Section 3-7: Principle 5: Determine Corrective Actions

Asia-Pacific Economic Cooperation
FSCF Food Safety Cooperation Forum
PTIN Partnership Training Institute Network
THE WORLD BANK
MICHIGAN STATE UNIVERSITY

Principle 5: Determine Corrective Actions

Section Overview

The fifth principle of HACCP is to establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit. Taking appropriate corrective actions in the event of a deviation at a critical control point is essential to producing safe food. If corrective actions are not properly conducted, potentially unsafe food could leave your establishment and cause illness in consumers of your food products.

The following topics will be discussed in this section:

- Definition and preliminary considerations
- Determining and correcting the cause of non-compliance
- Identifying affected product and determining its disposition
- Recording corrective actions

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Learning Objectives

At the conclusion of this section, the learner will be able to:

- define “Corrective Action” and list the three things a corrective action must achieve in a HACCP system,
- Discuss considerations when determining and correcting the cause of a deviation in a HACCP system,
- describe the steps taken to identify product subject to a corrective action and the process for determining its final disposition, and
- describe how to document corrective actions in a HACCP plan.

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Definition and Preliminary Considerations

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

In a HACCP system, corrective actions taken in the event of a deviation at a CCP must accomplish the following:

1. determine and correct the cause of non-compliance,
2. identify the product that was produced during the process deviation and determine its disposition, and
3. Record the corrective actions that have been taken.

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Definition and Preliminary Considerations

Specific corrective actions must be developed for possible deviations at each CCP in the HACCP plan for a product.

To the extent possible, corrective actions should be pre-planned. However, it is not possible to pre-plan for all corrective actions. You need to have a process in place to control nonconforming product and evaluate it to determine its ultimate disposition.

As a minimum, the HACCP plan should specify:

- what is done when a deviation occurs,
- who is responsible for implementing the corrective actions, and
- what records will be developed and maintained of the actions taken.

Individuals who have a thorough understanding of the process, product and HACCP plan should be assigned the responsibility for oversight of corrective actions. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.

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Determining and Correcting the Cause of Non-compliance

The first corrective action to be taken in the event of a deviation at a CCP should be to bring the process back under control.

This corrective action may simply require a process adjustment to bring the process back into compliance with the established critical limits. For example, if monitoring of a cooking process indicates that the product has not achieved an appropriate internal temperature, an appropriate corrective action might be to increase the cooking time and/or temperature until the appropriate internal temperature is met.

In some cases, it may not be possible to immediately bring the process back under control. In these instances, an appropriate corrective action may be to stop the processing line and hold all affected product (and products in process) until the cause of the non-conformity can be assessed and corrected.

Corrective actions may require root cause analysis to determine the cause of the non-conformity and provide assurance that continued deviations do not occur.

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Identifying Affected Product and Determining its Disposition

The second important task a corrective action must accomplish is to identify product affected by the deviation and determine its final disposition.

With regard to identification and isolation of the affected product, the following steps must be accomplished:

1. All affected product (i.e. that processed since the last point at which the CCP was known to be under control) must be isolated.
2. Isolated product must 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.
3. The producer must maintain control of the product from the hold date to the date of final disposition.

Furthermore, the product must be held under conditions that minimize its further deterioration (e.g. refrigeration or freezing where necessary).

If products that have left control of the organization are subsequently determined to be unsafe, the organization must initiate a withdrawal.

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Identifying Affected Product and Determining its Disposition

After the affected product has been identified and isolated, the establishment must evaluate these products to determine their final disposition.

Product evaluation should be conducted by a qualified person. For example, thermal process deviations should be evaluated by a competent process authority or someone having similar expertise.

The evaluation of affected product should be adequate to detect potential hazards. It should be ensured that sampling is adequate to identify the extent of the problem, that the tests are appropriate, that the judgment is based on sound science, and that the product is not released until the evaluation has determined that no potential hazard exists.

Each lot of nonconforming product can only be released as safe when any of the following apply:

- Other evidence demonstrates that the control measures have been effective.
- Evidence shows that the combined effect of the control measures for that particular product complies with the performance intended.
- Sampling, analysis and/or other verification activities demonstrate that the affected product complies with the identified acceptable levels for the food safety hazard(s) concerned.

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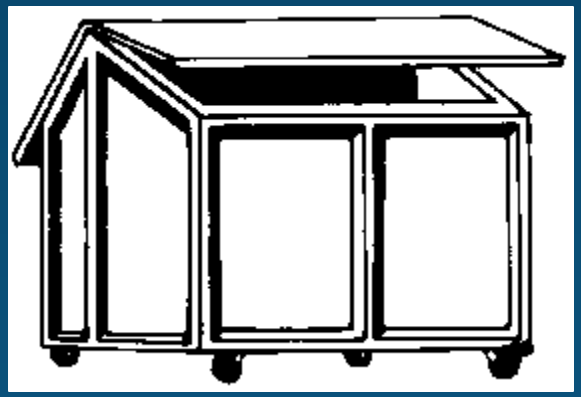
Identifying Affected Product and Determining its Disposition

Following evaluation, there are several possible fates for the product affected by the non-conformity. The product could be:

1. determined to be safe for the intended use,
2. determined to be safe for some other use,
3. reprocessed in a manner to ensure it becomes safe,
4. used for purposes other than originally intended, or
5. destroyed and/or disposed as waste.



For example, in the United States it is legal under specific circumstances to divert ground beef which tests positive for *E. coli* O157:H7 (considered to be an adulterant in this product in the United States) to a process which results in the production of a fully-cooked product.

The ultimate decision on the product disposition must be made by a person or persons with authority from the establishment. Product disposition decisions must be based on testing results, current scientific understanding, expert consultation, regulatory requirements, or other pertinent information.

Illustration: FAO

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Identifying Affected Product and Determining its Disposition

The following is a summary of the process to determine the disposition of nonconforming products.

1. Determine if the product presents a safety hazard, based on:
   - Expert evaluation
   - Biological, chemical, or physical testing
2. If no hazard exists, the product may be released.
3. If a potential hazard exists, determine if the product can be:
   - Reworked/reprocessed
   - Diverted for an alternate use
4. If potentially hazardous product cannot be handled as described in Step 3, the product must be destroyed.

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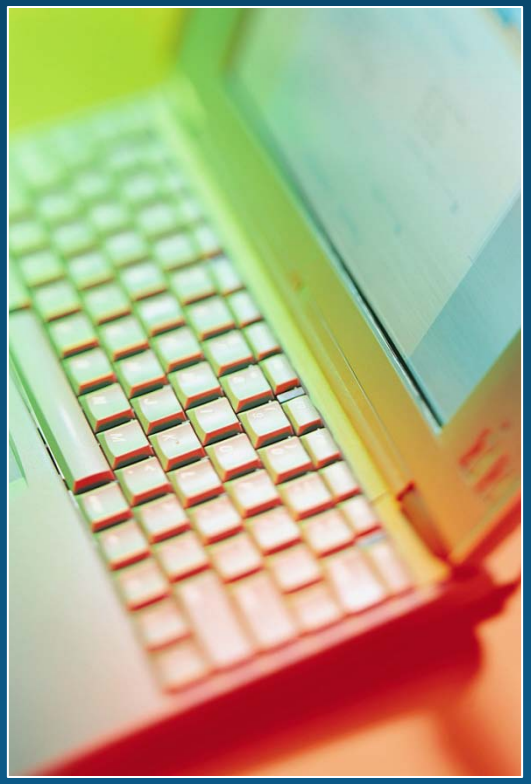
Recording Corrective Actions

Records for corrective actions and nonconformities must include the following information:

- The actual production records for the product
- A standard form listing the following:
  - Hold number, deviation, reason for hold, date and code of product held, quantity of product held, name and signature of responsible individual
- Results of product evaluation: Authority recommendations, product testing results, decision on final disposition of product in question
- Accurate accounting of all units in question
- Statement of the procedure for handling the nonconformity
- Cause of deviation identified
- Corrective action taken to prevent recurrence of deviation



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