science texts, microbiology texts etc
Regulatory guidelines	National/International guidelines, BIS, EIA/MPEDA publications, tolerance and action levels, FDA or EU guidelines, tolerance and action levels
Subject experts consultants,	CIFT, CIBA, CMFRI, thermal process authorities, food scientists, microbiologists, universities etc.
Experimental studies with validated data	In house experiments, Accredited laboratories

A few examples of critical limits are given below

Hazard	CCP	Critical Limit
Microbial Pathogens	Cooking	85° C for 3 minutes for elimination of pathogens from shrimp
Microbial Pathogens	Drying	$a_w < 0.7$
Microbial Pathogens	Acidification	Batch schedule – pH <2, time 28 h

We should understand that a variety of options are available for managing and controlling a hazard. Only experience and practicality will help you to select the best control measure that has to be adopted.

Monitoring :

Monitoring is the process by which hazard control is effected by ensuring the operations is well under critical limit. It is a planned sequence of observations or measurements to assess whether a CCP is under control. Monitoring also helps to produce an accurate record of operation, which will be useful verification.

Monitoring procedures can either be qualitative or quantitative. Sensory observation for decomposition is an example of a qualitative observation, whereas a temperature reading from a thermometer is a quantitative observation. Monitoring can be performed either in a continuous or in a periodic (non-continuous) basis. It is always desirable to have a continuous monitoring procedure, however, if it is non continuous, procedures should be reliably indicate that the hazard is under control. The means by which the observation is done should be given in the HACCP plan. Monitoring should be done on a real time basis, so that corrective actions can be taken in time, whenever deviations are observed.

Monitoring a CCP can be categorised into five viz. visual observation, sensory evaluation, physical measurement, chemical testing and microbiological examination. Visual monitoring needs no expensive equipment and may not even require highly specialized staff. Sensory evaluation can sometimes provide a quick indication of loss of control. It can be used to check the quality of incoming raw materials. Bad odours can also provide a quick indication of loss of control. Physical measurements such a temperature, pH, water activity, humidity can be made rapidly and are thus useful in monitoring processes where these factors are the means to control a particular CCP. Rapid chemical tests (eg. Chlorine level in water) are useful as means of monitoring CCPs. Microbiological testing and detailed chemical analysis are of limited use in monitoring CCPs. It can be employed for the testing of raw materials before starting processing, and for testing critical finished products (eg. Ready to eat fish curry) before release. Monitoring also provides a record that products were produced in compliance with the HACCP plan. This information is useful in the verification of the HACCP plan as discussed in Principle 7.

Components of Monitoring System

The monitoring procedure ensures that the required control measures are effective and hazards are kept below critical limits. This is done in the plan form by indentifying following parameters :

- What will be monitored (Direct/Indirect). (Column 4)
- How the critical limits and control measures will be monitored. (Column 5)
- How frequently monitoring will be performed. (Column 6)
- Who will perform the monitoring. (Column 7)

What will be monitored

It can be a measurement of a product characterestic or a processing

Examples

- Measurement of boiler compartment temperature
- Measurement of the pH of pickle.
- Measurement of conveyor belt speed

It can also a subjective measurement which involves observation of a control measure to manage a hazard..

Examples

- Checking that a supplier's certificate accompanies a lot of raw material.
- Auditing the farm premises to check whether the fish farmer is using the permitted antibiotic and whether he applies it as per guidelines.

How Critical Limits and Control Measures will be monitored?

Monitoring must be designed to provide rapid (real-time) results. There is no time for lengthy analytical testing because critical limit failures must be detected quickly and an appropriate corrective action instituted before distribution.

Examples

- Time and temperature using a calibrated thermometer and stowatch.
- Water Activity (a_w) using a calibrated RH meter.
- Acidity (pH) using a calibrated pH meter.
- Visual observation for subjective evidences like supplier's guarentee, freshness using sensory evaluation etc.

Frequency of monitoring

As mentioned above, monitoring can be continuous or non-continuous. Where possible, continuous monitoring should be used. Continuous monitoring is possible for many types of physical and chemical parameters.

Examples of continuous monitoring include:

- The time and temperature of a batch cooker process for IQF shrimps may be continuously monitored and recorded on a temperature-recording chart.
- Checking for presence of metals in frozen shrimp blocks using a metal detector.

Examples of non-continuous monitoring include:

- Routine, daily checks for temperature of stored fish waiting for processing.
- Periodic sensory examination for decomposition in histamine forming seafood.

Who will do the Monitoring?

Assignment of the responsibility for monitoring is an important consideration when developing a HACCP plan.

Individuals assigned to CCP monitoring can be:

- Line personnel,
- Equipment operators,
- Supervisors,
- Technologist

Corrective Actions

Corrective actions are predetermined procedures to be adopted when critical limits at a CCP is compromised. These procedures should restore process control and state clearly the method of disposing the product produced during the deviation.

An effective corrective action plans must:

- Correct and eliminate the cause of the noncompliance to assure that the CCP is brought back under control.
- Segregate, assess and determine the disposition of the noncompliant product.

All corrective actions taken must be documented. Documentation will assist the firm in identifying recurring problems so that the HACCP plan can be modified. Additionally, corrective action records provide proof of product disposition.

An example of disposition procedure for an affected product is given below:

- Isolating and holding product for safety evaluation. If the product was found to be safe, release the product.
- Diverting the affected product or ingredients to another line where deviation would not be considered critical.
- Reprocessing.
- Destroying product.

It may be necessary to determine the cause of the deviation to prevent future recurrence. A critical limit failure that was not anticipated or reoccurs should result in an adjustment to the product or process or a re-evaluation of the HACCP plan.

Verification Procedures

Verification are those activities, other than monitoring, that determine the validity of the HACCP plan and that verify the system is operating according to the plan. The purpose of the HACCP plan is to prevent food-safety hazards, and the purpose of verification is to provide a level of confidence that the plan is based on solid scientific principles, is adequate to control the hazards associated with the product and process, and is being followed.

Parts of Verification:

- Validation
 - CCP verification activities
 - Calibration of monitoring devices
 - Calibration record review
 - Targeted sampling and testing
 - CCP record review
 - HACCP system verification
 - Observations and reviews
 - Microbiological end-product testing
- Regulatory agencies

Validation: 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. Validation can be performed by the HACCP team or by an individual qualified by training or experience.. Validation involves a scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy.

Verification of CCPs Verification activities developed for CCPs are essential to ensure that the control procedures used are properly functioning and that they are operating

and calibrated within appropriate ranges for food-safety control. CCP verification may also include targeted sampling and testing.

- **Calibration**

Verification activities at CCPs include calibration of monitoring devices

to ensure the accuracy of the measurements taken with traceability. Calibration is conducted

to verify that monitoring results are accurate.

Calibration of CCP monitoring equipment is fundamental to the successful implementation and operation of the HACCP plan. If the equipment is out of calibration, then monitoring results will be unreliable. Frequency

of calibration should also be influenced by equipment sensitivity.

- ***Calibration Record Review***

Reviewing the equipment calibration records involves checking the dates and methods of calibration and the test results

- ***Targeted Sampling and Testing***

Verification may also include targeted sampling, testing and other periodic

activities. Vendor compliance may be checked by targeted sampling when receipt of material is a CCP and purchase specifications are relied on as critical limits. Typically, when a monitoring procedure is not as stringent as desired, it should be coupled with a strong verification strategy.

- ***CCP Record Review***

At least two types of records are generated at each CCP: monitoring and corrective action. These records are valuable management tools, providing

documentation that CCPs are operating within established safety parameters and that deviations are handled in a safe and appropriate manner. However, records alone are meaningless unless someone in a supervisory capacity reviews them on a periodic basis to “verify” that the HACCP plan is being followed.

HACCP System Verification

In addition to the verification activities for CCPs, strategies should be developed for scheduled verification of the complete HACCP system. The frequency of the system-wide verification should be yearly (at a minimum) or whenever there is a system failure or a significant change in the product or process. The HACCP team is responsible for ensuring that this verification function is performed. Often, the HACCP team will contract an independent third party to conduct the system-wide verification

Activities

• *System Verification Activities*

Systematic verification activities include on-site observations and record reviews. Reviews are usually performed by an unbiased person who is not responsible for performing the monitoring activities. System verification should occur at a frequency that ensures the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and product.

• *End-Product Microbiological Testing in HACCP Verification*

As explained in Chapter 2, microbiological testing is ineffective for routine monitoring but can be used as a verification tool. Microbiological testing can be used to determine (e.g., during verification audits or on periodic basis that the overall operation is under control.)

Record-Keeping Procedures

Accurate record keeping is an essential part of a successful HACCP program. Records provide documentation that the critical limits have been met or that appropriate corrective actions were taken when the limits were exceeded. Likewise, they provide a means of monitoring so that process adjustments can be made to prevent a loss of control.

Four kinds of categories are kept as part of the HACCP system.

1. HACCP plan and support documentation used in developing the plan
2. Records of CCP monitoring
3. Records of corrective action
4. Records of verification activities

Conclusion

HACCP was designed to prevent hazardous products from leaving the manufacturing or processing facility. The key to the success of HACCP is employee training, behavior and attitude. Some companies are under the misconception that they already have a HACCP plan because they are adequately controlling all areas where safety could be compromised. The difference is that, rather than monitoring isolated processing steps, an HACCP approach controls the entire production process as an integrated system.

Although HACCP provides insurance that poultry is safe, there is no way to completely eliminate all hazards. HACCP is most effective when used with other control systems. Total Quality Management programs and Standard Operating Procedures should be used along with HACCP to improve product safety, product quality, and plant productivity by providing intimate knowledge of the production process, production environment and processing equipment.