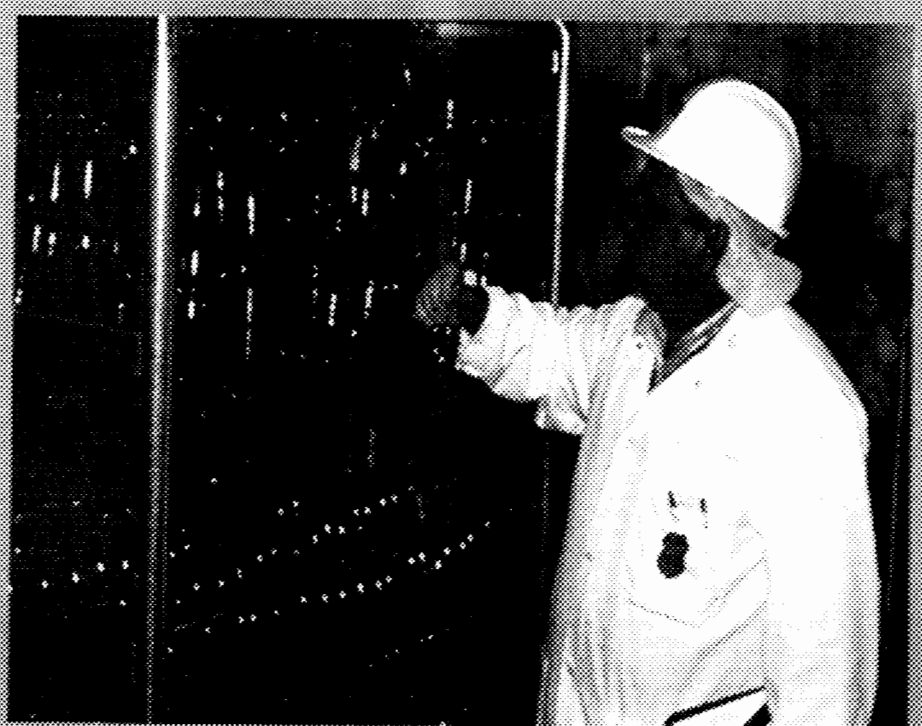
PN-ADC-839

HACCP IMPLEMENTATION WORKBOOK



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Abt

Products: 1- Cole Slaw

Ingredients: Cabbage, Carrot, Mayonnaise

Product Construction: Ready to eat , chilled coleslaw produced in 150g portion packs

2- Pasteurised Cured Canned Meat

Ingredients: Beef, brine, (nitrate/nitrite, polyposhphate, ascorbate and sugar)

Product Construction: Pasteurised Canned beef. Beef is injected with brine, filled into hermetically seadled cans and pasteurized. The product is distributed and stored under refrigeration.

3- Shredded Lettuce

Ingredients: Lettuce

Product construction: Raw lettuce is received, washed and disinifected, shredded and vacuum packed. The product has a shelf life of 7 days

4- Breaded Chicken Nuggets

Ingredients: Chicken, breadcrumbs, oil, binder, coloring, spices

Product Construction: Chicken is minced, all other raw materials are added. Mixture is formed into nuggets and then covered with crumbs. Nuggets are frozen, then packed into 250g packs. The product has a shelf life of 9 months.

(Tip: Decide on team leader and scribe. Agree to the HACCP study terms and terms of reference and scope)

This HACCP plan for (name your product) was prepared by the HACCP Team of (company name), as follows:

Company:	Address:
Contact :	Phone:
Fax:	E-mail:

HACCP Team Members:

Name	Title	Dept	Contact #

The formation of the HACCP Team has been approved by management.

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HACCP Team Leader Management Rep

Date: Date:

Product Description :

Include all ingredients, processing methods, packaging materials, used in the formulation of the product. In brief, the product description should include the name of the product, ingredients and composition, pH, brief details of the process and technology used in production,

1- Product Name
2- Important end-product characteristics
3- How the product is to be used (ready-to-eat, heat prior to consumption)
4- Shelf life including storage temperature
5- Type of Package and packaging conditions
6- Where will the products will be sold (retail, institutions, further processing)
7- Labeling Instructions (handling and usage instructions)
8- Special distribution control (eg shipping conditions)

Product Name	
Important Product Characteristics	
How Product is to be Used	
Packaging	
Shelf-Life	
Where the product will be Sold	
Labeling Instructions	
Special Distribution Control	

Date:---------- Approved by:----------

Identify Intended Use of the Product

This refers to the consumers intended to use this product. The HACCP team must specify where the product will be sold, as well as the target group, especially if it happens to be a sensitive portion of the population (i.e. elderly, immuno-suppressed, pregnant women and infants)

Construct a Flow Diagram of the Process then Verify It

The process flow diagram identifies the important process steps (from raw material receiving and up to shipping)Each process step should be considered in detail and the information expanded to include all relevant process data. Data may include but is not restricted to:

- All ingredients and packaging used
- Sequence of all process operations (including raw material addition)
- Time/temperature history of all raw materials and intermediate and final products, including the potential for delay
- Flow conditions for liquids and solids
- Product recycle/ rework loops
- Equipment design features

After that, verify the flow chart for each process on site, and then get the process owner to sign the flow chart for approval.

Process Flow Chart for:

PLACE YOUR FLOW CHART HERE

Draw a Plant Schematic then Verify It

A plant schematic must be developed, to show product flow and employee traffic patterns within the plant for a specific product. The diagram should include the flow of all ingredients and packaging materials from the moment they are received at the plant, through storage, preparation, processing, packaging, finished product holding and shipping.

Personnel flow should include employee movement through the plant, including the changing rooms, washrooms and lunch rooms. The location of the hand-washing facilities and footbaths should be noted.

Data included on the schematic could include, but is not limited to:

- Personnel routes
- Routes of potential cross-contamination
- Area Segregation
- Flow of ingredients and packaging materials
- Location of changing rooms, washrooms, lunchrooms, hand-washing stations and footbaths

After drafting your plant schematic, do an on-site verification for it and then have the HACCP team leader or process owner sign it for approval, then place it on the following page.

PLANT SCHEMATIC

Date:

Approval:

Hazard Analysis

Hazard Analysis must be performed for all existing and new products. Changes in raw materials, product formulations, processing or preparation procedures, packaging, distribution and /or the use of product will require review of the original hazard analysis. The first step in the development of the HACCP plan for a food operation will is the identification of all potential hazards associated with the product at all stages from raw materials to consumption. All biological, chemical and physical hazards should be considered.

Hazards will vary among firms making the same products because of differences in:

- Sources of ingredients
- Formulations
- Processing Equipment
- Processing and preparation methods
- Duration of processes
- Storage Conditions
- Experience, attitudes and knowledge of personnel

Sources of Information for Hazard Analysis

- Reference texts: such as the BAD BUG BOOK on www.fda.gov
- Company Complaints File: This file should be thoroughly examined, the cause of the complaint should be reviewed to assist in hazard identification
- Scientific Research and Papers

How to Conduct a Hazard Analysis

State all the biological, chemical and physical hazards that may be reasonably expected at each step from primary production , processing, manufacturing, and distribution until the point of consumption, the HACCP team should assess the potential significance or risk of each hazard by considering its likelihood of occurrence and severity.

By applying the following five activities, the HACCP team will have an extensive list of realistic potential hazards.

Review Incoming Materials

1- Use your product description form and the list of product ingredients and incoming material.

2- Be specific in describing the hazards. For example, instead of writing "bacteria in incoming ingredient", write " *C. botulinum* in incoming mushroom"
3- Consider the presence of pathogens, toxins, chemicals, physical objects, preservatives or additives
4- Consider the ingredients that could be hazardous if used in excessive amounts (like nitrite)
5- The likelihood of adding ingredients in an amount lower than recommended to add to spore formation, cellular growth, etc

Evaluate processing operations for hazards

1- Review the process flow diagram and plant schematic to identify any potential hazard(biological, chemical or physical)
2- Consider personnel hygiene, potentials for cross-contamination, leaking valves, splashing
3- Could temperature and time contribute to the multiplication of microbes during the process operation

Observe Actual Operating Practices

The HACCP tam shall:

- Observe the operation long enough to be confident that it comprises the usual process or practices
- Observe employee practices
- Analyse if there is a kill step in the process , so that attention is focused on preventing cross contamination after this step

Take measurements

It may be necessary to take measurements of important processing parameters to confirm actual operating conditions. Before measuring, make sure all devices are accurate and correctly calibrated.

- Measure product temperatures: the coolest place when heat processing is evaluated and the warmest point of the product when evaluating cooling or freezing (usually the center of the biggest piece)
- Measure time/temp for cooking, pasteurizing, canning, thawing, measure pH and Aw.

Analyse Measurements

A qualified individual (with proper scientific background) must analyse the measurements to interpret correctly the data collected.
For example:

- Plot time/ temp measurements using a computer or on graph paper
- Interpret collected data versus optimal growth temperatures of microorganisms and temperatures at which they can multiply
- Compare Aw and pH values to ranges at which pathogens multiply or are eliminated
- Evaluate the shelf stability of the product

Control Measures

After the hazard analysis is completed, the team must then consider what control measures, if any, exist which can be applied for the control of each hazard. Control measures are any actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. More than one measure may be required to control a specific hazard and more than one hazard may be controlled by a specified measure.

Controlling Biological Hazards

The following are examples of control measures for biological hazards. For bacteria, control measures. For bacteria, control measures include:

- Temp/time control (proper control of refrigeration and storage time, for example, minimizes the profileration of microbes)
- Heating and cooking for an adequate time and at an adequate temp to eliminate microbes or reduce them to acceptable levels
- Cooling and freezing
- Fermentation and/or pH control
- Addition of salts or preservatives, which at acceptable levels may inhibit growth of microorganisms
- Drying
- Cleaning and sanitizing
- Personnel and hygienic practices
- Visual examination

Controlling Chemical Hazards

- Formulation control
- Proper segregation of non-food chemicals during
- Control of incidental contamination from chemicals(lubricants, water and steam treatment chemicals, paints)
- Labeling control, ie ascertaining that the finished product is accurately labeled with ingredients and known allergens

Controlling Physical Hazards

- Controlling incoming materials
- Process control; use of magents, metal detectors, sifter screens, de-stoners
- Environmental control: ensuring adherence to GMPs

Hazard Assessment

Use the information you have gathered from the hazard analysis to determine:

- The severity of hazards
- Risks associated with the hazards identified at different points of the operation

Severity

Severity is the magnitude of a hazard or the degree or consequences that can result when a hazard exists. Disease-causing hazards can be categorized according to their severity .

- High(life-threatening) examples include *Clostridium botulinum, Salmonella typhi, Listeria Monocytogenes, E. coli* 0157:H7, *Vibrio cholarae,* paralytic shellfish poisoning
- Moderate (severe or chronic): examples include illnesses caused by Brucella spp., Campolybacter spp., *Salmonella* spp., *Shigella* spp., *Yersinia entercolitica,* hepatitis A virus, mycotxins
- Low (moderate or mild)- examples include illnesses caused by *Bacillus* spp., *Clostridium perfringens*, *Staphylococcus aureus,*Norwalk virus, most parasites, histamine-like substances and most heavy metals that cause mild acute illnesses

Risk of Hazard

Risk is a function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard in food. Degrees of risk can be categorized as high, moderate, low and negligible.

Significance of a hazard is then determined by weighing its **severity** to its **risk.**

Evaluation Sheet for Product Ingredients and Incoming Material

Material/Ingredient	Biological Hazard	Chemical Hazard	Physical Hazard

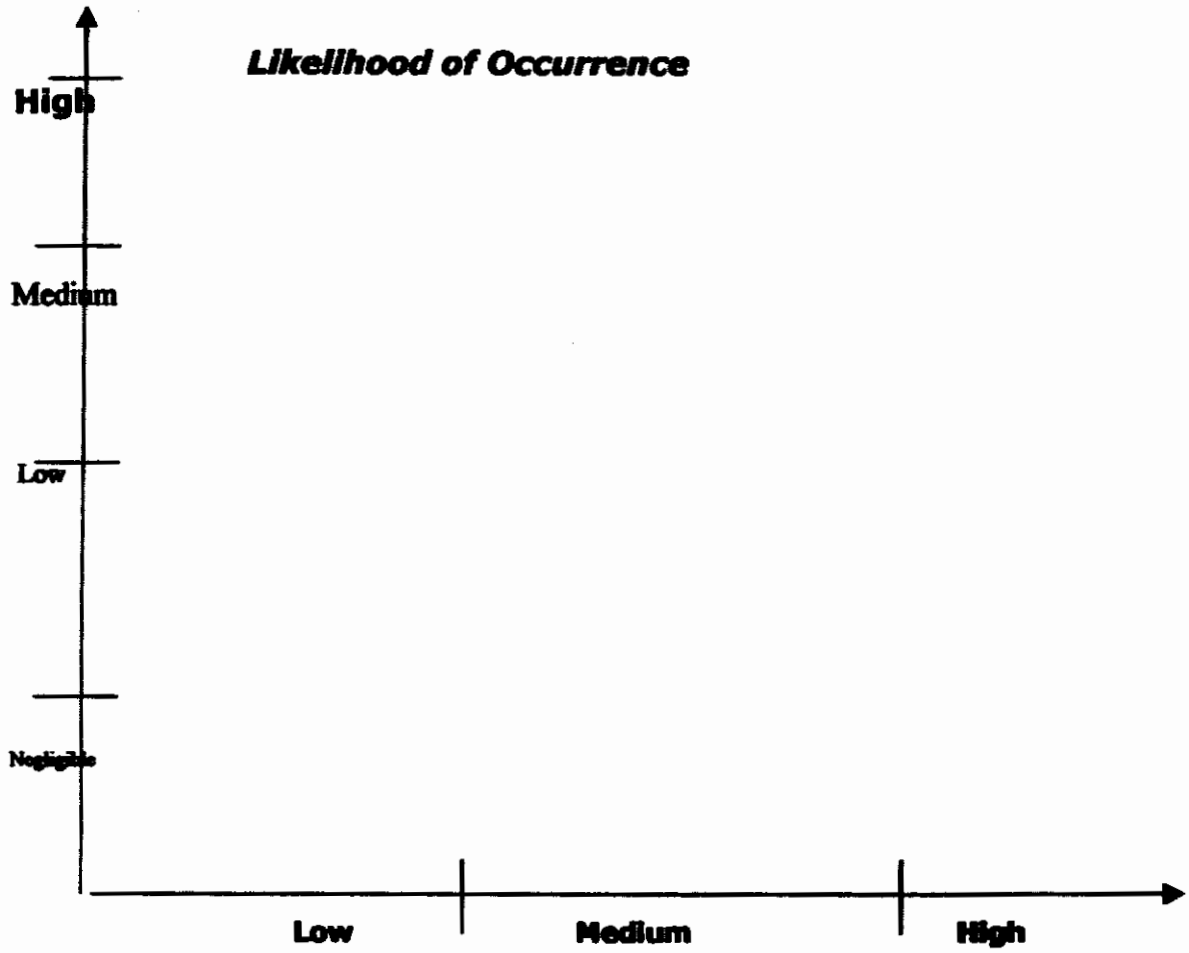
Date:

Approved by:

Identification of Hazards for Process Steps
(make on for every type of hazard; b,c,p)

Process Step	Hazard Type and Description	Control Measure	Prob	Risk

Assessment of Hazards



Position all the hazards you've identified as per the previous table, then plot them.

The data can then be used to ascertain the appropriate locations to establish control points, the degree of monitoring and any changes that could be made that would reduce the magnitude of the hazards that exist.

Determine Critical Control Points

Hazards that are fully controlled by GMPs should be verified on-site by the HACCP team. Hazards which are not fully controlled by GMPs should be analysed to determine if they are CCPs or not.

The CCP Decision Tree consists of a systematic series of four questions designed to assess objectively whether a CCP is required to control the identified hazard at a specific operation of the process.

Question 1: Do control measures exist?
Question 1 should be interpreted as asking whether or not the operator could use a control measure at this operation or anywhere else in the food establishment to control the identified hazard. Control measures could include, for example, temperature control, a visual examination, or use of a metal detector.

Yes: proceed to Q2

No: If a control measure does not exist, indicate how the identified hazard will be controlled. You could modify the process, so that a control measure exists.

Question 2: Is the step specifically designed to eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?

Examples for such steps are: retorting in a canning operation, pasteurization, chlorination of cooling water, addition of a metal detector in a processing line, a particular sanitation procedure performed to clean contact surfaces without which the line would be stopped and the product contaminated.

If the answer is yes, that is this step is specifically designed to eliminate or reduce the identified hazard, the this step is a CCP.

Question 3: Could contamination with the identified hazard occur in excess of acceptable levels or increase to unacceptable levels?

This question refers to both likelihood and seriousness. The response is a judgment call involving risk assessment based on all the information

that has been gathered. It is advisable to write the justification for the answer to this question, for future reference.

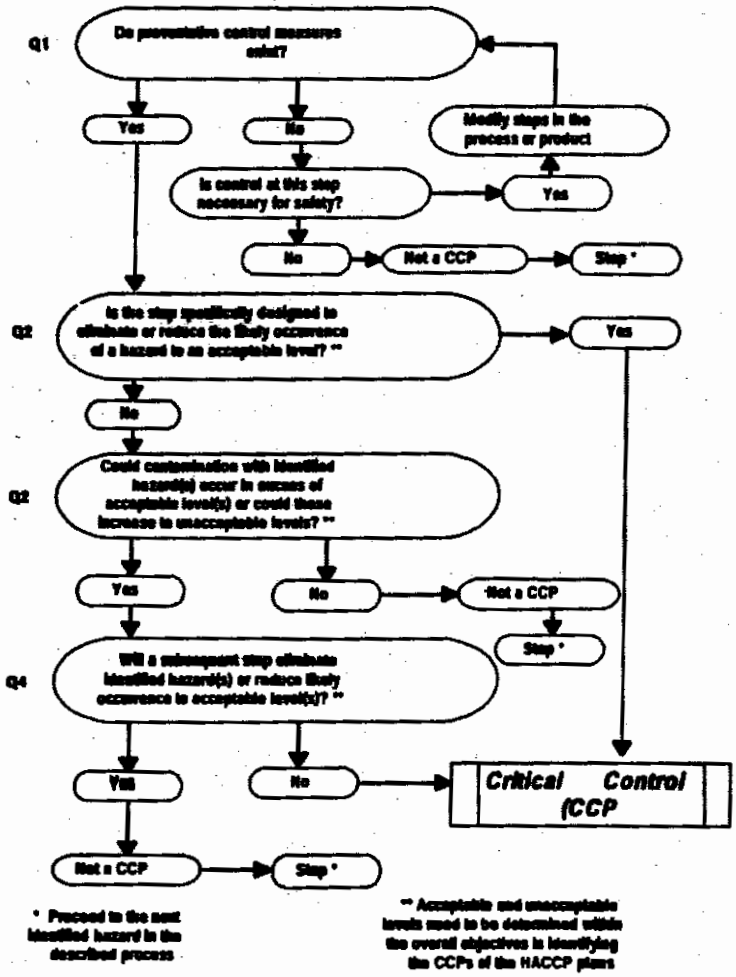
Yes: proceed to next question
No: Not a CCP, proceed to next hazard

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

This question is designed to identify hazards that are known to represent a human health threat or that could increase to an unacceptable level, and that will be controlled by a subsequent process operation.

If no subsequent operation is scheduled in the process to control this identified hazard, answer 'no. This step automatically becomes a CCP and should be identified as such.

DIAGRAM 2
EXAMPLE OF DECISION TREE TO IDENTIFY CCPs
(answer questions in sequence)



Using the Decision Tree, fill the following table for all of the hazards:

Step	q1	q2	q3	q4	ccp

Establishing Critical Limits

At each critical control point (CCP) , critical limits are established and specified. Critical limits are defined as the criteria that separate acceptability from unacceptability. A critical limit represents the boundaries that are used to judge whether an operation is producing safe products. Critical limits may be set for factors such as temperature, time (minimum time exposure), physical product dimensions , water activity, moisture level, etc. These parameters, if maintained within boundaries, will confirm the safety of the product.

The critical limits should meet or exceed requirements of governmental regulations and/or company standards and/or be supported by scientific data. In some cases, food control regulatory authorities provide information on which to establish the critical limits based on known food hazards and the result of risk analysis (e.g. the time/temperature requirements for thermal processes such as pasteurization, cooking,, retorting, maximum number and size of physical contaminants, chemical residues).

It is essential that the persons responsible for establishing critical limits have a knowledge of the process and the legal and commercial standards required for the product.

Sources of Information on Critical Limits include:

- Scientific publications/research data
- Regulatory requirements and guidelines
- Experts (thermal process authorities, consultants, food scientists, microbiologists, equipment manufacturers, sanitarians, academics)

Operating Limits:
If monitoring shows a trend towards lack of control at a CCP, operators can take action to prevent loss of control of the CCP before the critical limit is exceeded. The point at which operators take such action is called the operating limit. Operating limits should not be confused with critical limits. Often, the operating limits are more restrictive and are established at a level that would be reached before the critical limit is violated.

An operator may observe a trend towards the loss of control, such as the failure of a cooker to maintain the desired temperature consistently.

Observing a trend towards loss of control early and acting on it can save product rework, or worse yet, product destruction. When the critical limit is exceeded, corrective action is required. For this reason, a processor may choose to operate a CCP at a limit more conservative than the critical limit. Such operating limits may be selected for various reasons:

- For quality reasons: higher cooking temperatures for flavour development or product texture.
- To avoid exceeding a critical limit, using cooking temperature that is higher than the critical limit as an alarm point, to warn the operator that the temp is approaching the critical limit and needs adjusting.
- To account for normal variability, eg setting a cooker with 2 C°. variability at least 2°C above the critical limit to avoid violating it.

The process may need to be adjusted when the operating limit is exceeded. Such actions are called process adjustments. A processor should use these adjustments to prevent loss of control and the need for product disposition.

After reviewing the sources, write down the Critical Limits for each CCP.

Step	CCP #	Hazard description	Critical limits

Establish a Monitoring System

Design of a Monitoring System

The control measures discussed earlier are intended to control a hazard at each CCP. The monitoring procedures will determine if the control measures are being implemented and ensure that critical limits are not exceeded. The monitoring specifications for each CCP should be written on the specific form. They should give information on:

- What will be monitored
- How critical measures and preventive measures will be measured
- Frequency of Monitoring
- Who will monitor

What will be monitored?

- Monitoring may mean measuring a characteristic of the product or process to determine compliance with the critical limit.

Examples include :

- Measurement of time and temperature of a thermal process
- Measurement of cold-storage temperatures
- Measurement of pH
- Measurement of Aw

Deviation from a critical limit should be detected in as short a time as possible to allow corrective action to limit the amount of adversely affected product.

Effective monitoring depends upon the proper selection and calibration of the measuring equipment. Examples of monitoring equipment would include:

- Thermometers
- Clocks
- Scales
- PH-meters
- Water activity meters
- Chemical analytical equipment

Equipment should undergo periodic calibration or standardization as necessary to ensure accuracy.

The frequency of monitoring should be determined from historical knowledge of the product and process. The following questions will help in determining the correct frequency.

- How much does the process normally vary?
- How close is the operating limit to the critical limit?
- How much product is the processor prepared to risk if there is deviation from the critical limit?

Who will monitor?

Individuals assigned to monitor CCPs may include:

- Line operators
- Equipment supervisors
- Supervisors
- Maintenance personnel
- Quality assurance personnel

Once assigned, the individual responsible for monitoring a CCP must:

- Be adequately trained in the CCP a monitoring techniques
- Fully understand the importance of CCP importance
- Have ready access (to be close) to the monitoring activity
- Have the authority to take appropriate action as defined in the HACCP plan '
- Immediately report critical limit deviation

Step	CCP	Critical	Monitoring			
			What	How	When	Who

Establish Corrective Action

The corrective action as " any action to be taken when results of monitoring at the CCP indicate a loss of control."

More than one corrective action might be necessary for one CCP. Deviation and corrective action procedures are prescribed so that employees responsible for monitoring CCPs understand and are able to perform the appropriate corrective actions in the event of a deviation.

Process adjustments should also be made when monitoring results indicate a trend towards loss of control at a CCP. Action should be taken to bring the process within the operating limits before a deviation occurs.

Deviation:
Deviation is defined as" failure to meet a critical limit" . Procedures should be in place to identify, isolate and evaluate products when critical limits are exceeded. Inadequate deviation procedures could result in unsafe products and the eventual recurrence of the deviation.

The procedure should control deviation as follows:

Identification of deviation:
The producer should have a system to identify deviations as they occur

Isolation of Affected Product
The producer should have effective procedures in place to isolate, mark clearly and control all product produced during the deviation period.

- All affected product, i.e. that processed since the last point at which the CCP was known to be under control, should be isolated.
- Isolated product should be clearly marked, eg with firmly attached tag, with information for product qty, name, reason for holding, name of person
- Maintain control of the product from hold date until date of final disposition.

Evaluation of Affected Product
Product evaluation should be conducted by a qualified person. For example, thermal process deviation would be evaluated by a competent process authority or reference center.

The evaluation of affected product should be adequate to detect potential hazards, i.e it should be ensured that sampling is adequate to identify the extent of the problem, that the test are appropriate, that the judgement is based on sound scientific reasons and that the product is not released until the evaluation has determined that no potential hazard exists.

Corrective Action Procedures
Since the main reason for implementing HACCP is to prevent problems from occurring, corrective action should be taken to prevent deviation at a CCP. Corrective action should be taken following any deviation to ensure that the action taken is effective. If the corrective action does not address the root cause of the deviation , the deviation could recur. Reassessment of the hazard analysis or modification of the HACCP plan may be necessary to eliminate further occurrence.

The producer's corrective action programme should include the following:
- Investigation to determine the cause of the deviation
- Effective measures to prevent recurrence of the deviation
- Verification of the effectiveness of the corrective action taken

Deviation and Corrective Action Records
Records should be available to demonstrate the control of products affected by the deviation and the corrective action taken. Adequate records permit verification that the producer has deviations under control and has taken effective corrective action.

The following information should be recorded in the corrective action and deviation records.

Deviation
- Product Code
- Date produced/held/released
- Reason for the hold
- Amount of product held
- Results of evaluation: amount analysed, analysis report, number and nature of defects
- Signature of personnel responsible for hold and evaluation
- Disposition of held product (if possible)
- Signed authorization for disposal

Corrective Action

- Cause of deviation identified
- Follow-up/assessment of effectiveness of corrective action
- Corrective action taken to correct deficiency
- Date
- Signature of responsible person

Process Step	CCP#	Hazard Description	Critical Limit	Monitoring Procedures	Corrective Action

Date:---------- Approved:----------

Establish Verification Procedures

Verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

Each HACCP plan should include verification procedures for individual CCPs and for the overall plan. HACCP plans are expected to evolve and to improve with experience and new information. Periodic verification helps improve the plan by exposing and strengthening weaknesses in the system and eliminating unnecessary or ineffective control measures.
Verification activities include :

- HACCP plan validation
- HACCP system audits
- Equipment Calibration
- Targeted sample collection and testing

HACCP Plan Validation: is assessing whether the plan for the particular product and process adequately identifies and controls all significant food safety hazards or reduces them to an acceptable level. HACCP plan validation should include:

- Justification for critical limits, based on current good science and regulatory requirements
- Determination of whether monitoring activities, corrective actions, record keeping procedures and verification activities are appropriate and adequate

The process of validating an existing HACCP plan should include :

- Review of HACCP audit reports
- Review of changes to the HACCP plan and the reason for those changes
- Review of past validation reports
- Review of deviation reports
- Assessment of corrective action effectiveness
- Review of information on customer complaints
- Review of linkages between HACCP plan and GMP programmes

HACCP System Audits: Audits are performed to compare the actual practices and procedures of the HACCP system with those written in the HACCP plan.

Audits may be performed for individual CCPs or for the whole HACCP plan.

During the audit, take a look at records that demonstrate the following:

- Monitoring activities have been performed at the locations specified in the HACCP plan
- Monitoring activities have been performed at the frequency stated in the HACCP plan
- Affected product has been controlled and corrective actions have been taken
- Equipment has been calibrated at the frequencies specified in the HACCP plan.

Calibration

Calibration involves checking instruments or equipment against a standard to ensure accuracy. Calibration should be documented and the records should be available for review during verification.
Calibration of appropriate equipment and instruments used in the development and implementation of the HACCP plan should be carried out, during monitoring and/or verification.

Establishing documentation and record keeping

A record shows the process history, the monitoring, the deviations and the corrective actions that occurred at the identified CCP.

Four types of records should be kept as part of the HACCP program:

1- Support documentation for developing the HACCP plan
2- Records generated by the HACCP system
3- Documentation of methods and procedures used
4- Records of employee training programmes

Your final HACCP plan should look like this:

Step	CCP #	Hazard Description	Critical Limit	Monitoring	Corrective Action	Ver	Records