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Beverage Operations

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

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Hazard Analysis and Critical Control Points (HACCP) Program

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Purpose

To identify and ensure the control and prevention of food safety hazards.

Scope

Each operation engaged in the manufacture, storage or distribution of products of the Company and its business partners.

Definitions

HACCP: a disciplined, systematic approach to the identification of Food Safety Hazards in the manufacturing, distribution, and end use of a product; an assessment of the likelihood of occurrence; and a definition of measures for the control and prevention of such hazards.

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

Significant Food Safety Hazard: a potential food safety concern in a process analyzed by the HACCP Team and determined to be *significant* for food safety.

HACCP Coordinator: the local designated team leader, trained in HACCP concepts and principles, responsible for controlling the scope of the HACCP study, managing the design and implementation of the HACCP Program, and ensuring that the program is maintained and meets all applicable requirements.

HACCP Team: a multidisciplinary group with HACCP training that has the responsibility of implementing, maintaining and validating a HACCP Program. The team must have a representative from each area within the scope of the HACCP Program.

Hazard Identification: review of operational processes by a HACCP Team to identify *potential* hazards associated with each process step.

Hazard Analysis: the procedure used by a HACCP Team to identify potential Food Safety Hazards and conditions leading to their presence in food. A Hazard Analysis evaluates both the severity of a hazard and the likelihood that it will occur. When Significant Food Safety Hazards are identified, measures for their elimination or control must be established in a HACCP Plan.

HACCP Plan: a document prepared by the HACCP Team in accordance with the principles of HACCP to ensure control of identified, significant Food Safety Hazards in a process.

Critical Control Measure (CCM): any action that can be used to prevent or eliminate an identified, significant Food Safety Hazard or reduce it to an acceptable level.

Supportive Safety Measure (SSM): a specified control step, procedure or action in a process other than a Critical Control Measure.

Critical Control Point (CCP): a step in a process including a raw material, location, practice, procedure, formulation or associated process where particular control measures can be applied to prevent, eliminate or reduce identified, significant Food Safety Hazards.

Critical Limit: a value established to which a biological, chemical or physical parameter must be controlled at a CCP in a process to prevent, eliminate, or reduce to an acceptable level the occurrence of a significant Food Safety Hazard. It is not an operating limit. A Critical Limit is used to distinguish between safe and unsafe operating conditions at a CCP. Measurements of temperature, time, concentration, and water activity are examples of Critical Limits.

Deviation: failure to meet a Critical Limit established for a CCP in a process. *Any associated product must be considered unsafe and cannot be distributed to consumers.*

Validation: an element of verification that is focused on collecting and evaluating scientific and technical information to determine if the HACCP Plan, when properly implemented, will effectively control Food Safety Hazards.

Verification: The activities, other than monitoring, that determine the validity of the HACCP Plan and that the system is operating according to the plan (for example, an audit, equipment calibration and/or record review).

General Requirements

Complete a HACCP study of each operational process following the seven-principle, twelve-step model described in the Codex Alimentarius, and relevant local authority.

Prerequisite Requirements

Prior to application of HACCP to any sector of the food chain, that sector must be operating according to appropriate food safety legislation, current Good Manufacturing Practices (GMP), and where applicable, the Codex General Principles of Food Hygiene.

The following operational prerequisites must be considered and appropriately addressed.

Hazard Analysis and Critical Control Points (HACCP) Program

Prerequisite	Objectives
Primary Production	To manage primary production to ensure that food is safe and suitable for its intended use. Where necessary, this will include: • avoiding the use of areas where the environment poses a threat to the safety of food; • controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety; and • adopting practices and measures to ensure food is produced under appropriately hygienic conditions.
Premises, Equipment and Facilities Design	Depending on the nature of operations, and the risks associated with them, to locate, design and construct premises, equipment and facilities to ensure that: • contamination potential is minimized; • design and layout permit appropriate maintenance, cleaning and disinfections, and minimize air-borne contamination; • surfaces and materials that come in contact with food are non-toxic in intended use, and where necessary, suitably durable, and easy to maintain and clean; • where appropriate, suitable facilities are available for temperature, humidity, and other controls; • there is effective protection against pest access and harborage; and • waste treatment and disposal are operated in a manner in which they do not constitute a source of contamination in areas where food is exposed.
Control of Operation	To produce food that is safe and suitable for human consumption by: • following design requirements with respect to raw materials, composition, processing, distribution, and consumer use to be met in the manufacture and handling of specific food items; and • designing, implementing, monitoring and reviewing effective control systems.

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Prerequisite	Objectives
Maintenance and Sanitation	To ensure effective maintenance and sanitation by: • providing adequate and appropriate facilities and equipment maintenance to endure sanitary conditions throughout the operation; • controlling pests; • managing waste; and • routinely monitoring effectiveness of maintenance and cleaning and sanitation procedures.
Personal Hygiene	To ensure that those who come into contact with food are not likely to contaminate food by: • maintaining an appropriate degree of personal cleanliness; and • behaving and operating in an appropriate manner.
Transportation	To ensure measures are taken as necessary to: • protect food from potential sources of contamination; • protect food from damage likely to render it unsuitable for consumption; and • provide an environment which effectively controls the growth of pathogenic or spoilage microorganisms and the production of toxins in food.
Product Information and Consumer Awareness	To make information readily accessible throughout the supply chain that communicates: • appropriate and correct handling, storage, processing, preparation, display, and safe use of the product; and • the lot or batch identification for recall if necessary.
Training	To train and/or instruct food or beverage operations personnel in food hygiene to a level appropriate to the activities they are to perform.

Hazard Analysis and Critical Control Points (HACCP) Program

HACCP Program Requirements

- The successful application of HACCP requires full commitment and involvement of management and the workforce.
- To ensure the HACCP Program remains effective and up to date, it must be reviewed at least annually.
- The HACCP Team must be kept informed, review the program and its application, and make any needed updates each time a change is made to the process, product, or equipment.
- HACCP must be defined separately by product type, process line, and location.
- All personnel involved with the HACCP Program must be trained in HACCP principles and its practical application.

HACCP Methodology – The Seven Principles

1. Identification of Potential Hazards and assessment of their severity and probability of occurrence (Hazard Analysis).
2. Determination of CCPs required to control identified, significant Food Safety Hazards.
3. Specification of Critical Limits that assures the operation is under control at a particular CCP.
4. Establishment and implementation of monitoring systems.
5. Execution of corrective actions when Critical Limits are not met.
6. Establishment of procedures for verifying that the HACCP Program is being followed, including Validation.
7. Establishment of documentation for all procedures and records appropriate to these principles and their application.

HACCP Implementation – The Twelve Steps

Apply the following twelve-step logic sequence (see Figure 1).

Step 1

Assemble HACCP Team

- Each operation must appoint a local HACCP coordinator (or team leader).
- The HACCP Team must consist of individuals who have the process and product-specific knowledge and expertise required to develop an effective HACCP Program. Typical teams include representatives from engineering, production, sanitation, quality, and food microbiology. Where expert advice is not available on site, it must be obtained from external sources.
- The HACCP Team defines the scope of the HACCP Program, where to start, where to finish and what to include.

NOTE: Details of HACCP application may vary depending on the nature, size and circumstances of the operation.

Step 2

Describe product type

The HACCP Team develops a full description of the product, including:

- Product name
- Relevant food safety information
  - Physical/chemical structure
  - Composition (ingredients), substances and food contact materials described to the extent necessary to identify and assess hazards, including possible allergens
- Process/ Preservation Method
- Packaging
- Distribution and storage
  - Duration and shelf-life
  - Storage conditions
  - Methods of distribution and transportation

NOTE: Refer to RF-PF-155 for product description examples.

Step 3

Identify intended use

The HACCP Team defines the normal and expected use of the product and any vulnerable groups of the population that may have to be considered.

NOTE: Steps 2 and 3 may be combined.

Step 4

Create flow diagrams

The HACCP Team creates flow diagrams covering each step in the processes within the identified scope. Consideration must be given to steps preceding and following the specified operation. This includes outsourced processes, subcontracted work, rework, recycling, and waste removal.

NOTE: Refer to RF-PF-155 for an example of a process flow diagram.

Step 5

On-site confirmation of flow diagrams

The HACCP Team must confirm the flow diagrams are correct by comparing them to actual operations during all stages and hours of operation, and must amend the diagrams where appropriate.

Step 6

Conduct a Hazard Analysis (Principle 1)

In every operation, the HACCP Team must conduct a Hazard Analysis for each product type and production line. The analysis must be completed initially and repeated prior to any significant change in ingredients, packaging materials, product use, formulation and production line layout.

6a) Identify all potential hazards associated with each step in the process

Categorize and list all potential biological, chemical, and/or physical hazards reasonably expected to occur at each process step, from receiving, primary production and distribution to the point of consumption.

6b) Evaluate each potential hazard

The HACCP Team must then conduct a Hazard Analysis to identify which potential hazards are of such a nature that their prevention, elimination, or reduction to acceptable levels is essential.

- Each potential hazard must be evaluated against the following criteria:
  - Severity or seriousness of the consequences of exposure;
  - Likeliness of occurrence;
  - A combination of experience, epidemiological data, survival or multiplication of microorganisms of concern, production or persistence of chemicals, toxins, or other scientific data;
  - Consumer complaint data; and
  - Effectiveness of existing control measures, including sanitation standard operating procedures and work instructions.
- Records of deliberations and rationale developed during the Hazard Analysis must be maintained.

NOTE:

1. For an aid to Hazard Analysis, refer to Figure 2.
2. Potential hazards are categorized as follows:
   a. *Biological*: harmful microorganisms, viruses or parasites.
   b. *Chemical*: compounds that can cause illness or injury due to immediate or long-term exposure.
   c. *Physical*: foreign objects in food that can cause harm to a consumer.
3. Even among experts, there can be differences of opinion about the likely occurrence and severity of a potential Food Safety Hazard. The HACCP Team may need to seek the opinion of experts to assist in the development of the HACCP Program.
4. Significant Food Safety Hazards identified in one operation may not be significant in another operation producing the same or a similar product. For example, due to differences in equipment and/or an effective maintenance program, the probability of bottle failure resulting in product contamination may be significant in one operation but not in another.

6c) Determine control measure of each Significant Hazard

- Once the HACCP Team decides a potential hazard must be specifically addressed in a HACCP Plan, it is categorized as an identified, significant Food Safety Hazard.
- The HACCP Team then must decide control measures that can be applied.
- Control measures then must be categorized as either Critical Control Measures (CCM) or Supportive Safety Measures (SSM).
- Critical Control Measures must be established for each CCP and included in a HACCP Plan.
- A Supportive Safety Measure may be a process, procedure or component of a functioning prerequisite program such as GMP.

Step 7

Determine CCPs (Principle 2)

- Each identified, significant Food Safety Hazard must be addressed in determining CCPs.
- Complete and accurate identification of each CCP is required.
- A CCP must be justifiable, validated and measurable, and carefully developed to ensure its effectiveness in preventing, eliminating, or reducing the identified Significant Hazard to acceptable levels.
- Records of determination of each CCP must be maintained.
- CCPs must be monitored and the procedure and/or method documented in a HACCP Plan.
- At a process step where control is necessary for a Significant Hazard, yet no control measure exists, the product or process must be modified at that step, or at any earlier or later stage, to include a control measure.

NOTE:

1. More than one Critical Control Measure may control a Significant Food Safety Hazard, and a single Critical Control Measure may control more than one Food Safety Hazard.
2. To facilitate identification of CCPs, a decision tree or other assessment tool may be helpful (see Figure 3. Example of Decision Tree to Identify CCPs); however, there is no substitute for expert knowledge. Risk training is also highly recommended.

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Step 8

Establish Critical Limits for each CCP (Principle 3)

- The HACCP Team must specify, validate, and document the justification and measurement criteria for Critical Limits at each CCP.
- A Critical Limit must be scientifically based and measurable.
- In some cases, more than one Critical Limit may be elaborated at a CCP.

NOTE: Critical Limits may be derived from the Company's requirements, regulatory standards, experimental results, or expert advice.

Step 9

Establish monitoring procedures for each CCP (Principle 4)

- Once the CCP is established, the HACCP Team must develop a HACCP Plan to address all activities associated with control of the CCP and the action to take when any Deviation occurs.
- Each CCP must be effectively monitored to ensure that if loss of control exists, action is taken to bring the process back into control before a Deviation from a Critical Limit occurs.
- The monitoring procedure for a CCP must be documented to include:
  - scheduled physical, chemical, or microbiological measurement or observation of a CCP relative to its Critical Limits to indicate control of the process;
  - detection of loss of control at the CCP and definition of how it is to be monitored;
  - evaluation of monitoring data by a responsible person with the knowledge and authority to carry out corrective actions;
  - sufficient frequency of monitoring, if not continuous, to ensure and document that the CCP is in control.

NOTE: When feasible, continuous monitoring is always preferred.

- All records and documents associated with CCP monitoring must be dated and signed by the person(s) responsible for the monitoring, and by a management representative trained in HACCP for evaluation (typically the HACCP Coordinator).

- Personnel who monitor the CCP must fully understand their purpose and importance, and be trained in the monitoring technique for the CCP for which they are responsible.

Step 10

Establish corrective actions (Principle 5)

- To address Deviations from Critical Limits and prevent affected product from reaching the consumers, specific corrective actions must be developed *in advance* for each CCP.
- At a minimum, these activities must be specified in the HACCP Plan:
  - what to do when a Deviation occurs;
  - who is responsible for implementing corrective actions; and
  - the development and maintenance of a record of actions taken and results.

NOTE: Refer to RF-PF-155 for an example HACCP Plan.

Step 11

Establish Verification procedures (Principle 6)

- The frequency of HACCP Plan Verification must not exceed 12 months, or when changes occur that could affect the Hazard Analysis or HACCP plan.
- Verification procedures must include:
  - review of the Hazard Analysis documentation;
  - review of the audit results, which review must occur within seven days from the day the records are made;
  - review of process monitoring data for confirmation that CCPs are kept under control;
  - review of Deviations, corrective actions, product disposition, and consumer complaints;
  - calibration of process monitoring instruments; and
  - communication of Verification results to the HACCP Team.

NOTE: Refer to RF-PF-155 for an example of a Verification checklist.

- Validation of the HACCP Program includes actions to confirm the elements of the HACCP Plan are effective, for example, documenting a Hazard Analysis associated with new process equipment installation or a change in product formulation.

Step 12

Establish documentation and record keeping (Principle 7)

- Establish, implement and maintain documentation and record keeping procedures appropriate to the nature and size of the operation.
- Documentation must include:
  - Hazard Analysis
  - CCP determination
  - Critical Limit determination
- Records must include:
  - CCP monitoring activity
  - Deviations and associated corrective actions
  - Modifications to the HACCP Program
  - Verification activities
- HACCP documentation must be included as part of the organization's Product Release Authorization plan and reviewed by the HACCP Coordinator. Product release must include confirmation that no Deviation(s) occurred.
- Establish record retention duration according to Company requirements and local regulations.

Figure 1. Twelve Steps for the Application of HACCP

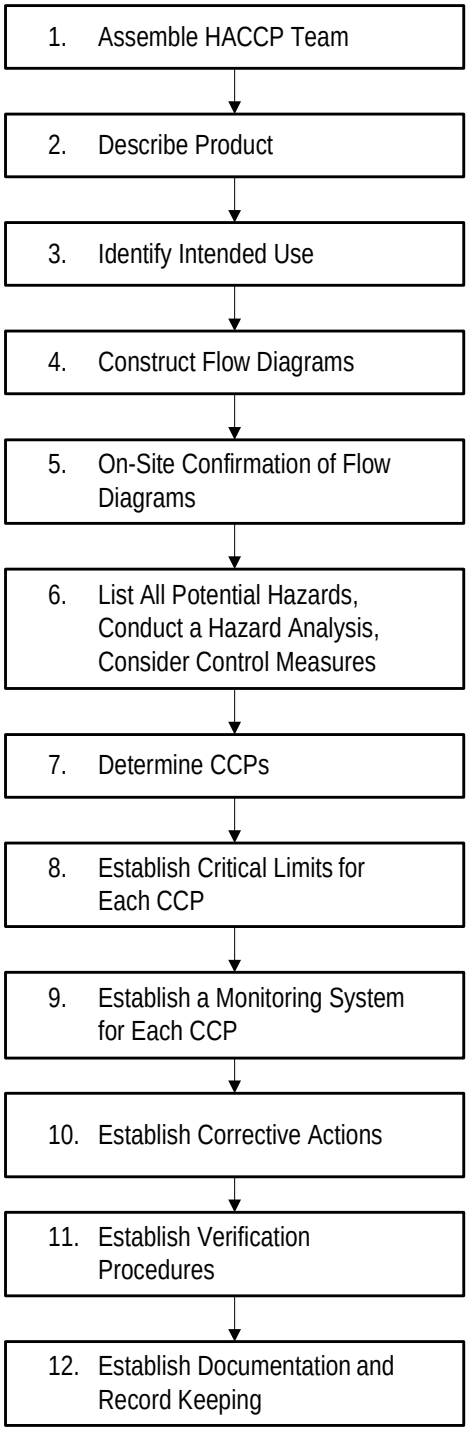
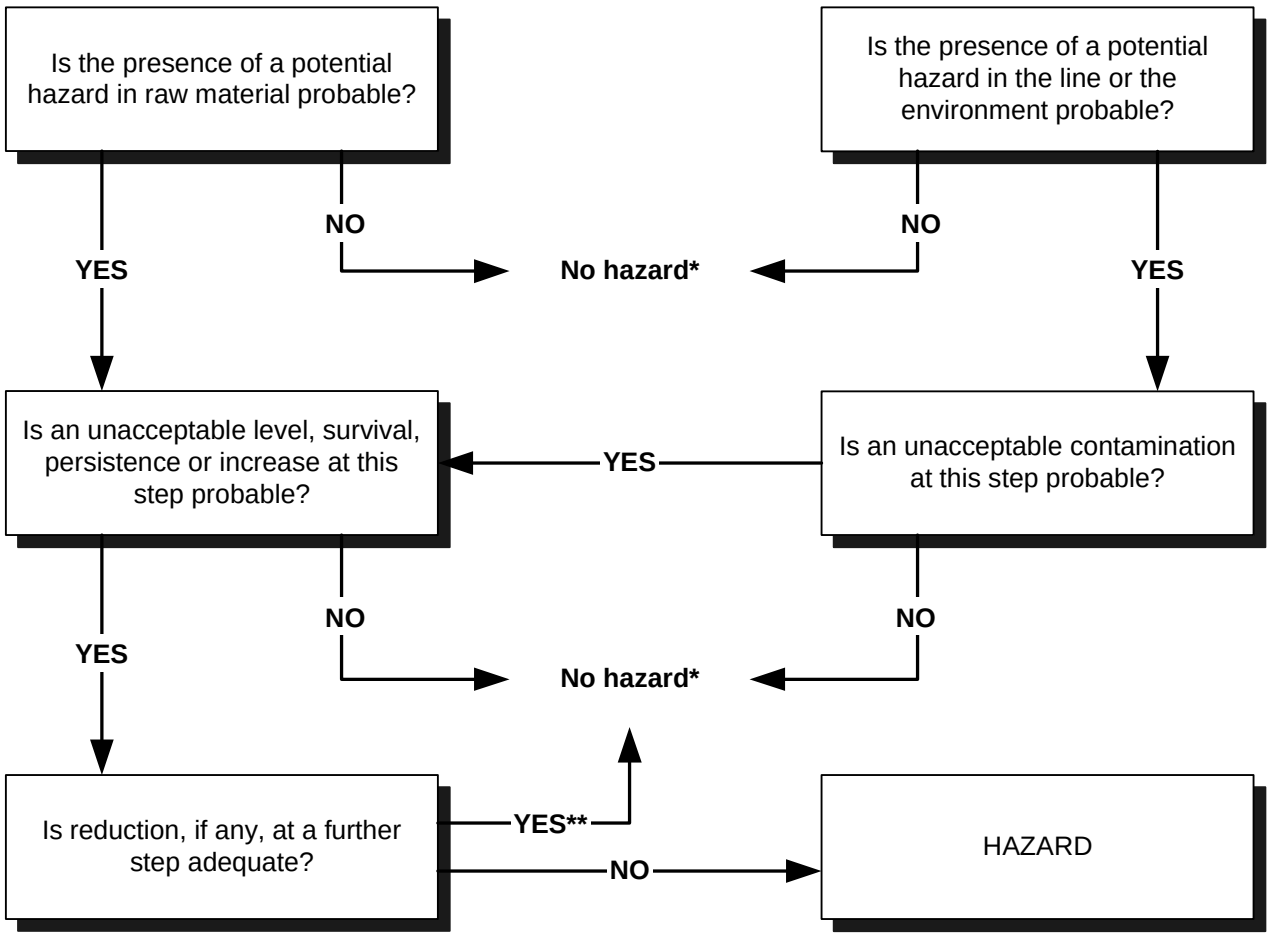


Figure 2. Hazard Determination

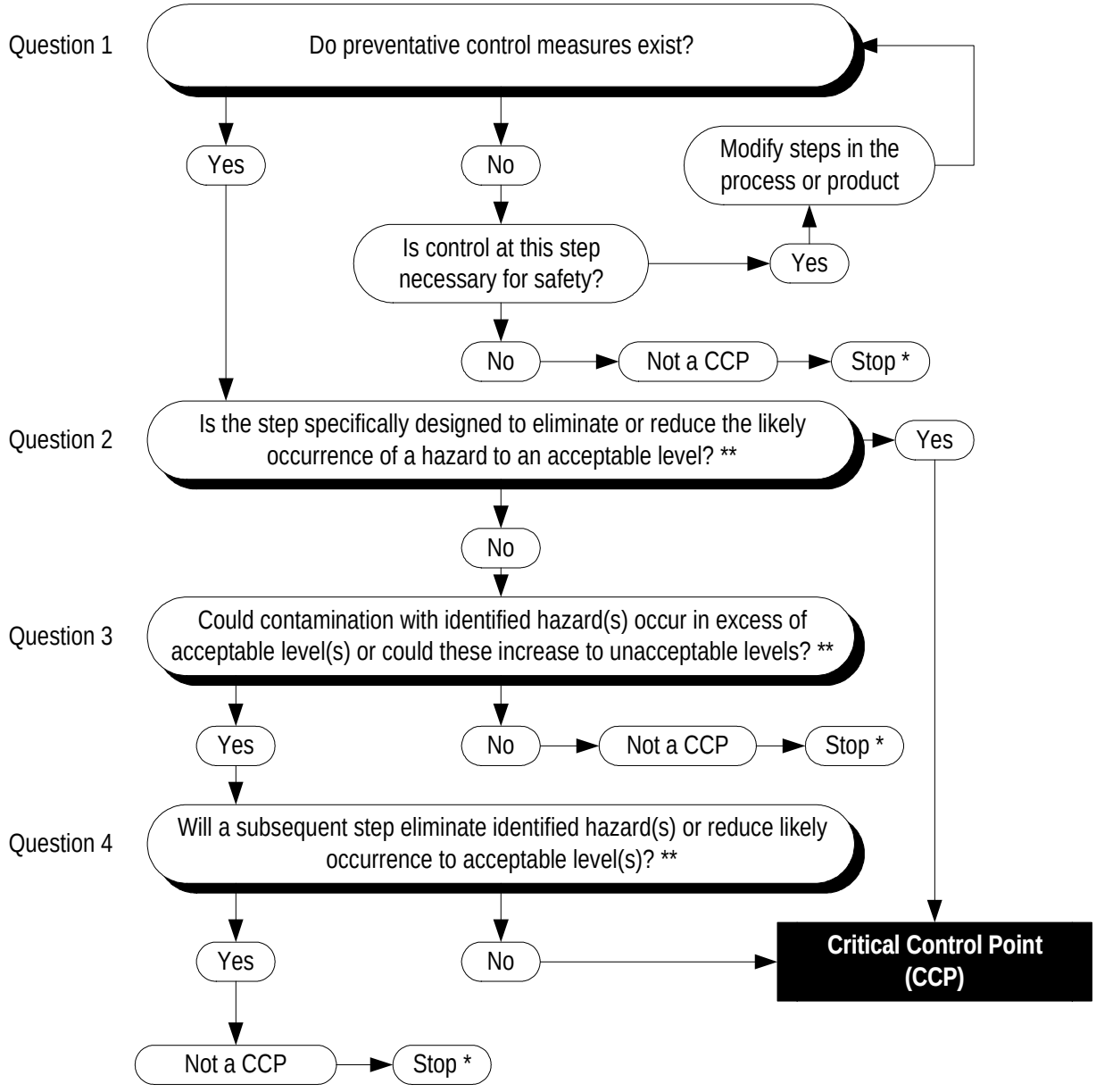
Questions to be answered for each potential hazard at each step



* Not a hazard to be controlled at this step.

** Reduction step becomes thus a CCP.

Figure 3. Example of Decision Tree to Identify CCPs



* Proceed to the next identified hazard in the described process

** Acceptable and unacceptable levels need to be determined

NOTE: The determination of a CCP can be facilitated by the application of a decision tree, which can be used for guidance in conjunction with professional judgment. Training in the application of the decision tree is recommended. Other approaches may be used.

References

Codex Alimentarius	Annex to CAC/RCP 1-1969, Rev. 3 (1997)
CFR	Title 21, Part 120
QMS-SD-001	Quality Management System Standard, element 3.11
BO-RQ-200	Good Manufacturing Practices-Design Criteria
BO-RQ-205	Good Manufacturing Practices-Bulk Storage Facilities
BO-RQ-225	Personnel Practices
BO-RQ-220	Cleaning and Sanitizing Requirements
BO-RQ-950	Pest Control

Revision History

Issue Date	Summary of Change
31-Aug-2003	This document is new. Some examples have been included from RF-PF-155.