

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH



TANZANIA FOOD AND DRUGS AUTHORITY (TFDA)

DRAFT

**Guidelines for Application of Hazard Analysis Critical
Control Points (HACCP) in Food Manufacturing**

*Prepared by
TFDA
September, 2005*

FOREWORD

The Tanzania Food and Drugs Authority (TFDA) is a regulatory agency established under section 4(1) of the Tanzania Food, Drugs and Cosmetics Act No. 1 of 2003. It is responsible among other functions to regulate the quality and safety of food for the purpose of protecting human health. Therefore, it regulates manufacturing, distribution, storage, and sale of food to ensure that products circulating in the market comply with prescribed specifications. To achieve this, efforts are made towards enforcing the legislation, and regulations made there under as well as using guidelines to enhance effective implementation and enforcement of the law.

To bring about effective enforcement of the legislation, TFDA has a role to institute mechanisms, which will enable manufacturers or dealers to apply quality assurance systems that will provide assurance on the quality and safety of food without merely relying on the quality of the end product. Similarly, TFDA need to standardize inspection carried by TFDA inspectors to bring about the anticipated impact. Manufacturers need guidance as to which quality assurance systems are required to be adhered to and the manner of their application. Such approach will help the local industry to produce safe products that can compete in local and international markets.

Currently, Hazard Analysis and Critical Control Points (HACCP) is synonymous with food safety, as it is a preventive system aimed at food safety assurance, It can be applied at any segment of the food chain and applied irrespective of the complexity or simplicity of the food processing or handling operation. Recognizing its importance, it is anticipated that in future, HACCP might become mandatory to some categories of food products or all as may be necessary for food safety considerations and in order to cope with global trade requirements.

These guidelines for HACCP application have been prepared to assist manufacturers, other food dealers and inspectors to play their roles in bringing about effective implementation of HACCP; as the guidelines will be useful in preparing appropriate HACCP plans and their application. Food inspectors will make use of the guidelines to carry out effective HACCP based food inspections. More important, it will save as training materials for various stakeholders who are obliged to be equipped with such knowledge. The information provided in these guidelines is not exhaustive, however; it highlights necessary issues in relation to HACCP principles and its application in preventing food safety problems. In the course of its application, new developments are expected that will necessitate its revision to accommodate such changes or making it user friendly. Use of the document will provide an opportunity to identify weaknesses and therefore refine it so that it brings the anticipated objectives as a result of getting feedback from users. It is my expectation that relevant stakeholders will fully utilize the guidelines for purpose of promoting voluntary compliance and enhancing adequate protection of food consumers' health.

M. Ndomondo - Sigonda
Director General.

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DEFINITIONS AND TERMS

Calibration: Involves checking instruments or equipment against a standard to ensure accuracy.

Compliance: The HACCP plan and prerequisites and their implementation meet regulatory requirements.

Conformity: Activities are carried out according to the established procedures, e.g. HACCP plan and prerequisites.

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: Any action taken to rectify a deviation(s) when the results of monitoring at the CCP indicate a loss of control.

Critical Control Point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Control Point (CCP) Decisions tree: A sequence of operations to assist in determining whether a control point is a CCP.

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 a hazard to an acceptable level. The occurrence of a food safety hazard or a criterion, which separates acceptability from unacceptability.

Criterion: A requirement on which a judgement or decision can be based

Deviation: Failure to meet a critical limit.

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

Generic HACCP plans: These are examples of HACCP plans developed for a food commodity or process that may be used as guidance for business operators producing such commodities or using such processes. Generic plans are not appropriate for use until customized for a specific food and food process.

HACCP: A system, which identifies, evaluates, and controls hazards, which are significant for food safety.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards, which are significant for food safety in the segment of the food chain under consideration.

HACCP system: The result of the implementation of the HACCP plan

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Third party

An independent assessor be it a person or an organization with competence to assess HACCP.

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

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

CHAPTER 1

1.0 INTRODUCTION

The need for a safe food is now an important agenda internationally partly due to globalisation as food borne health problems found in one part of the world can easily spread all over the world within a short time. Quality assurance programmes are being instituted to ensure quality and safety of food in order to protect human health and promote food industry. Approach towards ensuring safe food has been changing to meet evolving adverse health challenges.

To achieve food safety, quality assurance programmes which include Good Agricultural/Aquaculture Practices (GAP), Good Veterinary Practices (GVP), Good Hygienic Practices (GHP), Good Manufacturing Practices (GMP) and currently Hazard Analysis and Critical Control Points (HACCP) are being applied along the food chain from the farm to the folk. However, all over the world, HACCP has become synonymous with food safety. It is a science based and systematic; it identifies specific hazards and measures for their control to ensure the safety of food. It is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end product testing and inspection. The application of HACCP, which is cost effective system, has been prompted by lack of sufficient resources to deal with food borne illnesses and limitations of traditional approaches to food safety assurances

Implementing HACCP does not mean undoing quality assurance procedures or Good Practices already established. While the application of HACCP to all segments and sectors of the food chain is possible, it is assumed that all sectors should be operating according to Good Manufacturing Practices (GMP) and the general Principles of Food Hygiene.

The application of HACCP system has some inherent advantages, these include;

- i) It is a preventive system, therefore does not rely on end product testing,
- ii) It is capable of accommodating changes, such as advances in equipment design, processing procedures or technological developments,
- iii) It can be applied throughout the food chain from the primary producer to the consumer,
- iv) It brings more effective use of resources as more attention is paid to critical areas, savings to the food industry and more timely response to food safety problems,
- v) Enhances responsibility and degree of control at the level of a food industry.
- vi) A properly implemented HACCP system leads to greater involvement of food handlers in understanding and ensuring food safety, thus providing them with renewed motivation in their work.
- vii) Permits more efficient and effective government oversight, primarily because the record keeping investigators are able to see how well a firm is complying with food safety laws over a period rather than how well it is doing on any given day
- viii) Helps food companies compete more effectively in the world food market

and reduces barriers to international trade as it provides assurance on the quality and safety of food produced.

Government agencies and relevant stakeholders are key players for effective implementation of HACCP system. The food producer, manufacturer or dealer must have full commitment to the implementation of the HACCP plan. The role of the Government is to carry out regulatory assessment with the objective of obtaining evidence that the seven HACCP principles are effectively applied for enforcement purpose. Also assessment is carried out to enhance adoption and effective application of HACCP system.

CHAPTER 2

2.0 PRINCIPLES OF THE HACCP SYSTEM

HACCP system consists of the following seven principles

Principle 1: Conduct a hazard analysis

Identify the potential hazard(s) associated with food production at any segment along the food chain; from primary production, processing, manufacture, storage and distribution until the point of consumption. Assess the likelihood of occurrence of the hazard(s) and identify the measures for their control.

Principle 2: Determine Critical Control Points (CCPs).

Determine the points, procedures or operational steps that can be controlled to eliminate the hazard(s) or minimize its (their) likelihood of occurrence.

Principle 3: Establish critical limit(s)

Establish critical limit(s), which must be met to ensure the CCP is under control.

Principle 4: Establish a system to monitor control of the CCP.

Establish a system to monitor control of the CCP by scheduled testing and observation

Principle 5: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

Principle 6: Establish procedures for verification to confirm that the HACCP system is working effectively.

Principle 7: Establish documentation concerning all procedures and records appropriate to these principles and their application.

CHAPTER 3

3.0 APPLICATION OF THE HACCP SYSTEM

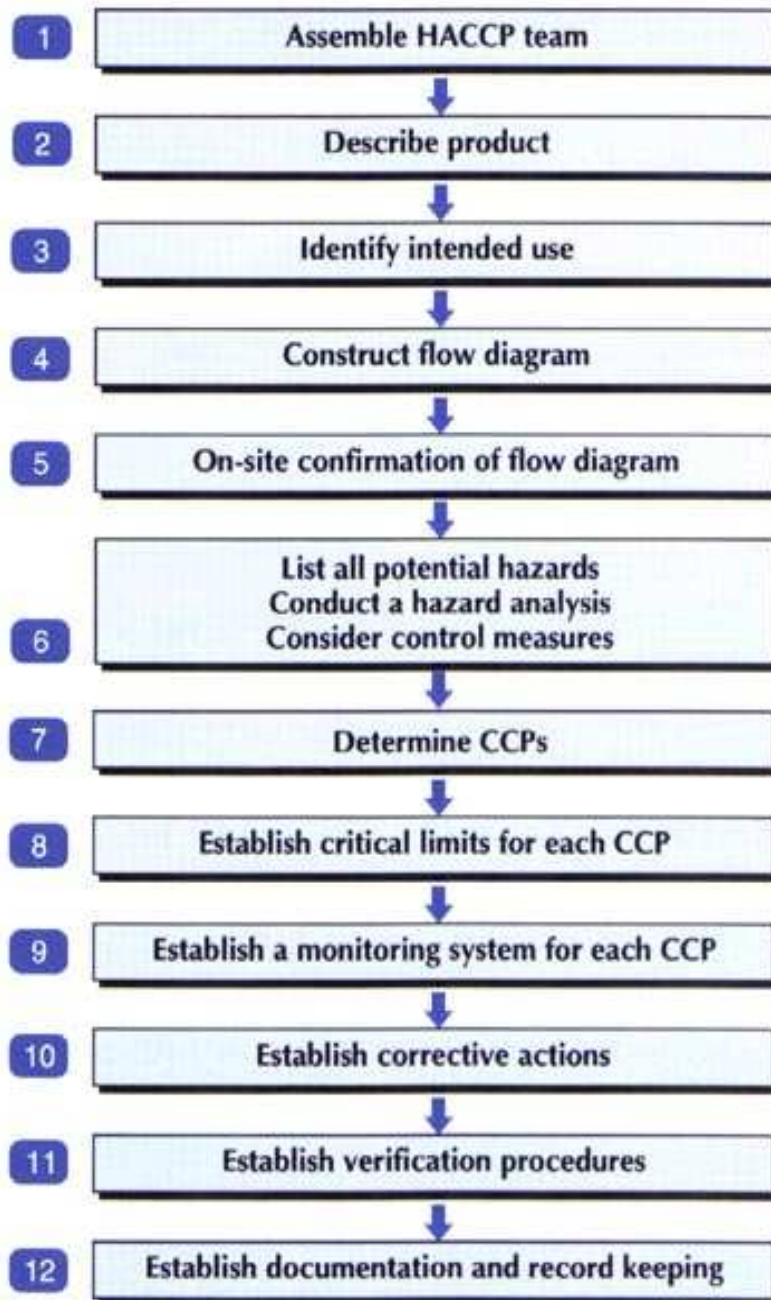
Prior to application of HACCP to any sector of the food chain, that sector should be operating according to the Food Hygiene Regulations or the appropriate Codex Codes of Hygienic Practices or Good Manufacturing Practices. Management commitment is necessary for implementation of an effective HACCP system.

HACCP should be applied to each specific operation separately. HACCP generic models are normally available however; these can serve as basis for preparing specific plan for particular situation of the plant or segment of the food chain.

The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP (figure 1)

Figure 1. CODEX logic sequence for application of HACCP



3.1 Assemble HACCP team

Prior to proceeding to HACCP team selection, it is extremely important to have full commitment to the HACCP initiative from Management and all the personnel in the development and implementation of the HACCP plan.

The HACCP team assembled should draw members from different disciplines (multidisciplinary team) having expertise and skills necessary for the development of HACCP plan such as sanitation, processing, quality control, and engineering. Where such expertise is not available on site, expert advice should be obtained from other sources. The team should be trained on development of HACCP plans before engaging them in the assignment.

The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain, the food product involved and the general classes of hazards, which need to be addressed (e.g. does it cover all classes of hazards or only selected classes).

3.2 Describe product

A complete description of the product should be drawn up, basing on relevant safety information such as: composition, physical/chemical characteristics including water activity (a_w), pH, etc. process and technology used in the production, packaging, shelf life, labelling information, intended use and target population, storage conditions and method of distribution. Form for description of the product is attached as Appendix 1 (form No. 1 and 2)

3.3 Identify intended use

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. infants, elderly, institutional feeding, may have to be considered.

3.4 Construct a flow diagram

The HACCP team should construct an accurate and a complete Process Flow Diagram (PFD) and Plant Schematic. The PFD should cover all-important steps in the operation. Plant schematic shows product flow and employee traffic. This is important to help identify potential areas of cross contamination within the establishment. Forms for construction of Process Flow Diagram and Plant Schematic are attached as appendix 1 (forms No 3 and 4 respectively).

3.5 On-site verification of flow diagram

The HACCP team should confirm the processing operation against the PFD during all stages and hours of operation to check its accuracy and completeness therefore amend the flow diagram where appropriate. This provides assurance that major process operations have been identified.

3.6.0 Conduct hazard analysis and measures to control identified hazards (see Principle 1)

Hazard analysis is one of the most important tasks in relation to development of HACCP plan, as inaccurate analysis would inevitably lead to development of inadequate HACCP plan.

Hazard analysis involves the following activities;

- i) List or identify potential hazards for the relevant segment e.g. primary production, processing, manufacture, or distribution.
- ii) Assess the severity of the hazards and likelihood of occurrence or which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.
- iii) Determine control measures corresponding to the hazard.

Hazards are categorized as Biological, Chemical or Physical. For each hazard, there are measures, which can be taken to eliminate or reduce it to the level where the risk is acceptable. Examples of potential hazards are attached as appendix 2.

Biological hazards

These include microbiological organisms such as bacteria, viruses, and fungi. Other biological hazards are parasites. These organisms are commonly associated with humans and with raw products entering the food establishment. Most are killed or inactivated by cooking, and numbers can be minimized by adequate control of handling and storage practices (hygiene, temperature and time).

Viruses can be food borne/water-borne or transmitted to food by human, animal or other agents

Chemical hazards

Chemical contaminants in food may be naturally occurring or may be added during handling and processing of food. Harmful chemicals at high levels have been associated with acute cases of food borne illnesses and can be responsible for chronic illness at lower levels.

Physical hazards

Physical agents may bring physical hazards, these include; stones, glasses, metallic materials, bones, plastic materials.

3.6.1 Hazard assessment

The information gathered from the hazard analysis can be used to determine: The severity of the hazard(s) and risks associated with hazards identified at various stages of the operation. Disease-causing hazards can be categorized according to their severity. Severity of the hazards can be high, moderate or low.

3.6.2 Severity of the hazard

Severity is the magnitude of a hazard

i) high (life-threatening) - examples include illnesses caused by *Clostridium botulinum*, *Salmonella typhi*, *Listeria monocytogenes*, *Escherichia coli* 0157:H7, *Vibrio cholerae*, *Vibrio vulnificus*, paralytic shellfish poisoning, amnesic shellfish poisoning

ii) moderate (severe or chronic) - examples include illnesses caused by *Brucella* spp., *Campylobacter* spp., *Salmonella* spp., *Shigella* spp., *Streptococcus* type A, *Yersinia enterocolitica*, hepatitis A virus, mycotoxins, ciguatera toxin

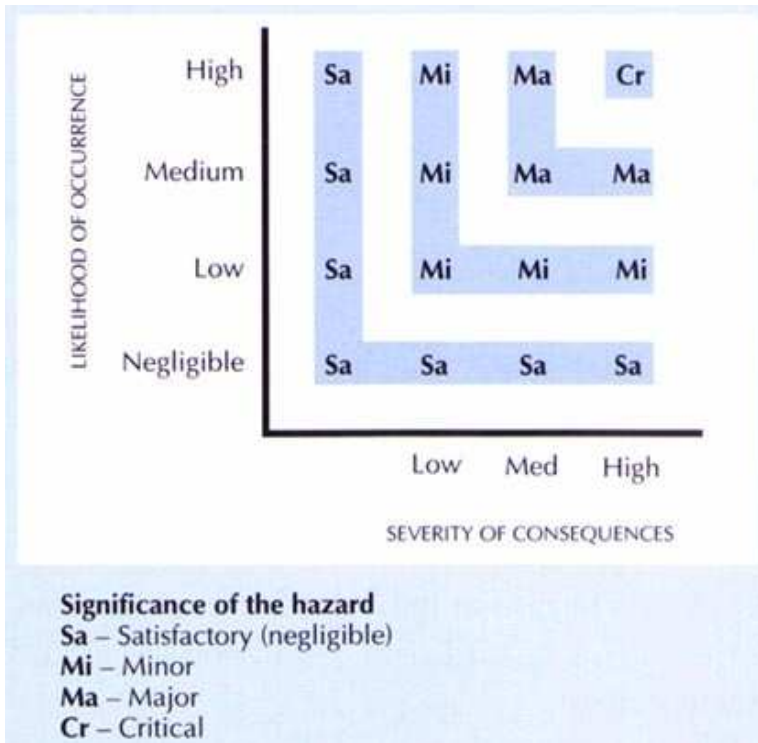
low (moderate or mild) - examples include illnesses caused by *Bacillus* spp., *Clostridium perfringens*, *Staphylococcus aureus*, most parasites, histamine-like substances and most heavy metals that cause mild acute illnesses.

3.6.3 Risk of a hazard

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

Figure 2 illustrates one method of assessing the significance of the hazard by taking into account the probability of occurrence (inverse to the degree of control) and the severity of consequences. The significance of the hazard can be differentiated as satisfactory (Sa), minor (Mi), major (Ma) or critical (Cr).

Figure 2: Two dimensional health risk assessment model (Source: CODEX HACCP document)



3.6.4 Control measures

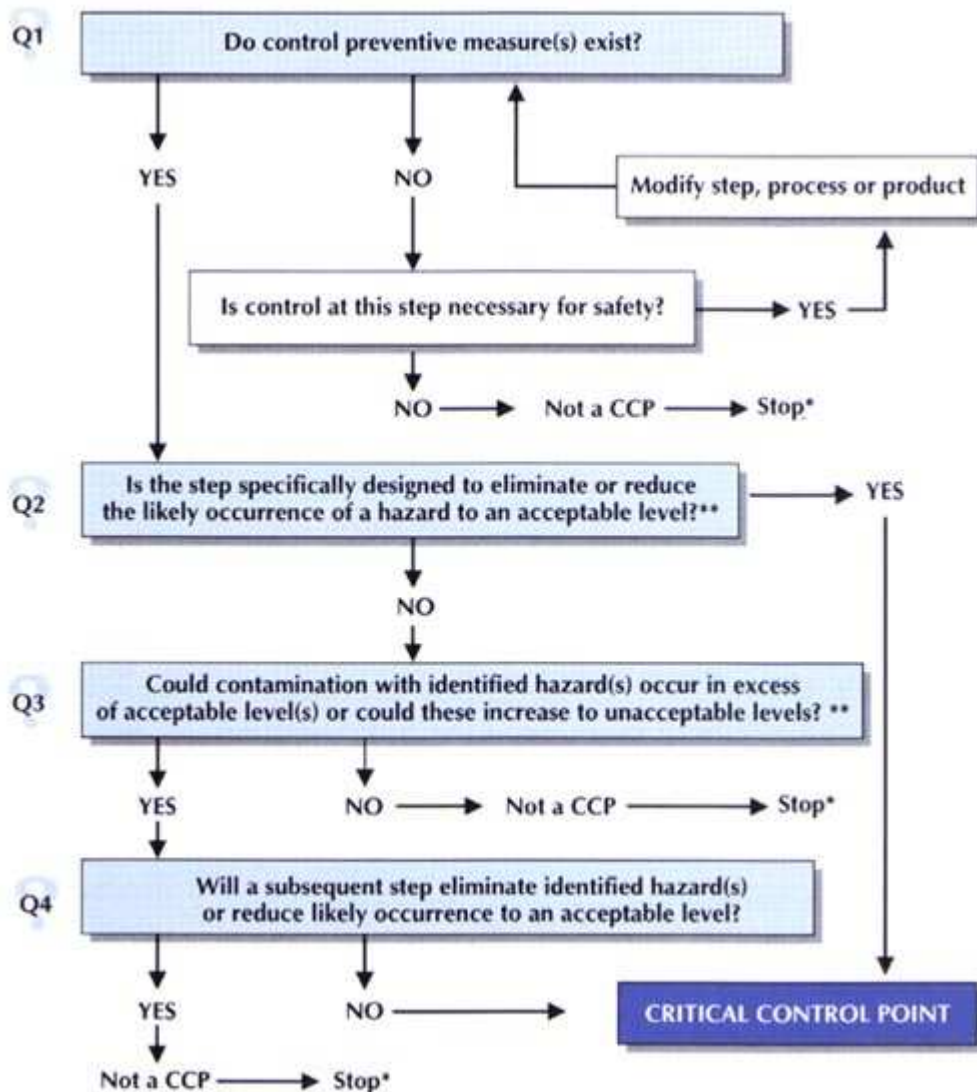
More than one control measures may be required to control a specific hazard(s) and more than one hazards may be controlled by a specified control measure.

Changes in raw materials, product formulations, processing or preparation procedures, packaging, distribution and/or use of the product will require review of the original hazard analysis.

3.7.0 Determine Critical Control Points (see Principle 2).

Determination of CCP is normally achieved by the use of decision tree published by Codex (see figure 3). This tree has been useful to explain the logical determination of CCPs. However, it is not specific to all food operations, e.g. slaughtering of animals, and therefore it should be used in conjunction with professional judgement, and modified in some cases. There may be more than one CCP at which control is applied to address the same hazard.

Figure 3: Codex decision tree to identify Critical Control Points



If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure. There are two types of CCPs namely CCP1 which assures control of the hazard by eliminating it whereas CCP2 will only minimize it but cannot assure control of a hazard since the hazard is only minimized, reduced or delayed. Examples of CCP1 include retorting of meat, pasteurisation of milk. Examples of CCP2 include refrigeration and proper cleaning.

3.7.1 Identification of CCPs

CCPs should be identified numerically with a category qualifier B, P or C for biological, physical or chemical hazards respectively. For example, if the first CCP identified will control a biological hazard, it is recorded as CCP-1 (B). If the second CCP identified will control a chemical hazard, it is recorded as CCP-2 (C). If the fifth CCP will control both a biological and a chemical hazard at the same processing operation, it is recorded as CCP-5 (BC). This identification protocol was developed to identify CCPs sequentially, independent of process operation numbering, and to indicate readily to the user of the HACCP plan which type(s) of hazard need(s) to be controlled at a particular process operation.

Once all hazards related to incoming materials and process operations have been analysed as per form provided as Appendix 1 (forms 5, 6, 7) to determine where and how they can be controlled, the right-hand column is completed to identify where each hazard is controlled.

For hazards fully controlled by application of the General Principles of Food Hygiene, write “GMP/GHP” on Forms 5, 6 and 7 and specify the applicable programme. For hazards for which the answer to Question 3 is “no”, write “not applicable” in the right-hand column on Forms 5, 6 and 7.

Hazards identified on Forms 5, 6 and 7 are either controlled at some point in the food establishment or cannot be controlled by the food operator. Each hazard not controlled by the operator should be re-examined to determine whether or not the operator could establish a control measure.

- If yes, then the appropriate control measure should be identified and Form 8 should be reviewed accordingly
- If no, then report these hazards on Form 9 and indicate how these hazards could be addressed outside the operator’s manufacturing process

3.8 Establish Critical Limits for each CCP (see Principle 3)

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 pH, available chlorine, sensory parameters such as visual appearance and texture, temperature, time (minimum time exposure), physical product dimensions, water activity, moisture level, salt concentration, etc. These parameters, if maintained within boundaries, will confirm the safety of the product.

The critical limits should meet requirements of government regulations and/or company standards and/or be supported by other 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 results of risk analysis (e.g. the time/temperature requirements for thermal

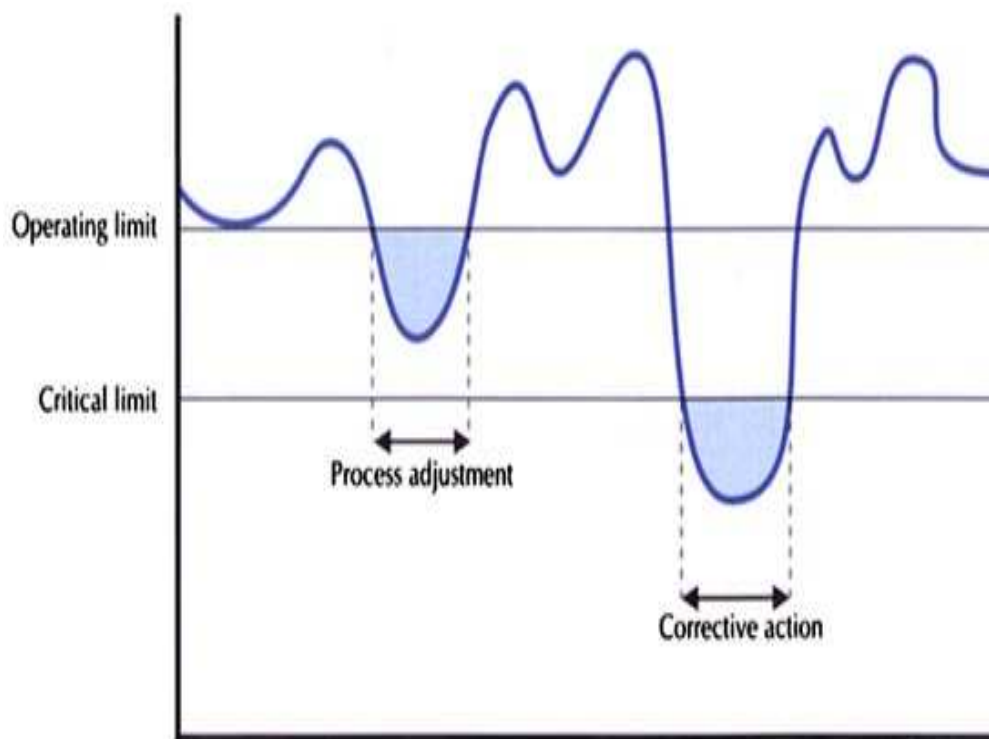
processes such as pasteurization, cooking, retorting or maximum number and size of physical contaminants, chemical residues).

It is essential that the person(s) responsible for establishing critical limits have knowledge of the process and of the legal and commercial standards required for the product.

Optimal limits must be specified and validated if possible for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. These are normally recorded in a form as indicated in appendix 3

Under practical conditions, operating limits are normally set by industries; these are more stringent and are established at levels that would be reached before critical limits are violated as indicated in figure 4 below.

Figure 4: Critical and operating limits (Source: CODEX HACCP document)



3.9 Establish a monitoring system for each CCP (see Principle 4)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits.

A designated person with knowledge and authority to carry out corrective actions when deviation is indicated must evaluate data derived from monitoring. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. However, with technological development, there are quick tests for carrying out microbiological status of food or surfaces. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible.

3.10 Establish corrective actions (see Principle 5)

Specific corrective actions must be developed for each CCP in the HACCP plan in order to deal with deviations when they occur.

The actions must ensure that the CCP has been brought under control, Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping. Examples of corrective measures include, Stop production, reheating, and disposal of non-reconditionable food.

Loss of control is considered as a deviation from a critical limit for a CCP. Deviation procedures are a predetermined and documented set of actions to be implemented when a deviation occurs. All deviations must be controlled by taking action(s) to control the non-compliant product and to correct the cause of non-compliance. The control and disposition of the affected product and the corrective action(s) taken must be recorded and filed.

The diversity of possible deviations at each CCP means that more than one corrective action may be necessary at each CCP. When a deviation occurs, it will most likely be noticed during the routine monitoring of the CCP. Deviation and corrective action procedures are prescribed so that employees responsible for CCP monitoring understand and are able to perform the appropriate corrective action(s) 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. The deviations at each CCP should be recorded on Form 10 (appendix 5).

3.10.1 Isolation of affected product

The producer should have effective procedures in place to isolate, mark clearly and control all products produced during the deviation period.

- All affected product, i.e. processed since the last point at which the CCP was known to be under control, should be isolated.
- Isolated product should be clearly marked, e.g. with firmly attached tags, with information including: hold number, product, amount, date held, the reason for the hold and the name of the person holding the product.

The producer should maintain control of the product from the hold date to the date of final disposition.

3.10.2 Corrective action procedures

Corrective action procedures are necessary to determine the cause of the problem, take action to prevent recurrence and follow up with monitoring and reassessment 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

3.10.3 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 deviation and corrective action records.

3.10.4 Deviation

- Product/code
- Date produced/held/release
- 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 appropriate)
- Signed authorization for disposition

3.10.5 Corrective action

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

3.11 Establish verification procedures (see Principle 6)

Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly.

Careful preparation of the HACCP plan with clear definition of all the necessary items does not guarantee the plan's effectiveness. Verification procedures are necessary to assess the effectiveness of the plan and to confirm that the HACCP system adheres to the plan.

Verification should be undertaken by an appropriately qualified individual or individuals who are capable of detecting deficiencies in the plan or its implementation. Verification should be undertaken at the completion of the HACCP study; whenever there is a change in product, ingredients, process, etc.; when a deviation occurs; in the event of newly identified hazards; and at regular predetermined intervals.

3.11.1 Description of verification activities

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

3.11.2 HACCP plan validation

HACCP plan validation should include:

- Review of the hazard analysis
- CCP determination
- Justification for critical limits, based for example on current good science and regulatory requirements

- Determination of whether monitoring activities, corrective actions, record keeping procedures and verification activities are appropriate and adequate

Validation involves ensuring that the HACCP plan is based on current good science and current information and is appropriate for the actual product and process.

The process of validating an existing HACCP plan should also include:

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

HACCP plan validation is an ongoing, periodic procedure. Validations may be scheduled at a pre-set frequency. However, other factors may trigger a review of the plan to determine if changes are necessary. These factors could include changes to the raw materials, product or process; adverse audit findings; recurring deviations; new scientific information about potential hazards or control measures; and consumer complaints and/or product rejections by customers.

3.11.3 HACCP system audits

As part of verification, audits are performed to compare the actual practices and procedures of the HACCP system with those written in the HACCP plan.

Audits are systematic and independent examinations involving on-site observations, interviews and review of records to determine whether the procedures and activities stated in the HACCP plan are implemented in the HACCP system. One or more independent persons who are not involved in implementation of the HACCP system usually perform these examinations. Audits may be performed for individual CCPs and/or for the overall plan.

On-site observation may include, for example, visual inspection to ensure that:

- The product description and flow chart are accurate
- Monitoring required by the HACCP plan at the CCPs is performed
- Processes are operating within established critical limits
- Records are filled out accurately and at the time observations are made
- Records to be reviewed during auditing of the HACCP plan include, for example, those demonstrating that:

- Monitoring activities have been performed at the locations specified in the HACCP plan
- Monitoring activities have been performed at the frequencies specified in the HACCP plan
- Affected product has been controlled and corrective actions have been taken whenever monitoring has indicated the occurrence of a deviation from critical limits
- Equipment has been calibrated at the frequencies specified in the HACCP plan Audits should occur frequently enough to ensure that the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and product.

3.11.4 Calibration

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:

- At a frequency sufficient to assure continuous accuracy
- According to procedures established in the HACCP plan (which can be based on instrument or equipment manufacturer specifications)
- By checking accuracy against a recognized standard
- Under conditions similar or identical to those under which the instrument or equipment will be used

Calibration of CCP monitoring equipment is important; if the equipment is out of calibration, then monitoring results will not be accurate and may be completely unreliable. When the equipment monitoring a CCP is out of calibration, the CCP is considered to have been out of control since the last documented calibration.

3.11.5 Targeted sample collection and testing

Verification may also include targeted sampling and testing and other periodic activities. Targeted sampling and testing involves taking product samples periodically and testing them to ensure that critical limits are appropriate for product safety.

Targeted sampling may be carried out to check vendor compliance when receipt of material is a CCP and purchase specifications are relied on as critical limits. For example, in the case of cooked shrimp, the processor may purchase shrimp under a supplier's guarantee for sulphite levels less than 100 ppm. A sample may be collected for laboratory analysis on a quarterly basis to ensure that sulphite levels are compliant with the supplier's guarantee.

When critical limits are set for equipment operation, product samples may be taken to ensure that the equipment settings are appropriate to provide product safety.

3.11.6 Role of microbiological testing in HACCP verification

Sampling and microbiological testing are usually not adequate by themselves to ensure food safety. Microbiological testing is seldom effective for monitoring CCPs and cannot be used as a means of process control because of the lengthiness of analytical procedures and the inability to provide results in real time. In addition, detection of pathogenic microorganisms can be difficult if contamination of the product at the CCP is at a low level or is unevenly distributed in the food sample, necessitating large and numerous samples.

However, microbiological testing does have a role in HACCP verification, when critical limits are established for the elimination of pathogens or their reduction to an acceptable level. It can be used to verify the HACCP plan's effectiveness and to ensure that the identified microbiological limits have not been exceeded. In this instance, the length of time involved in the analytical procedures does not create operational difficulties.

3.11.7 Verification frequency

Verification activities should be performed according to a pre-established schedule described in the HACCP plan or whenever there are indications that the food safety status may have changed. These indications may include:

- On-line observations that CCPs may not be operating within critical limits
- Record reviews indicating inconsistent monitoring
- Record reviews indicating that CCPs are repetitively operated outside critical limits
- Consumer complaints or product rejections by customers
- New scientific data

Verification procedures should be scheduled at a frequency that ensures that the HACCP plan is being followed continuously and that measurements remain accurate within established limits. Thus, the length of time between scheduled verification activities should match the level of confidence in the continuous and accurate performance of the HACCP plan.

The frequency of verification activities may change over time. A history of verification activities indicating that the process is consistently in control may support safe reduction of the frequency of verification activities.

3.11.8 Records of verification

Verification activities should be documented in the HACCP plan. Records should be made of the results of all verification activities. Records of verification

should include methods, date, individuals and/or organizations responsible, results or findings and action(s) taken.

Verification procedures for the overall HACCP plan should be documented in a file for the HACCP plan.

Routine monitoring activities for critical limits should not be confused with verification methods, procedures or activities.

Examples of verification activities include:

- Review of the HACCP system and its records;
- Review of deviations and product dispositions;
- Confirmation that CCPs are kept under control

Validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

3.12 Establish documentation and record keeping (see Principle 7)

Efficient and accurate record keeping is essential to the application of HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation.

Examples of documentation are:

- Hazard analysis;
- CCP determination;
- Critical limit determination.

Examples of records are:

- CCP monitoring activities,
- Deviations and associated corrective actions,
- Modifications to the HACCP system.

3.12.1 Documentation and record keeping

Records are essential for reviewing the adequacy of the HACCP plan and the adherence of the HACCP system to the HACCP plan.

A record shows the process history, the monitoring, the deviations and the corrective actions (including disposition of product) that occurred at the identified CCP. It may be in any form, e.g. processing chart, written record, computerized record. The importance of records to the HACCP system cannot be overemphasized. It is imperative that the producer maintains complete, current, properly filed and accurate records.

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

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

3.12.2 Support documents

The HACCP plan support documents include information and support data used to establish the HACCP plan such as the hazard analysis and records documenting the scientific basis for establishing the CCPs and critical limits. Examples of such data include:

- Data used to establish the control measures to prevent microbiological growth
- Data used to establish the shelf-life of the product (if age of the product can affect safety)
- Data used to establish the adequacy of critical limits in ensuring the safety of the product

The HACCP plan support documents should also include a list of the HACCP team members and their responsibilities, as well as all the forms produced during the preparation of the HACCP plan, showing:

- Product description and intended use
- Flow diagram
- Hazard analysis
- Identification of CCPs
- Identification of the critical limits for each CCP, including data from experimental studies or information collected to support the critical limits
- Documented deviation and corrective action plans
- Planned verification activities and procedures
- Identification of the preventive measures for each hazard

Support documents may also include correspondence with consultants, as well as documents detailing how the HACCP plan was developed.

3.12.3 Records generated by the HACCP system

HACCP system records are kept to demonstrate adherence of the HACCP system with the HACCP plan. These records are used to demonstrate control at CCPs in the food process. By tracking records generated by the HACCP system, an operator or manager can become aware that a process is approaching its critical limit. Review of records can be instrumental in identifying trends and in making operational adjustments. Timely corrective action can be taken if a critical limit is violated.

The required HACCP records to be kept at each CCP should be written on Form 10 (see appendix 5). Failure to document the control of a CCP would be a critical departure from the HACCP plan.

The records generated by the HACCP system include all activities and documentation required by the plan, as follows.

3.12.4. Monitoring records for all CCPs

All HACCP monitoring records should be kept on forms that contain the following information:

- Form title
- Time and date
- Product identification (including product type, package size, processing line and product code)
- Critical limits
- Monitoring observation or measurement
- Operator's signature or initials
- Corrective action taken, where applicable
- Reviewer's signature or initials
- Date of review

3.12.5. Deviation and corrective action records

- Identification of the deviant lot/product
- Amount of affected product in the deviant lot
- Nature of the deviation
- Information on the disposition of the lot
- Description of the corrective action

3.12.6 Verification/validation records

- In-house on-site inspection
- Equipment testing and evaluation
- Accuracy and calibration of monitoring equipment
- Results of verification activities, including methods, date, individuals and/or organizations responsible, results or findings and action taken

3.12.7 Documentation of methods and procedures used

The producer should maintain records of the methods and procedures used in the HACCP system. Examples include:

- Description of the monitoring system for the critical limit of each CCP, including: the methods and equipment used for monitoring, the frequency of monitoring and the person performing the monitoring
- Plans for corrective actions for critical limit violations or situations resulting in potential hazards

- Description of record keeping procedures, including copies of all record forms
- Description of verification and validation procedures

3.12.8 Records of employee training programmes

Records should be kept of all employees training. This is of particular importance for employees involved in monitoring critical limits for CCPs and those involved with deviation review, corrective actions and verification. These employees must be trained to understand fully the appropriate procedures/methods and actions to be taken regarding control of CCPs.

The HACCP plan for a particular segment of a food chain is recorded in the form 10 of the appendix 1.

CHAPTER 4

4.0 REGULATORY ASSESSMENT

Government agencies have both a strategic role in the implementation of HACCP plan as well as an operative role in organizing the effective and ongoing assessment of HACCP systems of the food industry.

Regulatory assessment is defined as a governmental activity carried out with the objective of obtaining evidence that the seven HACCP principles have been effectively applied; the HACCP plan and prerequisites are correctly implemented; and that the system has been maintained. In addition, government agencies have a duty to clearly communicate all health and safety standards, regulations, guidelines, and other requirements. Government agencies should provide the necessary infrastructure that is conducive to the implementation of HACCP systems by industry, including regulations, training, assessment of compliances, industry guidelines, and coordination among governmental agencies and other institutions when dealing with industry.

The primary reason for assessing HACCP is to establish whether the food business has the ability to consistently manufacture and/or distribute safe food, i.e. to ascertain that the HACCP system is effective.

Assessment of HACCP systems by government agencies is undertaken for a variety of other reasons and these may differ, depending on whether the application is mandatory or voluntary.

4.1 Reasons for assessing HACCP system when compliance is mandatory

- enforce relevant legislation and regulations;
- sensitize stakeholders on HACCP requirements;
- assess food industry compliance;
- engage in international relations (leading to government-to-government certification and assurances and providing feedback to industry);
- provide technical assistance and training for food control officials and food industry; and
- conduct research to improve decision-making capabilities.

4.2 Reasons for assessing HACCP system when compliance is voluntary

- establishing operating frameworks for voluntary programmes;
- advising on where HACCP may integrate with government programmes, such as certification;
- encouraging understanding and adoption of HACCP for improving food safety;
- providing technical assistance and training;
- providing relevant information;
- encouraging stakeholder ownership; and
- testing pilot HACCP systems and implementing modifications.

Under either mandatory or voluntary compliance to HACCP systems, assessment of the HACCP plan will need to determine whether:

- all required elements are present in the plan and addressed adequately;

- the system will satisfactorily maintain food safety; and
- the actual events comply with the documented procedures described in the plan. In addition to the above, prerequisites for HACCP and compliance with other regulatory should also be assessed.

4.3 HACCP based Food Inspection Checklist

This checklist contains points that may be considered during the assessment and which may be used as a tool for assessing the application of the HACCP system, including the prerequisites for HACCP, design, implementation and maintenance of the HACCP plan. It promotes uniformity in assessment. This checklist does not substitute the checklist used to check compliance to GMP. The inspection should at the same time evaluate compliance to GMP.

HACCP Principles Checklist

<p>Preparation</p>	<ul style="list-style-type: none"> • Check whether there is evidence to show Management commitment to the application of HACCP plan • Check the composition of the team that prepared the HACCP plan (disciplines, skills or expertise of team members) • Check whether external expertise was sought during preparation of the HACCP plan • Check whether the company has a food safety policy • Check whether the scope of HACCP plan has been clearly defined, • Check whether the product has been properly described, • Check whether the process flow diagram is accurate and comprehensive • Check whether important and key steps of the manufacturing process are included in the flow diagram, including raw materials reception and storage • Check whether changes have been made since the PFD was last drawn • How is the HACCP team notified when changes are made to the product parameters and the process, • If there are changes, how are they recorded and approved
<p>Principle1: Conduct a hazard analysis</p>	<ul style="list-style-type: none"> • Check how hazard analysis was conducted • Check whether all significant hazards were identified and categorized as chemical, physical or biological • Check if all the process steps have been considered including raw material reception • Check how the team assessed the likelihood of occurrence of the hazard, • Did the team institute appropriate corrective measure(s) for each hazard and how was it validated

<p>Principle 2: Determine the Critical Control Points</p>	<ul style="list-style-type: none"> • Check how the CCPs were identified (by the correct use of the decision tree or expert judgments or use of consultants) • Check if all the necessary CCPs have been identified • Check how hazards that are not controlled at CCP are addressed
<p>Principle 4: <i>Establish a system to monitor the control of the CCP</i></p>	<ul style="list-style-type: none"> • Check if realistic monitoring schedules have been established for all CCPs, • Check if the reliability of monitoring procedures have been assessed, • Check the status of the monitoring equipment and if they regularly calibrated, • Check if the CCP log sheets are being used at all CCPs and are being filled out correctly • Check if the frequency of monitoring adequately confirm control of the CCP • Check if the sampling plans are statistically valid, • Check for evidence that process control records being used demonstrate process control on daily basis, • Ascertain if monitoring personnel are properly identified and trained, • Are the monitoring records being reviewed by designated appropriate personnel?
<p>Principle 5: <i>Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control</i></p>	<ul style="list-style-type: none"> • Check if corrective actions being implemented ensure regain process control, • Check for evidence that demonstrate the corrective measures are instituted in the event of deviation in the CCP • Check if corrective actions are being recorded and how effectiveness is being verified • Check how the authority for corrective action is being assigned, • Check how non-conforming product are controlled and clearly recorded, • Check if there are clear disposition actions stipulated
<p>Principle 6: <i>Establish procedures for verification to confirm that the HACCP system is working effectively</i></p>	<ul style="list-style-type: none"> • Check if verification procedures have been clearly and appropriately established, • Check how the verification procedures are communicated through the business, • Ascertain how responsibilities for verification procedures have been allocated and being carried out effectively, • Check if all CCPs are covered by the verification programme, • Check if the information on the HACCP control chart is up to date • Check if there is a formal system to trigger amendments • Check if control parameters are being achieved, • Check if process capability studies are being carried out • Check how the data from HACCP is being used to improve the

	<p>system,</p> <ul style="list-style-type: none"> • Check how consumers' complaint data are being used within the verification system, • Check if there is regular review of CCP failure and product dispositions, • Are prerequisite support systems included within the verification programme?
<p>Principle 7: Establish documentation concerning all procedures and records appropriate to these Principles and their application.</p>	<ul style="list-style-type: none"> • What format is being used to document the system, • Check if the documentation cover all the HACCP system operation, • How is the documentation controlled with regard to update, • Are the records accessible? • Are the HACCP records clearly identified by unique reference numbers? • Check all documents if they are accurate and current, • Check if verification procedures are documented,

APPENDICES

Appendix 1: BLANK HACCP FORMS

Form 1: Product description

1. Product name(s) (common and brand names)	
2. Important characteristics of end product (e.g. a_w , pH, etc.)	
3. How the product is to be used	
4. Packaging	
5. Shelf-life	
6. Where the product will be sold	
7. Labelling instructions	
8. Special distribution control	

DATE: _____ APPROVED BY: _____

Form 2: Product ingredients and incoming material

PRODUCT NAME(S):

DATE: _____ APPROVED BY: _____

RAW MATERIALS	PACKAGING MATERIALS	OTHERS

DATE: _____ APPROVED BY: _____

Form 3: Process Flow Diagram (PFD)

PRODUCT NAME(S):

A diagram or an algorithm showing a sequence of steps used in the production of a particular food item

DATE: _____ APPROVED BY: _____

Form 4: Plant Schematic/Floor plan

PRODUCT NAME(S):

The diagram that shows the product flow and employees traffic pattern in the plant to identify and eliminate cross contamination potentials.

DATE: _____ APPROVED BY _____

Form 8: CCP determination

Process step/ incoming material	Category and identified hazard	Question 1	Question 2	Question 3	Question 4	CCP number

Instructions:

Category and identified hazard: Determine if hazard is fully controlled by adherence to General Principles of Food Hygiene. If Yes, indicate “GMPs”, describe and proceed to next identified hazard. If No, proceed to Question 1 and other questions as indicated by the CODEX CCP Decision Tree (figure 3)

Form 9: Unaddressed hazards

PRODUCT NAME(S):

List any biological, chemical and/or physical hazards that are not controlled at the establishment.

Unaddressed hazard from previous list	Identified methods of addressing the hazard (e.g. cooking instructions, public education, use by date, etc.)

DATE: _____ APPROVED BY: _____

Form 10: HACCP Plan

PRODUCT NAME(S):

Process step/ Incoming material: # 1 Receiving

CCP/ Hazard Number: CCP – 1BC

Hazard description	Critical limits	Monitoring procedures	Corrective measures	Verification Procedure	HACCP records

DATE: _____ APPROVED BY: _____

Appendix 2: POTENTIAL HAZARDS

EXAMPLES OF BIOLOGICAL, CHEMICAL AND PHYSICAL HAZARDS

BIOLOGICAL HAZARDS	CHEMICAL HAZARDS
Bacteria (spore-forming)	Naturally occurring chemicals
<i>Clostridium botulinum</i> <i>Clostridium perfringens</i> <i>Bacillus cereus</i>	Allergens Mycotoxins (e.g. aflatoxin) Scombrototoxin (histamine) Ciguatoxin Mushroom toxins Shellfish toxins Paralytic shellfish poisoning (PSP) Diarrhoeic shellfish poisoning (DSP) Neurotoxin shellfish poisoning (NSP) Amnesic shellfish poisoning (ASP) Pyrrolizidine alkaloids Phytohaemagglutinin
Bacteria (non-spore-forming)	Added chemicals
<i>Brucella suis</i> <i>Campylobacter</i> spp. Pathogenic <i>Escherichia coli</i> <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. <i>Shigella</i> (<i>S. dysenteriae</i>) <i>Staphylococcus aureus</i> <i>Streptococcus pyogenes</i> <i>Vibrio cholerae</i>	Polychlorinated biphenyls (PCBs) Agricultural chemicals Pesticides Fertilizers Antibiotics Growth hormones Prohibited substances
Virus	Toxic elements and compounds
Hepatitis A and E Norwalk virus group Rotavirus	Lead Zinc Cadmium Mercury Arsenic Cyanide Food additives Vitamins and minerals

	Contaminants
Protozoa and parasites	
<i>Cryptosporidium parvum</i> <i>Diphyllobothrium latum</i> <i>Entamoeba histolytica</i> <i>Giardia lamblia</i> <i>Ascaris lumbricoides</i> <i>Taenia solium</i> <i>Taenia saginata</i> <i>Trichinella spiralis</i>	Lubricants Cleaners Sanitizers Coatings Paints Refrigerants Water or steam treatment chemicals Pest control chemicals <ul style="list-style-type: none"> • Chemicals from packaging materials Plasticizers Vinyl chloride Printing/coding inks Adhesives Lead Tin

PHYSICAL HAZARDS

Material	Injury potential	Sources
Glass	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light fixtures, utensils, gauge covers, etc.
Wood	Cuts, infection, choking; may require surgery to remove	Field sources, pallets, boxes, building materials
Stones	Chocking, broken teeth	Fields, buildings
Metal	Cuts, infection; may require surgery to remove	Machinery, fields, wire, employees
Insulation	Chocking; long-term if asbestos	Building materials
Bone	Chocking	Improper processing
Plastic	Chocking, cuts, infection; may require surgery to remove	Packaging, pallets, equipment
Personal effects	Chocking, cuts, broken teeth; may require surgery to remove	Employees

Appendix 3: EXAMPLES OF CRITICAL LIMITS

Hazard	CCP	Critical limit
Bacterial (non-sporulating)	Pasteurization	72°C for at least 15 seconds
Metal fragments	Metal detection	Metal fragments larger than 0.5 mm
Bacterial pathogens	Oven Drying	$a_w < 0.85$ for controlling growth in dried food products
Excessive nitrite	Curing /brining	Maximum 200 ppm sodium nitrite in finished product
Bacterial pathogens	Acidification step	Maximum pH of 4.6 to control <i>Clostridium botulinum</i> in acidified food
Food allergens	Labelling	Label that is legible and contains a listing of correct ingredients
Histamine	Receiving	Maximum of 25 ppm histamine levels in evaluation of tuna for histamine

To account for normal variability, e.g. setting a cooker with 2°C variability, at least 2°C above the critical limit be added to avoid violating it.

Appendix 4: EXAMPLES OF CRITICAL LIMITS VERSUS OPERATING LIMITS

Process	Critical limit	Operating limit
Acidification	pH 4.6	pH 4.3
Drying	0.84 a_w	0.80 a_w
Hot fill	80°C	85°C
Slicing	2 cm	2.5 cm

Appendix 5: EXAMPLE OF APPLICATION OF HACCP PRINCIPLES FOR PRODUCTION OF ASEPTIC FRUIT JUICE

(source: Canadian Food Inspection Agency - CFIA)

Form 1	
Product Description	
Product Name: Aseptic Fruit Juice	
1. Product Name(s)	Apple Juice from Concentrate
2. Important Product Characteristics (a_w, pH, Salt, Preservatives,...)	a _w = 0.97 pH = 3.6 - 4.5 No preservatives Vitamin C added
3. How it is to be used	Ready-to-drink
4. Packaging	Hermetically sealed tetra-brick multi-laminated board (plastic, foil, paper)
5. Shelf Life	10 months at room temperature (less than or equal to 20°C)
6. Where it will be sold	Through retail, hotel, restaurant, institution to the general population, which would include vulnerable groups, such as infants, elderly, infirm & immuno compromised
7. Labelling Instructions	Refrigerate after opening None required for safety
8. Special Distribution Control	Shipping/storage temperature range between 5°C and 20°C Proper storage control

Date: _____

Approved by:

List of Product Ingredients and Incoming Material

Product Name: Aseptic Fruit Juice

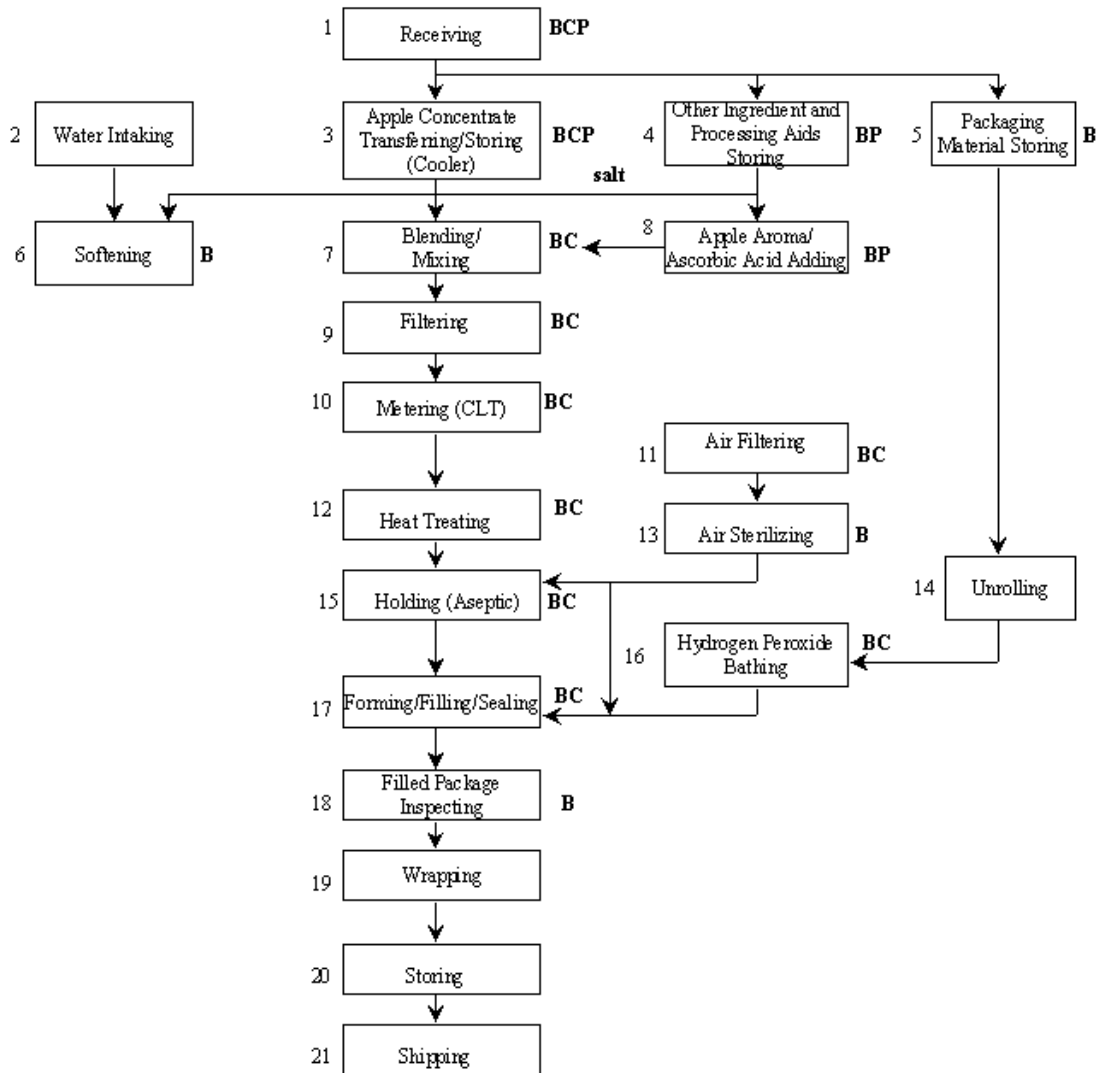
Basic ingredients	Food additives	Packaging material
Apple Concentrate BCP	Ascorbic Acid BP Apple Aroma BP	Tetra Brik Multi-laminated Board BCP Corrugated Cardboard Plastic Shrink Wrap
Water (Municipal source)	Process Aids	
Water BC	Air B Hydrogen Peroxide C Salt	

Date: _____

Approved by: _____

**Process Flow Diagram
Aseptic Fruit Juice**

Form 3



Date: _____ **Approved by:** _____

Plant Schematic

Product Name: Aseptic Fruit Juice

Plant specific (example be given)

jProduct flow diagram

and

Employees traffic pattern diagram

Date: _____

Approved by: _____

Critical Control Points (CCPs) Determination and hazard identification

Product Name: Aseptic Fruit Juice (Refer process diagram)- (continuation pages be indicated)

<p>Category and Identified Hazard Determine if fully controlled by Prerequisite Program(s) If YES = indicate Prerequisite Program and proceed to next identified hazard. If NO = proceed to question 1 (Q1)</p>	<p>Q1. Could a control measure(s) be used by the operator at any process step? If NO = not a CCP + identification on how this hazard will be controlled before and after the process + proceed to the next identified hazard If YES = description + next</p>	<p>Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level? If NO = not a CCP + proceed to the next identified hazard If YES = next question (Q3)</p>	<p>Q3. Is this process step specifically designed to eliminate/reduce the likely occurrence of the identified hazard to an acceptable level? If NO = next question (Q4) If YES = CCP + go to last column</p>	<p>Q4. Will a subsequent step eliminate the identified hazard or reduce likely occurrence to an acceptable level? If NO = CCP + go to last column If YES = not a CCP + identify subsequent step + proceed to the next identified</p>	<p>CCP Number + proceed to next identified hazard</p>
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	question (Q2)			hazard	
Incoming Material: Apple Juice Concentrate as delivered					
Biological Microorganisms	Yes Heat Treating	No But could result in spoilage if not controlled			
Biological Patulin	Yes Contractual specifications Receiving	Yes	N/A	Yes Step #1, Receiving	
Chemical Pesticide residues	Yes Contractual specifications Receiving	Yes	N/A	Yes Step #1, Receiving	
Physical Hazardous extraneous material	Yes Contract specifications Receiving and Filtering	No No evidence that this has been a problem			
Biological Microorganisms	Yes Heat Treating	No But could result in spoilage if not controlled			
Physical Hazardous extraneous material	Yes Contractual specifications Receiving and Filtering	No No evidence that this has been a problem			
Incoming Material: Ascorbic Acid as delivered					
Biological Bacterial spores	Yes Contractual specifications	No No evidence that this is a problem			
Physical Hazardous extraneous material	Yes Contractual specifications Receiving and Filtering	No No evidence that this is a problem			
Incoming Material: Water at intake					

Biological Water not meeting the drinking water standard					
Prerequisite programs					
Chemical Heavy metals					
Prerequisite programs					
Incoming Material: Packaging Material as delivered					
Biological Pathogens from damaged rolls					
Prerequisite programs					
Chemical Product contamination from non-food chemicals leaching from packaging material	Yes Contractual specifications Receiving	Yes	N/A	Yes Step #1, Receiving	
Physical Hazardous extraneous material	Yes Contractual specifications	No Because of method of packaging and no evidence that this has been a problem			
Incoming Material: Air at intake					
Biological Pathogens	Yes Air Sterilizing	No But could result in spoilage if not controlled			
Incoming Material: Hydrogen Peroxide as delivered					
Chemical Contamination from chemical impurities	Yes Contract specifications (food grade) Receiving	Yes	N/A	Yes Step #1, Receiving	

Process Steps					
Process Step: #1 Receiving Apple Juice Concentrate, Packaging Materials and Hydrogen Peroxide					
Biological Raw material received from non-contract suppliers without valid specifications could result in product contaminated with patulin	Yes Listed suppliers, contractual specifications	Yes	Yes		CCP-1BC
Chemical Ingredients and materials received from non-contract suppliers without valid specifications could result in product with harmful chemical residues	Yes Receiving	Yes	Yes		CCP-1BC
Process Step: #1 Apple Aroma/Ascorbic Acid Receiving					
Biological Contamination with microorganisms if damage occurs Prerequisite programs					
Physical Hazardous extraneous material Prerequisite programs					
Process Step: #1 Packaging Material Receiving					
Biological Pathogens could contaminate if rolls are damaged during handling (Pre-requisite programs)					

Hazards not Controlled by Operator

Product Name: Aseptic Fruit Juice

List all Biological, Chemical and Physical Hazards which are not Controlled by the Operator

Identified Hazards	Indicate the way the Hazard could be Addressed (Cooking Instructions, Public Education, Use Before Date ...)
Incoming materials	
Nil	---
---	---

Date: _____

Approved by: _____

HACCP Plan

Product Name: Aseptic Fruit Juice

Process Step/Incoming Material: #1 Receiving
CCP/Hazard Number: CCP-1BC

Hazard Description	Critical Limits	Monitoring Procedures	Corrective measures	Verification Procedure	HACCP Records
Reception of apple juice concentrate from non-contract suppliers without valid specifications could result in product contaminated with patulin	Must meet National specifications Suppliers must be listed with valid contract specifications	Receiver checks suppliers' names and addresses against list of approved suppliers with valid contract specifications	Receiver rejects lot, notifies management and records deviation	QC does periodic analysis of ingredients for patulin	Supplier lists Contractual agreements Lot receipt, reject/deviation report
Reception of ingredients and materials from non-contract	Must meet National or CODEX specifications	Receiver checks suppliers' names and	Receiver rejects lot, notifies management	QC does periodic analysis of ingredients for	Supplier lists Contractual

suppliers without valid specifications could result in product contaminated with hazardous chemical residues	for maximum tolerable Suppliers must be listed with valid contract specifications	addresses against list of approved suppliers with valid contact specifications	and records deviation	<i>pesticide residues</i> <i>QC checks with Health TFDA re approval of packaging material</i> <i>QC checks to ensure hydrogen peroxide is labelled food grade food and is contained in TFDA approved list of non-food chemicals and materials</i>	agreements Lot receipt, reject/deviation report
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Date: _____

Approved by: _____

NB: Subsequent steps can be dealt with in a similar manner as shown above.

REFERENCES

1. FAO (1998): Food safety, quality and safety systems. A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) system. FAO Information Division, Rome.
2. Canadian Food Inspection Agency (2005). HACCP principles for production of aseptic fruit juices
3. Food safety and Inspection series
4. FDA (2005). Juice HACCP
5. USDA Food safety and inspection series. HACCP based Inspection models and Implementation
6. USDA (1999). Guide Book for the Preparation of HACCP systems