Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application

Preamble

The first section of this document sets out the principles of the Hazard Analysis and Critical Control Point (HACCP) system adopted by the CAC. The second section provides general guidance for the application of the system while recognizing that the details of application may vary depending on the circumstances of the food operation.¹

The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from the primary producer to final consumer and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the workforce. It also requires a multidisciplinary approach; this multidisciplined approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry, and engineering according to the particular study. The application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems.

While the application of HACCP to food safety was considered here, the concept can be applied to other aspects of food quality.

¹ The Principles of HACCP set the basis for the requirements for the application of HACCP, while the Guidelines provide general guidance for practical application.
**Definitions**

**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 to be taken 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 Limit:** A criterion which separates acceptability from unacceptability.

**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.

**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.

**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.

**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 monitoring to determine compliance with the HACCP plan.
**Principles**

The HACCP system consists of the following seven principles:

**Principle 1**  
Conduct a hazard analysis.

**Principle 2**  
Determine the Critical Control Points (CCPs).

**Principle 3**  
Establish critical limit(s).

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

**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.

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**Guidelines for the 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 Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation. Management commitment is necessary for implementation of an effective HACCP system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found. HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature.

The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.
It is important when applying HACCP to be flexible where appropriate, given the context of the application taking into account the nature and the size of the operation.

**Application**

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

1. **Assemble HACCP team**

   The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

2. **Describe product**

   A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including $A_{eq}$, pH, etc.), microcidal/static treatments (e.g. heat-treatment, freezing, brining, smoking, etc.), packaging, durability and storage conditions and method of distribution.

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. institutional feeding, may have to be considered.

4. **Construct flow diagram**

   The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

5. **On-site confirmation of flow diagram**

   The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.

6. **List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (see Principle 1)**

   The HACCP team should list all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption.

   The HACCP team should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.
In conducting the hazard analysis, wherever possible the following should be included:

- The likely occurrence of hazards and severity of their adverse health effects;
- The qualitative and/or quantitative evaluation of the presence of hazards;
- Survival or multiplication of microorganisms of concern;
- Production or persistence in foods of toxins, chemicals or physical agents; and,
- Conditions leading to the above.

The team must then consider what control measures, if any, exist which can be applied for each hazard.

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

7. **Determine Critical Control Points (see Principle 2)**

There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree, e.g. Diagram 2, which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.

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.

8. **Establish Critical Limits for each CCP (see Principle 3)**

Critical 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. Criteria often used include measurements of temperature, time, moisture level, pH, available chlorine, and sensory parameters such as visual appearance and texture.

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. Where possible, process adjustments should be made when monitoring

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Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g. slaughter, and therefore it should be used in conjunction with professional judgement, and modified in some cases.
results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is 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. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

10. Establish Corrective Actions (see Principle 5)

Specific corrective actions must be developed for each CCP in the HACCP system 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.

11. Establish Verification Procedures (see Principle 6)

Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. 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

Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

12. Establish Documentation and Record Keeping (see Principle 7)

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

Documentation examples are:

- C Hazard analysis
- C CCP determination
- C Critical limit determination
Record examples are:

- CCP monitoring activities
- Deviations and associated corrective actions
- Modifications to the HACCP system
- An example of a HACCP worksheet is attached as Diagram 3.

**Training**

Training of personnel in industry, government and academia in HACCP principles and applications, and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each Critical Control Point.

Cooperation between primary producer, industry, trade groups, consumer organizations, and responsible authorities is of vital importance. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.