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**Hazard Analysis and Critical Control Point
(HACCP) System - General Requirements for
Food Processing Plant**

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Foreword

Appendix A of this standard is informative.

This Standard is proposed by and under the jurisdiction of the National Technical Committee on Attestation & Authorization of Standardization Administration of China (SAC/TC 261).

Chief drafting organizations of this standard: Registration Administration Department of Certification and Accreditation Administration of the People's Republic of China, China Certification & Accreditation institute, State 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, HSL Certification Service, China Quality Certification Center, China Quality Mark Certification Group Co., Ltd. and Beijing Zhongdahuayuan Certification Center.

Chief drafting staff of this standard: Shi Xiaowei, Liu Xiande, Duan Qijia, Li Jingjin, Li Likai, Li Yuanchao, Yang Zhigang, Chen Encheng, Liu Ke, Zhang Shuyi, Xi Liqun, Ma Litian, Gu Shaoping, Wang Maohua, Chen Zhifeng, Yang Qian, Wang Xin and Wang Yu.

Introduction

Food production processing (including purchasing, processing, packaging, storing and shipping of raw material) is an important procedure to prevent, control and avoid food safety hazard.

Hazard Analysis and Critical Control Point (HACCP) System is a scientific and reasonable preventive system to control food production processing; the establishment and application of this system may guarantee that the food safety hazard is effectively controlled, and the matter jeopardizing public health is avoided.

This standard aims at paying attention to food safety, preventing and eliminating the food safety risk or reducing it to an acceptable level by the virtue of HACCP principle on the basis of scientificity and systematicness.

Hazard Analysis and Critical Control Point (HACCP)

System General Requirements for Food Processing Plant

1. Scope

This standard specifies the general requirements of Hazard Analysis and Critical Control Point (HACCP) System for food processing plant, so as to make sure they are able to provide safe food complying with laws and regulations and the customer's requirements.

This standard is applicable to the establishment, implementation and assessment of HACCP system of food processing (catering) plant, including the purchasing, processing, packaging, storing and transporting of raw material and food packaging material.

2. Normative References

The following normative documents contain provisions which, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments to (excluding amending errors in the text), or revisions of, any of these publications do not apply.

However, all parties coming to an agreement according to this standard are encouraged to study whether the latest edition of the normative document is applicable. For undated references, the latest edition of the normative document applies.

GB/T 19538 Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application

GB/T 22000 Food Safety Management Systems - Requirements for Any Organization in the Food Chain

3. Terms and Definitions

For the purposes of this standard, the terms and definitions specified in GB/T 22000 and GB/T 19538 and those listed below apply.

3.1 Raw material

All intended products articles or substances constituting food constituent or composition.

Note: including materials, auxiliary materials and additives contained in foods or all intended substances of other source.

3.2 Potential hazard

Food safety hazard which may occur in case of no precaution.

3.3 Significant hazard

Potential hazard which is much more likely to occur and may result in disease or injury in case of no control.

Note: "much more likely to occur" and "result in disease or injury" mean that the hazard has "probability" and "severity".

3.4 Operation limit

The operation index established in order to avoid deviation of monitoring index from critical limit.

3.5 Food defense plan

Measures established and implemented to protect food supply from deliberate biological, chemical or physical contamination or artificial damage.

4. HACCP System of Plant

4.1 General Requirements

The plant shall plan and establish HACCP system according to the requirements of this standard, form it into document for implementation, maintenance, update and continuous improvement, and guarantee its validity.

The plant shall:

- a) Plan, implement, inspect and improve the HACCP system process, and provide the required resource.
- b) Determine the scope of HACCP system, and define the relationship between the step involved in this scope and other steps of the food chain.
- c) Guarantee to control all operations (including the outsourced process) which may affect the food safety requirements, and to carry out identification and verification in HACCP system. During verification, main attention shall be paid to the conformance of product safety with relevant laws, regulations, and standards.
- d) Guarantee that the HACCP system is effectively implemented so as to effectively control the product safety. Where systematic deviation occurs to product safety, HACCP plan shall be reconfirmed to continuously improve the HACCP system.

4.2 Document Requirements

4.2.1 HACCP system documents shall include:

- a) Documented food safety guideline;
- b) HACCP manual;
- c) Documented procedure required in this standard;
- d) Documents required to guarantee the effective planning, operation and control of HACCP system process;
- e) Record required in this standard.

4.2.2 HACCP manual

The plant shall prepare and maintain HACCP manual, at least covering:

- a) Scope of HACCP system, including the covered product or product category, operation step, site, and the relationship with other steps of food chain;
- b) Procedure document of HACCP system or the quotation of such document;
- c) Expression for HACCP system process and its interaction.

4.2.3 Document control

Documents required for HACCP system shall be controlled.

The documented procedure shall be prepared to specify the control on the following aspects:

- a) The document is approved prior to issuance so as to guarantee that it is sufficient, proper and effective;
- b) Where necessary, review and update the document and re-approve it;
- c) Ensure that changes and the current revision status of the document are identified;
- d) Ensure that relevant effective version of applicable document is available at application location;
- e) Ensure that the document is clear and easy for identification;
- f) Ensure that documents related to HACCP system are identified, with their distribution controlled;
- g) Prevent the unintended use of obsolete documents, properly mark the obsolete documents which shall be reserved.

4.2.4 Record control

Record shall be established and maintained to provide effective operation evidence meeting relevant requirements and HACCP system.

Documented procedure shall be prepared, specifying the control required for mark, storage, protection, retrieval, storage life and disposal of the record.

The record shall be maintained clear and easy for identification and retrieval.

5 Management Responsibilities

5.1 Management Commitment

Top management shall, through the following activities, provide evidence for the commitment made to establish and implement HACCP system:

- a) Transmit the importance to meet the requirements of the customer and laws and regulations to plants;
- b) Establish food safety guideline;
- c) Ensure the establishment of food safety objective;
- d) Conduct management review;
- e) Ensure the obtaining of resource.

5.2 Food Safety Guideline

Top management shall focus on the consumer's edible safety, establish food safety guideline and food safety objective, and ensure food safety.

5.3 Responsibility, Authority and Communication

5.3.1 Responsibility and authority

Top management shall appoint a leader for HACCP working team, and confirm his responsibility and authority; meanwhile, it shall specify the responsibilities and authorities of all departments in a plant.

5.3.2 Communication

In order to obtain necessary food safety information and guarantee the effectiveness of HACCP system, top management shall ensure that the plant has established, implemented and maintained the required internal communication, and has carried out necessary external communication with other suppliers, customers, food safety competent departments and other interested parties.

Communication personnel shall accept proper training, sufficiently learn about the product, relevant hazard and HACCP system of the plant, and reasonably authorized.

Communication record shall be maintained.

5.4 Internal Review

The plant shall carry out internal review according to planned time interval to determine whether the HACCP system meets relevant requirements or not, and whether it is effectively implemented, maintained and updated or not.

Consider the proposed review process, the regional condition and importance and the previous

review results; plan the review scheme; specify the accuracy, scope, frequency and method of review.

The selection and review by the internal reviewer shall ensure the objectivity and impartiality of review process; internal reviewer shall not review his own work.

Manager responsible for the reviewed region shall timely take measures to eliminate the discovered non-conformance item and its cause. Tracing activity shall include the verification for measures taken and the report for the verification result.

Internal review procedure for the documented shall be prepared, the review shall be specified, planned and implemented, the result shall be reported, and the record shall be maintained.

5.5 Management Review

Top management shall review HACCP system according to the planned time interval to ensure its continuous suitability, sufficiency and effectiveness; the review shall include the improvement and updating demand of HACCP system; record of management review shall be maintained.

6 Prerequisite Plan

6.1 General

Plant shall establish, implement, verify and maintain the prerequisite plan, and update and improve it where necessary, so as to continuously meet the sanitation condition required for HACCP system; prerequisite plan shall include human resource security plan, good manufacture practice (GMP), sanitation standard operation procedure (SSOP), safety and sanitation security system of packaging material of raw material or that directly contacting foods, recall and tracing system, equipment and facility maintenance plan and emergency plan. Plant prerequisite plan shall be approved and recorded.

6.2 Human Resource Security Plan

Plant shall establish and implement human resource security plan, so as to ensure that all personnel engaged in food safety work are competent.

The plan shall meet the following requirements:

- a) Provide continuous training on HACCP system, relevant professional technology knowledge, operating skills, laws and regulations, or take other measures to ensure that all managers and staff are equipped with necessary capacity;
- b) Assess the effectiveness of training provide or other measures taken;
- c) Maintain proper records of personnel education, training, skill and experience.

6.3 Good Manufacture Practice (GMP)

Plant shall establish and implement GMP according to food regulations and corresponding

sanitary regulations.

6.4 Sanitation Standard Operation Procedure (SSOP)

Plant shall at least meet the following requirements when establishing and implementing SSOP:

- a) Water and ice contacting foods (including raw material, semi-finished product and finished product) or those in articles contacting foods shall meet the safety and sanitation requirements;
- b) Instruments, gloves or interior and exterior packaging materials contacting foods shall be clean, sanitary and safe;
- c) Protect foods free from cross contamination;
- d) Ensure that hands of operators are cleaned and disinfected and the toilet facilities are clean;
- e) Protect food safety free of hazard by lubricants, fuels, articles for cleaning and disinfecting, condensate and other chemical, physical and biological contaminants;
- f) Correctly label, store and use various toxic chemicals;
- g) Ensure the physical health and sanitation of the personnel contacting foods;
- h) Prevent and eliminate damage caused by rats and insects.

SSOP record shall be preserved.

6.5 Safety and Sanitation Security System of Raw Material and Food Packaging Material

Plant shall protect raw material and food packaging material free of food safety hazard, and shall establish and implement its safety and sanitation security system so as to meet the following requirements:

- a) Establish valid qualification conditions for raw material and food packaging material suppliers, and determine the supplier name list;
- b) Assess the capacity of raw material and food packaging material suppliers to provide product safety and sanitation, and carry out document review or site review for the supplier's food safety management system;
- c) Establish acceptance requirements and procedure for raw material and food packaging material, including checking for inspection and quarantine, sanitation qualification and tracing mark of raw material and food packaging material; carry out targeted inspection and verification for the health and sanitation of raw material and food packaging material where necessary;
- d) Establish control measures for food additives where necessary;
- e) Establish the supplier's assessment system, including elimination system for rejected suppliers.

6.6 Maintenance Plan

Plant shall establish and implement maintenance plans for plant area, plant, facility and equipment, maintain them in good conditions and protect them free from contamination.

6.7 Marking and Tracing Plan and Product Recall Plan

6.7.1 Marking and tracing plan

Plant shall ensure that it has capacity to identify products and trace their states. It shall establish and implement product marking and tracing plan, which shall at least meet the following requirements:

- a) Identify product with proper method, and ensure its traceability during the whole food production process;
- b) Mark the product state in allusion to monitoring and verification requirements;
- c) Maintain product shipment record, including all distributors, retailers, customers and the consumers.

6.7.2 Product recall plan

Plant shall establish product recall plan, and ensure that all released products under safety hazard effect are recalled. This plan shall at least cover the following requirements:

- a) Ensure the responsibilities and rights of personnel starting and implementing product recall plan;
- b) Ensure relevant laws and regulations and related requirements which shall be complied with;
- c) Establish and implement recall measures for products under safety hazard effect;
- d) Establish analysis and disposal measures for recalled products;
- e) Periodic drill and verify its effectiveness.

Implementation record for product recall plan shall be maintained.

6.8 Emergency Plan

Plant shall identify and determine potential food safety accident or emergency situation, pre-establish response plan and measure, and make response where necessary to reduce the effect of potential safety hazard.

Where necessary, especially in or after accident or emergency situation, plant shall review and improve the emergency plan.

Implementation record for emergency plan shall be maintained. Periodic drill shall be conducted and its effectiveness shall be verified.

Note: emergency situations include conditions put the plant's products under effect of force majeure, like natural disaster, epidemic situation and biohazard.

7 Establishment and Implementation of HACCP Plan

7.1 General

HACCP team shall establish and implement food HACCP plan according to the following 7 principles and systematically control the significant hazard, so as to prevent and eliminate such hazard, or reduce it to an acceptable level, and further to guarantee food safety.

- a) Carry out hazard analysis and establish control measures;
- b) Determine critical control point;
- c) Determine critical limit;
- d) Establish monitoring system of critical control point;
- e) Establish correction measures;
- f) Establish verification procedure;
- g) Establish maintenance system for documents and records.

Any change in factors affecting the effectiveness of HACCP plan, like the change in product formula, process and processing condition, may affect the change of HACCP plan. Thus, the HACCP plan shall be confirmed and verified, and updated where necessary.

7.2 Preliminary Steps

7.2.1 Composition of HACCP team

The capacity of personnel in plant HACCP team shall meet the specialized technical requirements of food production in this plant; the team shall consist of personnel from different departments, including the departments of sanitary quality control, product R&D, production process technology, equipment and facility management, raw material purchasing, marketing, storing and transporting. Where necessary, outside expert may be invited.

Team members shall be provided with professional knowledge and experience on product, process and hazard involved in this plant, and shall be properly trained.

Top management shall designate a HACCP team leader, and empower him with responsibility and authority on the following aspects:

- a) Ensure that the process required for HACCP system is established, implemented and maintained;
- b) Report the effectiveness, suitability and updating or improving demand (if any) of HACCP system to top management;
- c) Lead and organize the work of HACCP team, and ensure that the HACCP team members are continuously improved in professional knowledge, skill and experience through education, training and practice.

Record of education background, experience, training, approval and activity of HACCP team

member shall be maintained.

7.2.2 Product description

HACCP team shall identify and determine the applicable information (as listed below) required for hazard analysis in allusion to the product:

- a) Name, category, composition as well as biological, chemical and physical properties of raw material and food packaging material;
- b) Source, production, packaging, storage, transportation and delivery mode of raw material and food packaging material;
- c) Reception requirement, reception mode and use mode of raw material and food packaging material;
- d) Name, category, composition as well as biological, chemical and physical properties of the product;
- e) Processing mode of the product;
- f) Packaging, storage, transportation and delivery modes of the product;
- g) Marketing mode and mark of the product;
- h) Other necessary information.

Record of product description shall be maintained.

7.2.3 Determination of intended use

HACCP team shall identify and determine the applicable information (as listed below) required for hazard analysis on the basis of product description:

- a) Consumption or use expectation of the customer on the product;
- b) Intended use, storage condition and warranty period of the product;
- c) Intended edible or use modes of the product;
- d) Intended customer of the product;
- e) Applicability of directly consumed product to vulnerable group;
- f) Unintended (but much more likely to occur) edible or use modes of product;
- g) Other necessary information.

Record for intended use of the product shall be maintained.

7.2.4 Establishment of flow diagram

HACCP team shall draw process flow diagram of the product according to the operation requirements within the production scope of the plant. This diagram shall include:

- a) Each step and corresponding operation;

- b) Sequence and interrelationship of such steps;
- c) Rework point and cycle point (where suitable);
- d) External process and outsourced content;
- e) Input point of raw material, auxiliary material and intermediate product;
- f) Discharge point of waste.

The establishment of flow diagram shall be complete, exact and clear.

The operation requirements and process parameters of each processing step shall be listed in process description. If applicable, plant location diagram, plant area plan, workshop plan, people and material flow diagram, supply and drainage network diagram, moth-proof layout diagram shall be provided.

7.2.5 Confirmation of flow diagram

HACCP team personnel who are familiar with operation process shall carry out on-site verification for all operation steps under operating state, so as to confirm and verify that they are consistent with the established flow diagrams, and to carry out modification where necessary.

The confirmed flow diagram shall be maintained.

7.3 Hazard Analysis and Control Measures Preparation

7.3.1 Hazard identification

HACCP team shall consider the following factors when analyzing the biological, chemical and physical hazards in processing step according to the food risk degree:

- a) Product, operation and environment;
- b) Safety and sanitation requirements for product, raw material and food packaging materials by the consumers, customers, laws and regulations;
- c) Monitoring and assessment results on edible and use safety of the product;
- d) Disposal, correction, recall and emergency plan of unsafe product;
- e) Historical and current data and food safety accidents on epidemiology, animal and plant epidemic situation or morbidity statistics;
- f) Scientific and technical literature, including hazard control guideline for relevant product;
- g) Effect of other step on the product within the scope of hazard identification;
- h) Artificial destruction and deliberate contamination.
- i) Experience.

For each considered hazard from raw material production to final consumption, all potential hazards and their causes in each operation step on intended introduction, generation and

increase shall be identified.

Where any factor affecting the identification result is changed, HACCP team shall repeat the hazard identification.

Records of hazard identification criterion and result shall be maintained.

7.3.2 Hazard assessment

HACCP team shall assess its severity and probability in allusion to the identified potential hazard. If this potential hazard is much more likely to occur and will result in serious consequence in this step, it shall be determined as significant hazard.

Records of hazard assessment criterion and result shall be maintained.

7.3.3 Establishment of control measures

HACCP team shall establish corresponding control measures in allusion to each significant hazard, and provide evidence to verify its effectiveness; it shall define corresponding relationship between significant hazard and control measures, and consider the conditions where one control measure controls multiple significant hazards or multiple control measures control one significant hazard.

Food defense plan shall be established as a control measure in allusion to the significant hazard caused by artificial destruction or deliberate contamination.

Where operating change is involved in such measures, corresponding change shall be carried out and flow diagram shall be modified.

Since effective control measures for some significant hazard can't be established under existing technical conditions, plant shall plan and implement necessary technical renovation, and change the process, product (including raw material) or intended use where necessary, until establishing effective control measures.

All established control measures shall be confirmed.

Where the effectiveness of control measures is affected, such measures shall be assessed, updated, improved and then reconfirmed.

Establishment criterion and document of control measures shall be maintained.

7.3.4 Hazard analysis sheet

HACCP team shall provide hazard analysis sheet for documentation according to the results of process flow, hazard identification, hazard assessment and control measures, including processing step, considered potential hazard, judgment criterion of significant hazard and control measures; it shall also define the interrelationship among factors.

Relationship between control measures and corresponding significant hazard shall be described in the hazard analysis sheet, so as to provide criterion for the determination of critical control point.

HACCP team shall make necessary update or revision for hazard analysis sheet where the

hazard analysis result is affected.

Hazard analysis sheet for documentation shall be maintained.

7.4 Determination of Critical Control Point (CCP)

HACCP team shall identify proper step for control of each significant hazard according to the relationship between significant hazard and control measures provided in hazard analysis, so as to determine CCP, and ensure that all significant hazards are effectively controlled.

Plant shall adopt suitable method (like judgment tree in Appendix A) to determine CCP. However, the following factors shall be considered when adopting judgment tree:

- a) Judgment tree is only a tool contributing to the determine CCP, and cannot supersede professional knowledge;
- b) Judgment tree is used after hazard analysis and during determination of significant hazard;
- c) Subsequent processing step may be more effective to control hazard, and may be the preferred CCP which shall be selected;
- d) In processing, above I step may control I hazard.

Where significant hazard or control measures are changed, HACCP team shall repeat the hazard analysis to judge CCP.

Criterion and document determined by CCP shall be maintained. Where standard operating procedure (SOP) control is identical with CCP control according to analysis, the criterion, parameter document determined by SOP shall be maintained.

7.5 Determination of Critical Limit

HACCP team shall establish a critical limit for each CCP, and one CCP may have one or more critical limit (s).

The establishment of critical limit shall be scientific, visual and easy for monitoring, so as to ensure that the product safety hazard is effectively controlled and within the acceptable level.

The assessed competent personnel shall carry out monitoring and judgment based on perceptive critical limit.

HACCP team should establish CCP operation limit to prevent or reduce deviation from critical limit.

Records of critical limit determination criterion and result shall be maintained.

Note: critical limits may be time, rate, temperature, humidity, moisture content, water activity, pH value and salt content.

7.6 CCP Monitoring

Plant shall establish and implement effective monitoring measures in allusion to each CCP, and guarantee that CCP is controlled; monitoring measures include monitoring object, method, frequency and personnel.

Monitoring objects shall include all critical limits involved with each CCP; the monitoring method shall be exact and timely; generally, continuous monitoring shall be implemented; where discontinuous monitoring is adopted, its frequency shall be able to guarantee the control requirements of CCP; monitoring personnel shall accept suitable training, understand monitoring purpose and importance, get familiar with monitoring operation, and timely and accurately record and report the monitoring result.

Where deviation from operation limit is indicated in monitoring, monitoring personnel shall timely take correction to prevent deviation from critical limit.

Where deviation critical limit is indicated in monitoring, the monitoring personnel shall immediately stop the operation procedure, and timely take correction measures.

Monitoring record shall be maintained.

7.7 Correction Measures for Establishment of Critical Limit Deviation

Plant shall pre-establish correction measures for deviation of each critical limit of CCP for implementation upon deviation.

Correction measures shall include personnel implementing correction measures and releasing affected products, identification and elimination of deviation causes, as well as isolation, assessment and disposal of affected products.

Measurement or inspection for biological, chemical or physical properties may be carried out when assessing affected products; where the inspection result shows that the hazard is within the acceptable index, the product may be released to subsequent operation; otherwise, it shall be reworked, degraded, altered or discarded.

Correction personnel shall be familiar with product and HACCP plan, and shall be properly trained and authorized.

Where the monitoring result of a critical limit repeatedly deviates or the deviation cause involves the control ability of corresponding control measures, HACCP team shall reassess the effectiveness and suitability of relevant control measures, and improve and update them where necessary.

Correction record shall be maintained.

7.8 Confirmation and Verification for HACCP Plan

Plant shall establish and implement confirmation and verification procedures for HACCP plan, so as to verify the integrity, suitability and effectiveness of HACCP plan.

Confirmation procedure shall include effectiveness verification for all elements of HACCP plan. Confirmation shall be carried out before the implementation or after change of HACCP plan.

Verification procedure shall include: criterion, method, frequency, personnel, content, result, measure and record of verification.

Monitor the review of equipment alignment record; where necessary, carry out technical verification for the required control equipment and method through qualified inspection

organization, and provide technical verification report for documentation.

Verification result shall be input into the management review to ensure that such data resources are duly considered and can contribute to the continuous improvement of the whole HACCP system; where the verification result fails to meet the requirements, corrective measures shall be taken and then verification shall be repeated.

7.9 Maintenance of HACCP Plan Record

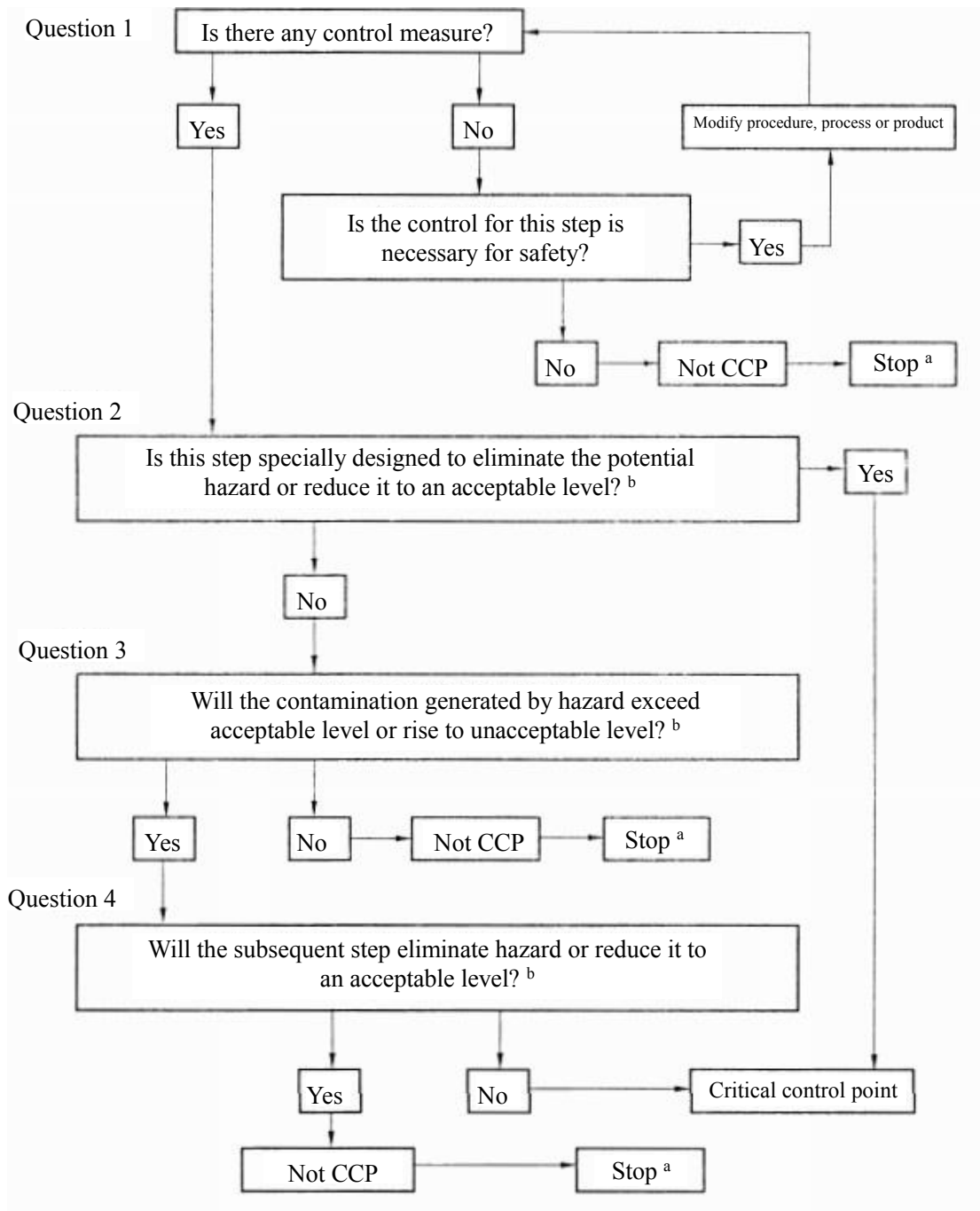
Establishment, operation and verification records of HACCP plan shall be maintained.

Control of HACCP plan record shall be consistent with that of the system record.

HACCP plan record shall include relevant information. Verification record shall at least include the following information:

- a) Product description record: name and address of plant; processing category; type, name, dosing and characteristic of the product; intended use and customer; edible (use) method; packaging type; storage condition and warranty period; label instruction; marketing and transportation requirements.
- b) Monitoring record: name of address of plant; product name; processing date; operation procedure; CCP; significant hazard; critical limit (operation limit); control measure; monitoring method and frequency; actually measured or observed result; monitoring personnel signature; monitoring date; review signature and date of monitoring record.
- c) Correction record: name and address of plant; product name; processing date; description and cause of deviation; correction measure and result; batch, isolated location, assessment method and result and final disposal of affected product; correction personnel signature; correction date; review signature and date of correction record.
- d) Proper records for HACCP plan shall be maintained. For example, main records required for verification activity are HACCP plan amendment record, semi-finished product and finished product periodical inspection record, CCP monitoring review record, CCP correction review record and CCP site verification record.

Appendix A (Informative) Judgment Tree for CCPs



^a Proceed to the next hazard according to the described process.

^b When critical control point in HACCP plan is identified, the acceptable level and unacceptable level shall be defined within the overall objective.

Figure A.1 Judgment Tree for CCPs