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Hazard Analysis and Critical Control Point（HACCP）System General Requirements for Food Processing Plants

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Preface

Appendix A to this Standard is an informative appendix.

This Standard is submitted and put under centralized management by SAC/TC261.

This Standard is drafted by the Registration Management Department of the Certification and Accreditation Administration of the People's Republic of China, China Certification and Accreditation Institute, the 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, HSL Certification Service, China Quality Certification Center, China Quality Mark Certification Group Co., Ltd. and Beijing Zhongdahuayuan Certification Center.

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Introduction

Food production and processing procedures (including purchasing of raw materials, processing, packaging, storage, and transport) are important for preventing, controlling, and guarding against food safety hazards.

Hazard Analysis and Critical Control Point (HACCP) System is a scientific and reasonable preventive system for control of food production and processing procedure. Building and applying this system can ensure effective control of food safety hazards and prevent occurrence of hazard to the public health.

This Standard is designed to focus on safety of food scientifically and systematically, so to prevent, eliminate or reduce food safety risk to an acceptable level by applying HACCP principle.

Hazard Analysis and Critical Control Point System
General Requirements for Food Processing Plants

1. Scope

This Standard provides for the general requirements of Hazard Analysis and Critical Control Point (HACCP) System for Food Processing Plants, enabling them to provide safe food complying with laws, regulations and customer demand.

This Standard applies to the development, implementation and evaluation of HACCP System of food production (including meal distribution) enterprises, including purchasing of raw materials , processing, packaging, storage and transport and food packaging materials.

2. Normative references

The following referenced documents are indispensable for the application of this document. For datedreferences, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 19538 *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its application*

GB/T 22000 *Food Safety Management System--Requirements for any organization in the food chain*

3. Terms and Definitions

The terms and definitions given in GB/T 22000. GB/T 19538 and the following apply.

3.1 Raw Materials

All expected products, items or substances that can be taken as food components or ingredients.

Note: This include raw materials, excipients, additives contained in food, and all expected substances from other sources contained in food.

3.2 Potential Hazard

The food safety hazard that is likely to take place if without proper prevention.

3.3 Significant Hazard

The potential hazard that is very likely to take place and cause disease or injury if not controlled.

Note: The expressions "very likely" and "cause disease or injury" indicate the "possibility" and "severity" of the hazard.

3.4 Operation Limit

The operation index designed for preventing deviation of monitoring index from critical limit.

3.5 Food Defense Plan

The measures developed and implemented to protect food supply from intentional biological, chemical and physical pollution, or artificial damage.

4 HACCP System for Enterprises

4.1 General Requirements

Enterprises shall plan, establish, document, implement, maintain, update and continuously improve its HACCP System and ensure its effectiveness in accordance with this Standard.

Enterprises shall:

a) plan, execute, check and improve HACCP System process and provide resources required;

b) identify scope of HACCP System, and specify relationship between steps involved in this scope and other steps in food chain;

c) ensure any operation which affect food safety under control, including outsourced process, get them identified and verified under HACCP System, and pay great attention to the compliance of product safety with related laws and standard in verification; and

d) ensure effective implementation of HACCP System to effectively control product safety and re-confirm HACCP plan in case of systematic deviation of product safety to ensure continual improvement of HACCP system.

4.2 Documentation Requirements

4.2.1 The HACCP System documents shall include:

a) documented food safety guidelines;

b) HACCP manual;

c) documented procedures required by this Standard;

d) documents necessary for enterprises to ensure that HACCP system can be planned, operated and controlled effectively;

e) records required by this Standard.

4.2.2 HACCP Manual

Enterprises shall develop and maintain HACCP manual which shall at least includes:

a) scope of HACCP System, including products covered, or product category, operation steps and sites, as well as relationship with other steps in food chain;

b) procedure documents of HACCP system or reference to them;

c) description of HACCP System processes and their interaction.

4.2.3 Control of Documents

Documents required by HACCP System shall be controlled.

A documented procedure shall be established to define the controls needed.

a) to approve documents for adequacy, suitability and effectiveness prior to issuance;

b) to review and update documents as necessary, and re-approve documents;

c) to ensure changes and the current revision status of documents are identified;

d) to ensure relevant versions of applicable documents are available at points of use;

e) to ensure documents remain legible and readily identifiable;

f) to ensure documents of external origin related to HACCP System are identified and their distribution controlled; and

g) to prevent the unintended use of obsolete documents, and to ensure that they are suitably identified as such if they are retaind for any purpose.

4.2.4 Control of Records

Records shall be established and maintained to provide evidence of conformity to requirements and of

the effective operation of HACCP System.

A documented procedure shall be developed prescribing controls needed for record identification, storage, protection, retrieval, retention time and disposal.

Records shall be remain legible, readily identifiable and retrievable.

5 Management Responsibilities

5.1 Management Commitment

Top management shall provide evidence of commitment to the development and implementation of the HACCP System by:

a) communicating to its company the importance of meeting customer and statutory and regulatory requirements for food safety;

b) establishing food safety policy;

c) ensuring establishment of food safety objective;

d) conducting management review; and

e) ensuring the availability of resources.

5.2 Food safety policy

T\op management shall, focusing on food safety for consumers, define food safety policy and objective to ensure food safety.

5.3 Responsibility, Authority and Communication

5.3.1 Responsibility and Authority

Top management shall appoint a HACCP team leader and identify its responsibility and authority, and meanwhile specify respondibility and authority undertaken by each internal department of the enterprise in HACCP System.

5.3.2 Communication

To obtain necessary food safety information and to ensure effectiveness of HACCP System, top management shall ensure the work to establish, implement and maintain necessary internal

communications, and properly communicate with other suppliers within food chain, customers, food safety authority within food chain, as well as with other stakeholders that can have impact.

People involved in communication shall receive proper training to get to know products, related hazards and HACCP System, and shall be authorized.

Records of communication shall be maintained.

5.4 Internal Audit

Enterprises shall conduct internal audit at planned time intervals to determine compliance of HACCP System with related requirements, and to ensure such system is effectively implemented, maintained and updated.

Considering the conditions and significance of the process and location proposed for audit and results of preceding audits, audit program shall be planned to define audit accuracy, scope, frequency and methodology.

The selection of internal auditors and performance of audit shall ensure the objectivity and impartiality of audit process. Internal auditors are not allowed to audit their own work.

The person(s) managing the area to be audited shall ensure timely measures to eliminate any non-compliance and reasons thereof. Tracking activities shall include reporting the verification of measures taken and results thereof.

Internal audit procedure shall be developed for documentation to define planning and performance of audit, results reporting and record-keeping.

5.5 Management Review

The top management shall review the HACCP System at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review shall include the need for improving and updating HACCP System. Records of management reviews shall be maintained.

6 Prerequisite Program

6.1 General

Enterprises shall establish, perform, verify, maintain and update or improve, if necessary, the prerequisite program to continuously meet sanitation requirements of HACCP System; such prerequisite program shall include Human Resources Security Plan, Good Manufacturing Practice (GMP), Standard Sanitation Operation Procedure (SSOP), Policy for Safety and Health Protection of Raw Materials and Packing Materials Directly Contacting Food, Recall and Traceability System, Equipment and Facilities Maintenance Plan, and Emergency Response Plan. Corporate prerequisite program shall be approved and record thereof shall be kept.

6.2 Human Resources Assurance

Enterprises shall establish and execute a Human Resources Assurance to ensure persons involving in food safety work are eligible for their work.

This plan shall:

a) continuingly provide all personel associate with food production and employees with training in HACCP System, related professional technical knowledge, operation skills, and laws and regulations, or take other measures to ensure they have necessary capability;

b) evaluate effectiveness of training programs offered or other measures taken; and

c) keep proper records of employee education, training, skills and experiences.

6.3 Good Manufacturing Practice (GMP)

Enterprises shall establish and implement their GMP in accordance with food regulations and related sanitation requirements.

6.4 Standard Sanitation Operation Procedure (SSOP)

When establishing and implementing SSOP, enterprises shall at least meet the following requirements:

a) water and ice contacting food (including raw materials, semi-finished products and finished products) or the articles packing food shall comply with safety and hygienic requirements;

b) instruments, gloves, and external and internal packing materials exposed to food must be kept clean, hygienic and safe;

c) to ensure food free from cross-pollution;

d) to ensure operators' hands be sterilized and to keep the washroom clean;

e) to prevent food from being damaged by lubricants, fuels, cleaning and sterilization articles, as well as by condensed water, or other chemical, physical and biological pollutants;

f) to correctly label, store and use toxic chemicals;

g) to ensure persons exposed to food are physically healthy and hygienic; and

h) to eliminate and prevent damage by rats or insects and so on.

Records of SSOP-associated shall be maintained.

6.5 Policy for Safety and Sanitation Protection of Raw Materials and ingredients and Food Packaging Materials

Enterprises shall ensure raw materials and food packaging materials be free of food safety hazards, and shall establish and implement its safety and hygienic protection system which shall at least:

a) establish valid qualifications of suppliers of raw materials and food packaging materials, and identify a list of suppliers;

b) evaluate ability of suppliers of raw materials and food packaging materials to provide safe and sanitary products, and whenever necessary audit the documentation of a supplier's food safety management system, or conduct field inspection of a supplier;

c) develop requirements and procedures for inspecting raw materials and food packaging materials, including inspection, quarantine, hygiene certificate, and traceability label of raw materials and food packaging materials, and if necessary, carry out inspection and verification of safety and sanitation index thereof;

d) develop control measures for food additives if necessary; and

e) develop evaluation system for suppliers, including elimination system for unqualified suppliers.

6.6 Maintenance Plan

Enterprises shall establish and implement maintenance plan for the premises, factory buildings,

facilities and equipments to keep them in good status and prevent pollution of products.

6.7 Labeling & Tracing Plan, Product Recall Plan

6.7.1 Labeling & Tracing Plan

Enterprises shall have tracing ability to identify products and their status, and shall develop and implement product labeling and traceability plan, including at least the following:

a) identify products with proper methods and have traceability during food production;

b) label product status according to the inspection and verification requirements; and

c) keep product shipping records, including all distributors, retailers, customers or consumers.

6.7.2 Product Recall Plan

Enterprises shall establish the product recall plan to ensure recall of all distributed products affected by hazards. The plan shall include at least:

a) determine responsibility and authority of persons involved in starting and implementing product recall plan;

b) determine that the product recall plan should compliance with related laws, regulations and relevant requirements;

c) establish and implement recall measures for products affected by hazards;

d) establish measures for analysis and disposal of recalled products; and

e) regularly practice the product recall plan and verify its effectiveness.

Records of implementation of product recall plan shall be maintained.

6.8 Emergency Response Plan

Enterprises shall identify and determine potential food safety accidents or emergencies, and establish countermeasures and solutions in advance, and give response if necessary, to reduce impact of any possible food hazards.

Enterprises shall audit and improve emergency situations response plan if necessary, especially after accidents or emergency.

Records of implementation of emergency response plan shall be maintained. Emergency response plan shall be regularly exercise, and its effectiveness shall be verified regularly.

Note: Emergency situation include situations where products of a company are affected by force majeure, such as natural disaster, unexpected outbreak of epidemic and bio-terrorism, etc.

7 Development and Implementation of HACCP Plan

7.1 General

HACCP team shall establish and implement food HACCP Plan, and systematically control significant hazards to prevent these hazards, and eliminate or reduce them to an acceptable level to ensure food safety, based on requirements of the following seven principles:

a) conduct hazard analysis and establish control measures;

b) identify critical control points;

c) identify critical limit;

d) develop monitoring system for critical control points;

e) develop correction measures;

f) develop verification procedures; and

g) develop maintenance system for documents and records.

Any change to any factor that may affect the effectiveness of HACCP Plan, including change of product ingredients, process and processing conditions, may affect change of HACCP Plan. And HACCP Plan shall be valiated and verified, and be updated if necessary.

7.2 Preliminary Steps

7.2.1 Composition of HACCP Team

The capacity of HACCP team members in a company shall meet its technical requirements on food production. HACCP team is composed of members from different departments, including Hygiene & Quality Control Department, Product R&D Department, Production Engineering Department, Equipment Management Department, Raw Materials Procurement Department, Sales Department,

Warehouse Department and Transportation Department, and also external experts will be invited to participate therein if necessary.

Team members shall have expertise and experiences related to the products, process, and involved hazards of a company and shall be properly trained.

The top management shall appoint a HACCP team leader, and shall have the following responsibility and authority:

a) to ensure that the procedures necessary to HACCP System is established, implemented and maintained.

b) report to the top management the effectiveness and suitability of HACCP System and any need for updating or improvement; and

c) lead and organize HACCP team work, and ensure continuous improvement of HACCP team members in expertise, skills and experiences through education, training, and practice.

Record shall be maintained for education background, working experiences, trainings, approvals and activities of HACCP team members.

7.2.2 Description of Products

HACCP team shall identify and determine the following applicable information necessary for hazard analysis of targeted products:

a) name, category, and components and their biological, chemical and physical properties of raw materials and food packaging materials ;

b) source and mode of production, packaging, storage, transport and delivery of raw materials and food packaging materials;

c) receipt requirements and methods as well as usage mode for raw materials and food packaging materials;

d) name, category, and components, and their biological, chemical and physical properties of products;

e) processing modes of products;

f) packaging, storage, transport and delivery mode of products;

g) mode of sales and labels of products; and

h) other necessary information.

Records of products description shall be maintained.

7.2.3 Determination intended use

HACCP team shall identify and determine the following information necessary for hazard analysis based on product descriptions:

a) consumption or usage expectation of customers on products;

b) expected usage, storage conditions, and shelf life of products;

c) expected consumption or usage mode of products;

d) expected target customers of products;

e) suitability of direct consumption of products to vulnerable person;

f) non-expected consumption or usage mode of products (but very likely to happen); and

g) other necessary information.

Records of expected usage of products shall be maintained.

7.2.4 Development of flow diagrams

HACCP team shall prepare flow diagrams of products according to the operation requirements thereof within the products range of the company, including:

a) each step and its corresponding operation;

b) sequence and interaction of all steps;

c) reworking point and recycling point (whenever proper);

d) external process and subcontracted contents;

e) input point of raw materials, excipients and intermediate products; and

f) discharge point of wastes.

Flow diagrams shall be developed in a complete, accurate and clear.

Operation requirements and process parameters of each processing step shall be listed in the process description. Factory location map, factory plan view, workshop plan view, worker and logistics flow chart, water supply and drainage network diagram, pest control distribution diagram, etc. shall be offered whenever appropriate.

7.2.5 Confirmation of Flow dagrams

HACCP team members familiar with operation process shall conduct on-site examination of operation steps under operation status, identified and confirmed their consistence with the developed flow diagrams, and make modification thereto if necessary.

The confirmed flow chart shall be maintained.

7.3 Hazard Analysis and esablishment of Control Measures

7.3.1 Hazard Identification

Based on the food risk level, HACCP team when analyzing biological, chemical and physical hazards shall consider the following factors:

a) products, operation and environment;

b) safety and hygienic requirements of consumers and laws and regulations regarding products, raw materials, and food packaging materials;

c) monitoring and evaluation results of food consumption and use of;

d) disposal, correction, recall of and emergency response plan for unsafe products;

e) historical and current statistical data of epidemiology, animal and plant epidemics and diseases, and cases of food safety accident;

f) scientific and technical literature, including hazard control guidelines for products of relevant category;

g) impact of other steps within hazard identification scope on products;

h) man-made damages and intentional pollutions etc.; and

i) experiences

From production of raw materials to final consumption, all potential hazards introduced, produced or incurred as expected in each operation step and reasons thereof shall be identified for all hazards required to consider.

When any factor that may affect the hazard identification results changes, HACCP team shall re-identify hazards.

Records of basis and results of hazard identification shall be kept.

7.3.2 Hazard Evaluation

For potential hazard identified, HACCP team shall evaluate the severity and possibility of its occurrence, and if this potential hazard is very likely to happen and will cause severe consequence in this step, such hazard will be defined as a significant hazard.

Record of basis and results of hazard evaluation shall be maintained.

7.3.3 Establishment of Control Measures

HACCP team shall establish corresponding control measures for each significant hazard, and provide evidence of confirming their effectiveness; and shall specify the correlation between significant hazards and control measures and take into account the situation where one control measure controls multiple significant hazards or multiple control measures control one significant hazard.

Food Defense Plan shall be developed as a control measure for significant hazards resulted from man-made damage or intentional pollution.

If these measures involve change of operation, corresponding change shall be made and flow diagrams shall be modified.

When effective control measures cannot be established for a certain significant hazard under the current technical, a company shall plan and implement necessary technical transformation, and if necessary shall change processing technique, or products (including raw materials and ingrediedts) or expected usage till effective control measures have been established.

Control measures established shall be validated.

When the effectiveness of control measures is affected, control measures shall be re-validated after evaluation, updating and improvement.

Basis for establishment of control measures and control measure documents shall be maintained.

7.3.4 Hazard Analysis Worksheet

HACCP team shall provide the Hazard Analysis Worksheet for documentation based on results of process flows, hazards identification, hazards evaluation, and control measures, including processing steps, potential hazards considered, significant hazards determination basis, control measures, and shall expressly specify mutual relationship of the factors.

In the hazard analysis worksheet, relationship between control measures and corresponding significant hazards shall be described to provide basis for determination of critical control point.

HACCP team shall make necessary updating or revising to the Hazard Analysis Worksheet when the hazards analysis results are affected by any factors.

Documented Hazard Analysis Worksheet shall be maintained.

7.4 Determination of CCP

HACCP team shall identify proper steps for each type of significant hazard control in accordance with the relationship between significant hazards and control measures shown in the hazard analysis to determine CCP and ensure effective control of all significant hazards.

Enterprises shall determine CCP with appropriate methodology, like Decision Tree method (please refer to Appendix A). However, when using CCP Decision Tree the following factors shall be considered:

a) Decision Tree is only good for determining CCP tools, and cannot replace expertise;

b) Decision Tree shall be used after hazard analysis and at the time when significant hazard is dererminated;

c) subsequent processing steps may be more effective for hazard control, and may be CCP which should be preferred; and

d) more than one step in processing can control one type of hazard.

If the significant hazard or control measure changes, HACCP team shall re-analyze hazards to determine CCP.

Basis and documents for determination of CCP shall be maintained. If it is analyzed that control by Standard Operation Procedure (SOP) is equivalent to CCP control, the basis, parameters and documents for determination of SOP shall be kept.

7.5 Determination of Critical Limit

HACCP team shall develop critical limit for each CCP, and each CCP can have one or more critical limits.

Critical limit shall be set scientifically, visually and readily for monitoring, to ensure effective control of product safety within acceptable level.

Perception-based critical limit shall be monitored and determined by persons evaluated to be competent.

To prevent or reduce deviation from critical limit, HACCP team shall establish CCP operation limit.

Records for basis and results of determining critical limit shall be maintained.

Note: Critical limit can be time, speed, temperature, humidity, moisture, water activity, pH, and salinity ,etc..

7.6 Monitoring of CCP

Enterprises shall establish and implement effective monitoring measures for each CCP to ensure CCP be under control. Monitoring measures include monitoring object, methods, frequency and personnel.

Monitoring object shall include the critical limit involved in each CCP; monitoring methods shall be accurate and prompt; for monitoring frequency, generally continuous monitoring will be performed; if non-continuous monitoring is adopted, monitoring frequency shall be sufficient for control of CCP; monitoring persons shall receive proper training, understand monitoring purpose and significance, familiarize themselves with monitoring operation, and record monitoring results promptly and

accurately.

When monitoring results show deviation from operation limit, the people in charge of monitoring shall take measures to correct, so to prevent deviation of critical limit.

When monitoring results show deviation from critical limit, the people in charge of monitoring shall stop such operation step and take corrective measures immediately.

Records of Monitoring shall be maintained.

7.7 Establishment the Corrective Measures for Deviation of Critical Limit

Enterprises shall establish corrective measures for any deviation of each CCP's critical limit in advance so as to implement them in case of deviation.

Corrective measures shall include persons who implement them and responsible for releasing affected products; identification and elimination of deviation reasons; and isolation, evaluation and disposal of affected products.

Biological, chemical or physical testing or inspection can be conducted while affected products are evaluated. If inspection results show that hazards are within the acceptable index, products shall be allowed to enter the subsequent operation. Otherwise, products shall be returned for rework, or degraded, changed in usage, or discarded.

Correction personnel shall get themselves familiar with products and HACCP Plan, and receive proper training and being authorized.

When monitoring results of certain critical limit show deviation repeatedly or reasons thereof involve control effect of corresponding control measures, HACCP team shall re-evaluate related control measures in effectiveness and suitability, and improve and update such measures if necessary.

Correction records shall be maintained.

7.8 Validation and verification of HACCP Plan

Enterprises shall develop and implement procedure for verification and validation of HACCP Plan to confirm integrity, suitability and effectiveness of HACCP Plan.

Validation procedure shall include confirmation of effectiveness of all elements of HACCP Plan. Validation shall take place before implementation or after modification of HACCP Plan.

Verification procedure shall include the basis, methods, frequency, staff, contents, results, and measures taken and records of validation, etc.

A qualified testing agency shall audit the calibration records for monitoring equipment, when necessary, and to conduct technical validation of required control equipment and methods and provide documented technical validation report.

Verification results shall be put into the management review to ensure these important data be properly considered and contribute to the sustained improvement of HACCP System. If the validation results do not meet requirements, corrective measures shall be taken and verification shall be conducted again.

7.9 Maintenance of HACCP Plan Records

Record of establishment, operation, and validation of HACCP Plan shall be maintained.

Control of HACCP Plan shall be in consistence with that in system record.

HACCP Plan records shall include related information which at least shall include the following:

a) Record of Product Description: corporate name and address, processing category, product type, product name, product ingredients, and product features, expected usage, target customers, consumption (usage) method, packing type, storage conditions, shelf life, labeling instructions, sales and transport requirements, etc.

b) Record of Monitoring: company name and address, product name, processing date, operation steps, CCP, significant hazards, critical limit (operation limit), control measures, methods and frequency of monitoring, actual measurement or observation results, monitoring operator signature and monitoring date, monitoring records audit signature and date, etc.

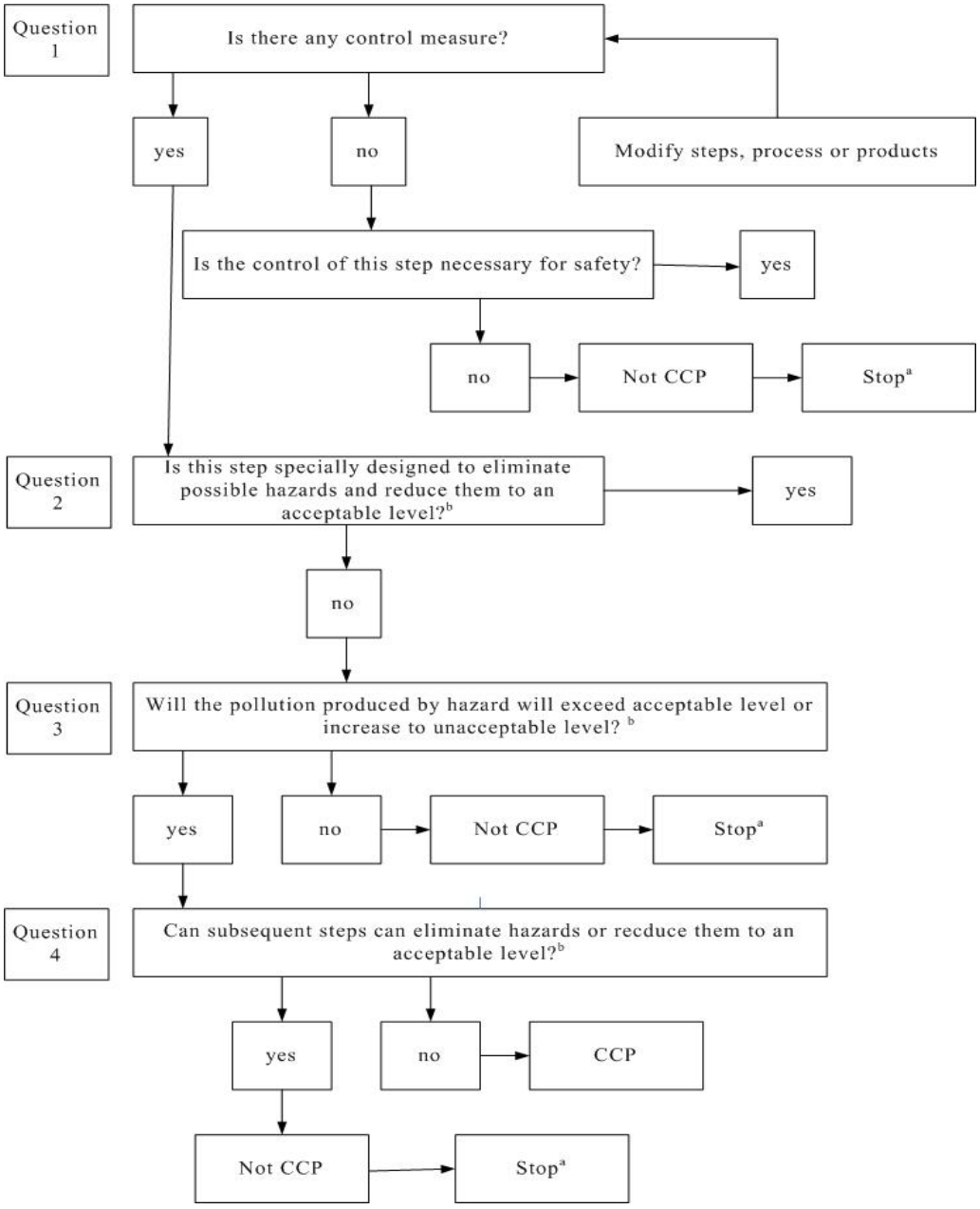
c) Recordd of Correction: company name and address, product name, processing date, descriptions and reasons of deviation, corrective measures used and correction results, batch number and isolation

position of affected products, evaluation methods and results of affected products, final disposal of affected products, corrector signature and correction date, correction records audit signature and date, etc.

d)Proper records of HACCP Plan shall be maintained. For example, the main records that verification activity records shall be maintained: records of HACCP Plan modification, regular testing record of semi-finished and finished products, CCP monitoring audit record, CCP correction audit record, and field validation record of CCP.

Appendix A

(Informative) Decision Tree for Determination of CCPs



A ,To the next hazard by describing the process

B, When identify the CCP of HACCP plan, rules need be provided in the context of the overall level of acceptable levels and unacceptable levels.