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Report Name: National Food Safety Standard for the General Requirements for Food Production Enterprises

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Report Highlights:

On June 1, 2009, the People’s Republic of China (PRC) released National Food Safety Standard for Hazard Analysis and Critical Control Point (HACCP) System for General Requirements for Food Production Enterprises (GB/T 27341-2009), which entered into force on February 17, 2009. This report contains an unofficial translation of the standard. This report is being published and shared by FAS China now owing to its relevance for several commodity sectors attempting to register as part of the PRC's Decree 248 facility registration requirements.

BACKGROUND

In some of the "checklists" that are a part of Decree 248 facility registration requirements, the following standard is included as a reference document that must be checked against when facilities attempt to register for exporting select categories of commodity products to China.

BEGIN TRANSLATION

Hazard Analysis and Critical Control Point (HACCP) System General Requirements for Food Production Enterprises GB/T 27341-2009

Contents

Foreword

Appendix A of this standard is an informative appendix.

This standard is proposed and managed by the National Certification and Accreditation Standardization Technical Committee (SAC/TC261).

The main drafting units of this standard: National Certification and Accreditation Regulatory Commission Registration Management Department, Certification and Accreditation Technology Research Institute, National HACCP Application Research Center, Beijing Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China, Tianjin Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China, Beijing Hua Silian Certification Center, China Quality Certification Center, Fangyuan Logo Certification Group Co., Ltd., Beijing Zhongda Huayuan Certification Center.

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Introduction

The food production and processing process (including raw material procurement, processing, packaging, storage, shipment, etc.) is an important link in prevention and control of food safety hazards.

The Hazard Analysis and Critical Control Point (HACCP) system is a scientific, reasonable, and preventive system for process control of food production and processing. The establishment and application of this system can ensure that food safety hazards are effectively controlled to prevent the occurrence of hazards to public health.

This standard aims to be scientific and systematic, focuses on food safety, and uses HACCP principles to prevent, eliminate or reduce food safety risks to an acceptable level.

Hazard Analysis and Critical Control Point (HACCP) System General Requirements for Food Production Enterprises

1 Scope

This standard specifies general requirements for the Hazard Analysis and Critical Control Point (HACCP) system of food production enterprises to provide safe foods that comply with laws, regulations, and customer requirements. This standard is applicable to the establishment, implementation, and evaluation of HACCP systems of food production (including catering) enterprises, including procurement, processing, packaging, storage, and shipment of raw materials and food packaging materials.

2 Normative References

Clauses in the following documents become clauses of this standard through references of this standard. For dated references, all subsequent amendments (excluding error corrections) or revisions do not apply to this standard. However, parties to agreements based on this standard are encouraged to study whether the latest versions of these documents can be used. For undated references, the latest version applies to this standard.

- GB/T 19538 Hazard Analysis and Critical Control Point (HACCP) system and its application guidelines
- GB/T 22000 Food safety management system on requirements for various organizations in food chains

3 Terms and Definitions

GB/T 22000, GB/T 19538, and the following terms and definitions apply to this standard.

3.1 Raw material

All intended products, articles or substances that constitute a food component or ingredient.

Note: including raw and auxiliary materials, additives, and all expected substances from other sources contained in food.

3.2 Potential hazard

Possible food safety hazards if no preventive measures are taken.

3.3 Significant hazard

Potential hazards of diseases or harms that are very likely to occur if no controlled measures are taken.

Note: "very likely to occur" and "cause diseases or harms" indicate "possibility" and "seriousness" of the hazards.

3.4 Operation limit

Operational indicators developed to avoid deviation of monitoring index from critical limits.

3.5 Food defense plan

Measures developed and implemented to protect the food supply from intentional biological, chemical, and physical contamination or damage.

4 Enterprise HACCP System

4.1 General requirements

Enterprises should plan and establish HACCP system according to the requirements of this standard to document, implement, maintain, update, and continuously improve it to ensure its effectiveness.

Enterprises should:
(a) Plan, implement, review, and improve processes of the HACCP system and provide the required resources.
(b) Determine the scope of the HACCP system and clarify relationships between the steps involved in the scope and other steps in the food chains.
(c) Ensure that any operations that will affect food safety requirements including out-sourcing processes are controlled and identified in the HACCP system. During verification process, product safety and compliance with relevant regulations and standards should be prioritized.
(d) Ensure that the HACCP system is effectively implemented so that product safety is effectively controlled. When systematic deviations occur in product safety, HACCP plan should be re-validated to continuously improve HACCP system.

4.2 Documents requirements

4.2.1 HACCP system documents should include:

(a) A documented food safety policy,
(b) HACCP manuals,
(c) Documented procedures required by this standard,
(d) Documents required by enterprises to ensure effective planning, operation, and control of HACCP system processes,
(e) Records required by this standard.

4.2.2 HACCP manual
Enterprises shall prepare and maintain the HACCP manual. The content shall at least include:

(a) Scope of the HACCP system including covered products or product categories, operating steps and locations, and relationships with other steps in the food chains,
(b) HACCP system program documents or references thereto,
(c) Description of HACCP system processes and their interactions.

4.2.3 Documents control
Documents required by HACCP system shall be controlled. A documented procedure shall be established to define the control measures required for:

(a) Documents are approved prior to issuance to ensure that they are adequate, appropriate, and valid,
(b) Review and update documents, if necessary, then re-approve it,
(c) Ensure changes and current revision status of documents are identified,
(d) Ensure valid versions of applicable documents are available at points of use,
(e) Ensure documentation remains legible and easily identifiable,
(f) Ensure external documents related to HACCP system are identified and control their distribution,
(g) Prevent unintended use of obsolete documents and properly identify obsolete documents that need to be retained.

4.2.4 Records control
Records shall be established and maintained to provide evidence of compliance with the requirements and effective operation of the HACCP system. A documented procedure shall be established specifying the controls required for the identification, storage, protection, retrieval, retention period, and disposal of the records. Records should remain legible, easily identifiable, and retrievable.

5 Management Responsibilities

5.1 Management commitment

Top management should provide evidence of commitment to establish and implement HACCP system through following activities:

(a) Communicate to business the importance of meeting requirements of customers and food safety laws and regulations,
(b) Formulate food safety policies,
(c) Ensure establishment of food safety goals,
(d) Conduct management reviews,
(e) Ensure access to resources.

5.2 Food safety policy

Top management should focus on food safety for consumers, formulate food safety policies and food safety goals, and ensure food safety.

5.3 Responsibilities, authorities, and communication

5.3.1 Responsibilities and authorities
Top management should appoint the leader of HACCP working group, confirm the responsibilities and authorities, at the same time stipulate the responsibilities and authorities of each department of the enterprise in HACCP system.

5.3.2 Communication
In order to obtain the necessary food safety information and ensure the effectiveness of HACCP system, top management should ensure that enterprise establishes, implements, and maintains the required internal communications, and communicates with other suppliers, customers, food safety authorities, and other parties within the food chain for necessary external communications.

The personnel implementing communication shall receive appropriate trainings to fully understand products of enterprises, related hazards, and HACCP system. The personnel should be authorized. Communication records shall be maintained.

5.4 Internal audits

Enterprises should conduct internal audits according to the planned time intervals to determine whether the HACCP system meets requirements and is effectively implemented, maintained, and updated.

Considering status and importance of the processes and areas to be audited and results of previous audits, an audit program shall be planned to define its accuracy, scope, frequency, and method.

The selection of internal auditors and implementation of audits shall ensure objectivity and impartiality of the audit process. Internal auditors shall not audit their own programs.

Managers responsible for audited areas shall ensure that timely measures are taken to eliminate non-conformities activities and their causes. Tracking activities should include verification of the actions taken and reporting of the results of verification.

A documented internal audit procedure shall be developed to provide guidance for planning, conducting audits, results reporting, and records maintaining.

5.5 Management review
Top management should review HACCP system at planned intervals to ensure its continued suitability, adequacy, and effectiveness. The review should include needs for improvement and updates of the HACCP system. Records of the management reviews should be maintained.

6 Prerequisite Program

6.1 General rules

Enterprises should establish, implement, verify, maintain, update, or improve the prerequisite plans when necessary to continuously meet the hygiene conditions required by HACCP system. Prerequisite plans should include human resource assurance plans, good manufacturing practice (GMP) of the enterprise, sanitation standard operational procedures (SSOP), safety and health assurance system for raw materials and packaging materials in direct contact with food, recall and traceability system, equipment and facility maintenance plan, emergency preparedness plan, etc. Prerequisite programs shall be approved, and records shall be maintained.

6.2 Human resources guarantee plan

Enterprises should formulate and implement human resources guarantee plan to ensure that the personnel engaged in food safety work are competent. The plan should meet the following requirements:

(a) Provide managers and employees with continuous trainings on the HACCP system, relevant professional and technical knowledge, operational skills, and laws and regulations, or take other measures to ensure competencies of managers and employees at all levels,
(b) Evaluate effectiveness of trainings provided or other measures taken,
(c) Maintain appropriate records of education, trainings, skills, and experiences of personnel.

6.3 Good manufacturing practice (GMP)

Enterprises shall establish and implement GMP in accordance with the provisions of food laws and regulations and requirements of corresponding sanitation standards.

6.4 Sanitation standard operating procedure (SSOP)

When formulating and implementing SSOP, enterprises should at least meet the following requirements:

(a) Water and ice in contact with foods (including raw materials, semi-finished products, and finished products) or articles in contact with foods shall meet safety and hygiene requirements,
(b) Utensils, gloves, and inner and outer packaging materials in contact with foods shall be clean, hygienic, and safe,
(c) Ensure foods are free from cross-contamination,
(d) Ensure operators wash and disinfect hands and keep toilet facilities clean,
(e) Prevent food safety hazards caused by lubricants, fuels, cleaning and disinfection utensils, condensed water, and other chemicals, physical, and biological pollutants,
(f) Properly label, store, and use various types of toxic chemicals,
(g) Ensure the physical health and hygiene of employees who contact with foods,
(h) Eliminate and prevent rodents and pests.

SSOP records shall be maintained.

6.5 Safety and hygiene assurance system for raw materials and food packaging materials

Enterprises should prevent food safety hazards in raw materials and food packaging materials, formulate and implement their safety and hygiene assurance systems, and at least meet the following requirements:

(a) Formulate corresponding valid qualification conditions for suppliers of raw materials and food packaging materials to determine the list of suppliers,
(b) Assess the ability of suppliers of raw materials and food packaging materials to ensure products safety and sanitation, and when necessary, conduct document reviews or on-site inspection of food safety management system of the suppliers,
(c) Formulate requirements and procedures for receiving raw materials and food packaging materials, including checking inspection and quarantine of raw materials and food packaging materials, sanitation certificates of conformity, traceability identification of raw materials, and food packaging materials. When necessary, conduct inspection and verification on safety and hygiene indicators for raw materials and food packaging materials,
(d) Develop control measures for food additives where necessary,
(e) Formulate an evaluation system for suppliers including an elimination system for unqualified suppliers.

6.6 Maintenance plan

Enterprises should formulate and implement maintenance plans for factory areas, workshops, facilities, equipment, etc., to keep them in good conditions and prevent contamination to products.

6.7 Identification and traceability plan, products recall plan

6.7.1 Identification and traceability plan
Enterprises should ensure that they have capacity to identify products and their status during traceability, formulate and implement product identification and traceability plans, at least meeting following requirements:

(a) Use appropriate methods to identify products and have traceability capacity during whole processes of food production,
(b) Identify the status of products for monitoring and verification requirements,
(c) Maintain products shipment records including all distributors, retailers, customers, or consumers.

6.7.2 Product recall plan
Enterprises should formulate product recall plans to ensure all distributed products affected by safety hazards can be recalled. The plan should include at least following requirements:

(a) Determine responsibilities and authorities of those who initiate and implement the products recall plan,

(b) Determine relevant laws, regulations, and other relevant requirements that products recall actions need to comply with,
(c) Develop and implement recall measures for products affected by safety hazards,
(d) Establish procedures for analysis and disposal of recalled products,
(e) Conduct regular drills and verify effectiveness.

Records of implementation of products recall plans shall be maintained.

6.8 Emergency plan

Enterprises should identify and determine potential food safety accidents or emergencies, formulate response plans and measures in advance, and respond when necessary to reduce the impact of possible food safety hazards.

When necessary, especially after an accident or emergency, enterprises should review and improve emergency plans. Records of implementation of emergency plans shall be kept and regular mock practices should be conducted to verify their effectiveness.

Note: Emergencies include situations in which products of enterprises are affected by force majeure factors such as natural disasters, sudden epidemics, bioterrorism, etc.

7 Establishment and Implementation of HACCP plan

7.1 General rules

The HACCP team shall formulate and organize implementation of food HACCP plans according to requirements of the following seven principles, systematically control significant hazards, and ensure that these hazards are prevented, eliminated, or reduced to acceptable levels to ensure food safety.

(a) Conduct hazard analysis and develop control measures,
(b) Identify critical control points,
(c) Determine critical limits,
(d) Establish a monitoring system for critical control points,
(e) Establish corrective actions,
(f) Establish verification procedures,
(g) Establish documentation and record-keeping systems.

Any changes in factors that affect the effectiveness of the HACCP plan, such as changes in product formula, processes, and processing conditions may affect changes in the HACCP plan. The HACCP plan must be confirmed, verified, and updated when necessary.

7.2 Preliminary steps

7.2.1 Composition of the HACCP team
The ability of the HACCP team personnel should meet professional and technical requirements of food production, and it should be composed of personnel from different departments including

personnel of sanitation quality control, products research and development, production technology, equipment and facility management, raw material procurement, sales, warehousing, and transportation. If necessary, external experts may be invited to participate.

Team members should have professional technical knowledge and experience related to products, processes, and hazards involved for enterprises, and have received appropriate trainings.

The top management shall designate a HACCP team leader, and shall assign the following responsibilities and authorities:

(a) Ensure processes required by the HACCP system are established, implemented, and maintained,
(b) Report effectiveness and suitability of the HACCP system and any need for updates or improvement to the top management,
(c) Lead and organize work of the HACCP team and ensure members of the HACCP team to work in a professional manner through education, training, practice, etc. with continuous improvement in professional knowledge, skills, and experience.

Records shall be maintained for qualifications, experience, trainings, approvals, and activities of HACCP team members.

7.2.2 Product description
The HACCP team shall identify and determine following applicable information required to conduct a hazard analysis for products:

(a) Names, categories, components, and biological, chemical, and physical characteristics of raw materials and food packaging materials,
(b) Sources of raw materials and food packaging materials, methods of production, packaging, storage, transportation, and delivery,
(c) Receiving requirements, receiving methods, and usage methods of raw materials and food packaging materials,
(d) Names, categories, compositions, and biological, chemical, and physical characteristics of the products,
(e) How the product is processed,
(f) Methods of packaging, storage, transportation, and delivery of products,
(g) Methods of sales and labeling of products,
(h) Other necessary information.

Records of products descriptions shall be maintained.

7.2.3 Determination of intended use
Based on products descriptions, the HACCP team should identify and determine following applicable information needed for hazard analysis:

(a) Customer's consumption or usage expectations of the products,

(b) Intended use and storage conditions of the products, as well as the shelf life,
(c) Intended manners of consumption or use of the products,
(d) Expected customers for the products,
(e) Suitability of the products for direct consumption by vulnerable groups,
(f) Unintended (but highly probable) ways of eating or using the products,
(g) Other necessary information.

Records of intended use of the products shall be maintained.

7.2.4 Formulation of flow diagrams
The HACCP team should draw process flow diagrams of the products according to operation requirements within scopes of products production including:

(a) Each step and its corresponding actions,
(b) Sequences and interrelationships between steps,
(c) Rework and recycling points (as appropriate),
(d) External processes and outsourced contents,
(e) Input points of raw and intermediate products,
(f) Discharge points of wastes.

Formulation of the flow diagrams shall be complete, accurate and clear. Operating requirements and process parameters for each processing step should be listed in process descriptions. When applicable, factory location map, floor plan, workshop floor plan, flow of personnel and logistics map, water supply and drainage network map, pest control distribution map, etc. shall be provided.

7.2.5 Validation of flow diagrams
The HACCP team personnel who are familiar with operating processes shall carry out on-site inspection of all operating steps under operating conditions, confirm and check whether it is consistent with the established flow diagrams, and modify the diagrams if necessary.

A validated flow diagrams should be maintained.

7.3 Hazard analysis and establishment of control measures

7.3.1 Hazard identification
The HACCP team shall consider following aspects when analyzing biological, chemical, and physical hazards in processing steps according to degrees of food safety risk factors:

(a) Products, operation, and environments,
(b) Safety and hygiene requirements on products, raw and auxiliary materials, and food packaging materials by consumers or customers and laws and regulations,
(c) Monitoring and evaluation results of products consumption and use safety,
(d) Status of unsafe products disposal, correction, recall, and contingency plans,
(e) Historical and current epidemiological, animal or plant epidemic or disease statistics, and food safety incident cases,

(f) Scientific literatures including hazards control guidelines for relevant categories of products,
(g) Effect on products of other steps within the scope of hazards identification,
(h) Intended damage, deliberate contamination, etc.,
(i) Experiences.

In scopes from production of raw materials to final consumption, all potential hazards and their causes introduced, produced, or increased based on its reasonable anticipation should be identified. When any factors affecting hazards identification results change, the HACCP team should re-identify the hazards.

Records of basis and results of hazards identification shall be maintained.

7.3.2 Hazard assessment
The HACCP team shall assess severity and likelihood of occurrence of the identified potential hazards, if such potential hazards are very likely to occur and consequences are serious, it should be determined as significant hazards.

Records of basis and results of the hazard assessment should be maintained.

7.3.3 Development of control measures
The HACCP team should formulate corresponding control measures for each significant hazard and provide evidence to prove their effectiveness. The corresponding relationships between significant hazards and control measures should be clarified. Situations such as one control measure controlling multiple significant hazards or multiple hazards measures controlling a significantly hazardous should be considered.

A food defense plan should be established as a control measure for obvious hazards caused by intentional damages or contamination,

When these measures change in operation, corresponding changes should be made, and the flow diagrams should be revised. When effective control measures cannot be established for a certain significant hazard under current technical conditions, enterprises shall plan and implement necessary technical transformation, and if necessary, change the processing technologies, products (including raw and auxiliary materials), or intended use until an effective control measure is established.

Control measures developed should be validated. When effectiveness of control measures is affected, the control measures should be evaluated, improved, then re-validated.

The basis for the establishment of control measures and the documentation of control measures shall be maintained.

7.3.4 Hazard analysis worksheet
The HACCP team should provide a documented hazard analysis worksheet based on results of process flows, hazard identification, hazard assessment, and control measures. The hazard

analysis sheet should include processing steps, potential hazards considered, basis for judging significant hazards, control measures, and their mutual relationships.

In the hazard analysis worksheet, relationships between control measures and corresponding significant hazards should be described to provide a basis for determining critical control points. The HACCP team should make necessary updates or revisions to the hazard analysis worksheet when hazard analysis results are affected by any factors.

A documented hazard analysis worksheet shall be maintained.

7.4 Determination of Critical Control Points (CCPs)

The HACCP team should identify appropriate steps for the control of each significant hazard based on the relationship between significant hazards and control measures provided by the hazard analysis to determine CCPs and ensure that all significant hazards are effectively controlled.

Enterprises should use an appropriate method to determine CCPs, such as the judgment tree table (see Appendix A), etc. When using CCPs judgement tree table, following factors should be considered:

(a) Judgment tree form is only a tool to help determine CCPs, but not a substitute for professional knowledge,
(b) Judgment tree form is used in steps after hazards analysis and when significant hazards are determined,
(c) Subsequent processing steps may be more effective in controlling hazards and may be a preferred CCP,
(d) More than one step might be needed to control a hazard.

When significant hazards or control measures change, the HACCP team should conduct hazard analysis again and determine CCPs.

The basis and documents determined by CCPs should be maintained. In some cases when the control by Standard Operating Procedure (SOP) can be equivalent to the control by CCPs in some cases, the basis, parameters, and documents determined by the SOP shall be maintained.

7.5 Determination of critical limits

The HACCP team shall establish critical limits for each CCP, and a CCP may have one or more critical limits. The establishment of critical limits values should be scientific, intuitive, and easy to monitor to ensure safety hazards of the products are effectively controlled and do not exceed acceptable limit levels.

Critical limits based on perception should be monitored and judged by assessed competent personnel.

In order to prevent or reduce deviation from critical limits, the HACCP team should establish operational limits for CCPs. Records of basis and results of critical limits determinations shall be maintained.

Note: Critical limits can be time, rate, temperature, humidity, moisture content, water activity, pH value, salt content, etc.

7.6 Monitoring of CCPs

Enterprises should formulate and implement effective monitoring measures for each CCP to ensure CCPs are under control. Monitoring measures include monitoring objects, monitoring methods, monitoring frequency, and monitoring personnel.

The monitoring objects should include key limits involved in each CCP, and the monitoring method should be accurate and timely. The monitoring frequency should generally implement continuous monitoring, and if non-continuous monitoring is used, it should be able to ensure CCP is controlled. Proper trainings need to be provided to the monitoring personnel for them to understand purpose and importance of the monitoring, be familiar with monitoring operations and record, and report monitoring results in a timely and accurate manner.

When the monitoring shows that it deviates from operating limits, the monitoring personnel should take timely corrections to prevent deviation from critical limits. When the monitoring shows that it deviates from critical limits values, the monitoring personnel should immediately stop operation of the production and take corrective measures in a timely manner.

Monitoring records should be maintained.

7.7 Corrective actions for deviations

Enterprises should prepare corrective measures in advance for the deviation of each critical limit value of CCPs, so that they can be implemented when deviation occurs.

Corrective measures shall include personnel who implements corrective actions and is responsible for release of affected products, identification and elimination for the cause of deviation, and isolation, evaluation, and disposition of affected products.

When evaluating affected products, biological, chemical, or physical properties measurements or tests may be carried out, if results show that the hazard is within an acceptable range, products can be released for subsequent operations. Otherwise, it should be re-produced, downgraded, changed for use, discarded, etc.

Correction personnel should be familiar with the products and HACCP plan, and they should be properly trained and authorized. When the monitoring results of a certain critical limit repeatedly deviate or the reason for deviation involves control capability of the corresponding control measures, the HACCP team should re-evaluate the effectiveness and suitability of the relevant control measures and improve them if necessary.

Correction records should be maintained.

7.8 Validation and verification of HACCP plan

Enterprises should establish and implement validation and verification procedures for the HACCP plan to verify integrity, suitability, and effectiveness of the HACCP plan.

The validation procedure shall include verification of effectiveness of all elements of the HACCP plan. Validation should be carried out before or after the implementation.

The verification procedure shall include basis and methods, frequency, personnel, contents, results, measures taken, verification records, etc.

The audit of calibration records of the monitoring equipment, if necessary, the technical inspection of the required control equipment and methods shall be carried out by a qualified inspection agency. A documented technical verification report should be provided.

The verification results need to be put into management review to ensure that these important data resources can be properly considered and play a role in continuous improvement of the entire HACCP system. Corrective measures should be taken and re-verification should be carried out if the verification results do not meet the requirements.

7.9 HACCP plan records keeping

Records of HACCP plan formulation, operation and verification shall be maintained.

The control of HACCP plan records shall be consistent with the control of system records.

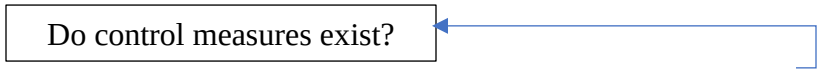
HACCP plan records should include relevant information. The verification records should include at least the following information:

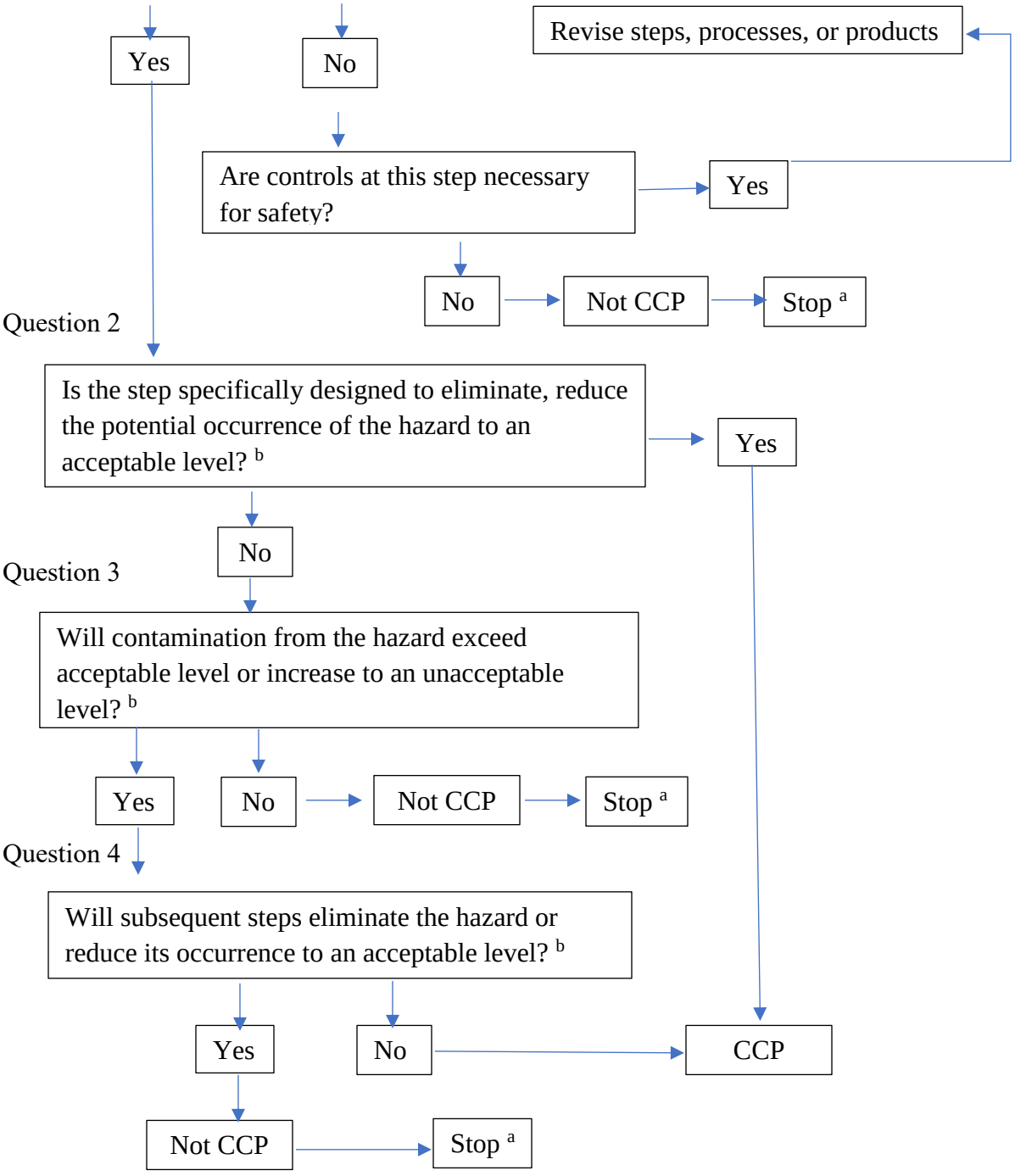
(a) Product description records: enterprise name and address, processing category, product type, product name, product ingredients, product characteristics, intended use and target customers, consumption (use) method, packaging type, storage conditions, shelf life, label instructions, sales, transportation requirements, etc.
(b) Monitoring records: enterprise name and address, product name, processing date, operating steps, CCPs, significant hazards, critical limits (operating limits), control measures, monitoring methods, monitoring frequency, actual measurement or observation results, monitoring personnel signature and monitoring date, audit signature and date for monitoring record, etc.
(c) Correction records: enterprise name and address, product name, processing date, description and reason of deviation, corrective measures taken and results, batches of affected products and isolation locations, evaluation methods and results of affected products, final disposal of the affected products, the signature and date of personnel for correction, the signature and date of correction record review, etc.

(d) The records required for the HACCP plan shall be maintained. For example, the main records that should be kept for verification activities include HACCP plan modification records, semi-finished and finished products routine inspection records, CCPs monitoring and audit records, CCPs deviation correction audit records, CCPs on-site verification records, etc.

Appendix A (Informative)
Flow A. 1: Decision Tree for Identifying CCPs

Question 1





[a] Continue with next hazard according to described processes.
[b] When recognizing CCPs in HACCP plan, the acceptable level and unacceptable level should be stipulated in the range of overall goals.

Attachments:

No Attachments.