CHAPTER 8
Control of Non-Conformity

8.1 Corrections and Corrective Actions

Corrections
The organization shall ensure that when critical limits for CCP(s) are exceeded, or there is a loss of control of operational PRP(s), the products affected are identified and controlled with regard to their use and release.

A documented procedure shall be established and maintained defining:
a) the identification and assessment of affected end products to determine their proper handling, and
b) a review of the corrections carried out.

Products manufactured under conditions where critical limits have been exceeded are potentially unsafe products and shall be handled in accordance with Handling of potentially unsafe products. Products manufactured under conditions where operational PRP(s) have not been conformed with shall be evaluated with respect to the cause(s) of the nonconformity and to the consequences thereof in terms of food safety and shall, where necessary, be handled in accordance with Handling of potentially unsafe products. The evaluation shall be recorded
All corrections shall be approved by the responsible person(s), and shall be recorded together with information on the nature of the nonconformity, its cause(s) and consequence(s), including information needed for traceability purposes related to the nonconforming lots.

Corrective actions
Data derived from the monitoring of operational PRPs and CCPs shall be evaluated by designated person(s) with sufficient knowledge and authority to initiate corrective actions.

Corrective actions shall be initiated when critical limits are exceeded or when there is a lack of conformity with operational PRP(s).

The organization shall establish and maintain documented procedures that specify appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to bring the process or system back into control after nonconformity is encountered. These actions include:
a) reviewing nonconformities (including customer complaints),
b) reviewing trends in monitoring results that may indicate development towards loss of control,
c) determining the cause(s) of nonconformities,
d) evaluating the need for action to ensure that nonconformities do not recur,
e) determining and implementing the actions needed,
f) recording the results of corrective actions taken, and
g) reviewing corrective actions taken to ensure that they are effective.

Corrective actions shall be recorded.

Generally, the records maintained for the HACCP System should include the following:

1. A summary of the hazard analysis, including the rationale for determining hazards and control measures.

2. The HACCP Plan
    - Listing of the HACCP team and assigned responsibilities.
    - Description of the food, its distribution, intended use, and consumer.
    - Verified flow diagram.
    - HACCP Plan Summary Table that includes information for:
    - Steps in the process that are CCPs
    - The hazard(s) of concern.
    - Critical limits
    - Monitoring*
    - Corrective actions*
    - Verification procedures and schedule*
    - Record-keeping procedures*

    * A brief summary of position responsible for performing the activity and the procedures and frequency should be provided

    The following is an example of a HACCP plan summary table:

CCP	Hazards	Critical limit(s)	Monitoring	Corrective Actions	Verification	Records

3. Support documentation such as validation records.
4. Records that are generated during the operation of the plan.

Examples of HACCP records are given in **Example 1 at the end of the chapter**.

8.2 Handling of Potentially Unsafe Products

The organization shall handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the food chain unless it is possible to ensure that:

a) the food safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels,
b) the food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering into the food chain, or
c) the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

All lots of product that may have been affected by a nonconforming situation shall be held under control of the organization until they have been evaluated.

If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal

The controls and related responses and authorization for dealing with potentially unsafe products shall be documented

NOTE The term “withdrawal” includes recall.

8.3 Withdrawals

To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe-

a) top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal, and

b) the organization shall establish and maintain a documented procedure for

1) notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
2) handling of withdrawn products as well as affected lots of the products still in stock, and
3) the sequence of actions to be taken.

Withdrawn products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe.

The cause, extent and result of a withdrawal shall be recorded and reported to top management as input to the management review.

The organization shall verify and record the effectiveness of the withdrawal programme through the use of appropriate techniques (e.g. mock withdrawal or practice withdrawal).

Examples 1: HACCP Records

A. Ingredients for which critical limits have been established.
    1. Supplier certification records documenting compliance of an ingredient with a critical limit.
    2. Processor audit records verifying supplier compliance.
    3. Storage records (e.g., time, temperature) for when ingredient storage is a CCP.
B. Processing, storage and distribution records
    1. Information that establishes the efficacy of a CCP to maintain product safety.
    2. Data establishing the safe shelf life of the product; if age of product can affect safety.
    3. Records indicating compliance with critical limits when packaging materials, labeling or sealing specifications are necessary for food safety.
    4. Monitoring records.
    5. Verification records.
C. Deviation and corrective action records.
D. Employee training records that are pertinent to CCPs and the HACCP plan.
E. Documentation of the adequacy of the HACCP plan from a knowledgeable HACCP expert.