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Hazard Analysis Critical Control Point (HACCP) systems — Requirements

EAST AFRICAN COMMUNITY

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 010, *Food Hygiene*.

This second edition cancels and replaces the first edition (EAS 151:2000), which has been technically revised.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

Introduction

Food safety and quality are often compromised as a result of efforts to reduce costs and increase efficiency along the food production chain. Oftentimes, food production companies are confronted with the challenges of hazard found in their products. These hazards can be biological, chemical or physical and allergens in nature and they can gain entry into food products at any stage of production. The consequences of their presence in food are incalculable: product recalls, with enormous financial losses as a direct consequence; loss of image, not only for the affected products, but also for other products produced by the company as an indirect consequence. Additionally, these hazards can be injurious to consumers and at worst, fatal. This therefore necessitates implementation of a food safety system to ensure supply of food products that are not harmful to consumers.

Hazard analysis critical control point (HACCP) is a preventive approach to controlling biological, chemical and physical hazards and allergens in food business operations. It is a risk management system that identifies, evaluates, and controls hazards related to food safety throughout the food supply chain and its implementation is guided by scientific evidence of risks to public health.

HACCP can be applied throughout the food chain; from primary production to final consumption and their implementation should be guided by scientific evidence of risks to human health. This varies from postharvest activities, restaurants, hotels, schools, hospitals, food processing units/factories/industries as well as pharmaceutical industries. In addition to enhancing food safety, implementation of HACCP can provide other significant benefits such as: improving product quality, creating a good reputation and boosting customer confidence, increasing product sales and profit, reducing final product losses due to non-conformances, and enhancing staff morale and loyalty. In addition, the application of HACCP aids inspection and audit by regulatory authorities.

The implementation of HACCP is guided by seven established principles and when a deviation occurs indicating that control has been lost, it is detected and appropriate steps are taken to re-establish control in a timely manner. This ensures that potentially hazardous products do not reach the consumer. In addition, an effectively implemented HACCP system is capable of accommodating changes such as advances in equipment design, new information concerning health hazards or risks, and new processing procedures.

The successful application of HACCP requires the commitment and involvement of management and personnel and the knowledge and/or training in its application for the particular type of food business. A multidisciplinary approach is strongly recommended; this multi-disciplinary approach should be appropriate to the food business operation and may include, for example, expertise in primary production, microbiology, public health, food technology, environmental health, chemistry and engineering, according to the particular application.

This document has been prepared to standardise and provide uniformity in application, training and evaluation of HACCP based food safety systems by the food industry and regulatory authorities. It can therefore be used as a guideline for the development of company/process specific HACCP systems and as a tool for assessment by auditing and/or certifying bodies for continuous compliance to HACCP systems developed and implemented at different stages of the food chain

Hazard Analysis Critical Control Point (HACCP) systems — Requirements

1 Scope

This Draft East African Standard specifies the requirements for establishment, implementation and maintenance of HACCP system as a preventive system to ensure food safety control measures at each step throughout the food chain.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EAS 39, *General principles of food Hygiene — Code of practice*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
audit
systematic, independent and documented process for obtaining objective evidence and evaluating it to determine the extent to which requirements are fulfilled.

3.2
control
to take all the actions necessary to ensure and maintain compliance with the criteria and/or requirements established in the HACCP plan

3.3
control points
any point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels

3.4
control measure
any action and activity that can be used to prevent, eliminate or reduce a food safety hazard or reduce it to an acceptable level

3.5
correction
any action to eliminate a detected non-conformity

3.6
corrective action
any action to be taken when results of monitoring at the critical control point (CCP) indicates a loss of control

3.7
critical control point (CCP)
a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level

3.8
critical limit
a criterion which separates acceptability from unacceptability

3.9
decision tree
sequence of questions applied to each step in the food handling process relating to an identified food safety hazard to determine which steps are CCPs

3.10
document
a written, drawn, presented or recorded evidence of intentions of activities to be and/or performed

3.11
flow diagram
a systematic representation of the sequence of steps of operations used in the production/manufacture of a particular food product or sequence of steps associated with the food handling process in the segment of the food chain under consideration

3.12
food chain
sequence of the stages in the production, preparation, processing, manufacturing, packaging, storage, transportation, distribution, and handling of a food, its ingredients and food contact materials, from primary production to consumption

3.13
food handling organization
business, which during its operations, processes, manufactures, stores, transports, distributes or sells foodstuffs or is engaged in any activity which may have impact on the safety of such foodstuffs

3.14
food safety
assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use

3.15
food safety hazard
any biological, chemical or physical agent in, or condition of food, with the potential to cause an adverse health effect

3.16
HACCP plan
a document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration

3.17
HACCP team
group of individuals (multi-disciplinary) who develop, implement and maintain a HACCP system.

3.18
hazard analysis
the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan

3.19
Hazard Analysis and Critical Control Point (HACCP)
a system that identifies, evaluates and controls hazards which are significant for food safety

3.20
monitor
the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control

3.21
non-conformity
non-fulfillment of a specified requirement

3.22
prerequisite programmes (PRPs)
basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption

3.23
record
a document that provides objective evidence of actions undertaken or results achieved

3.24
facility
any building or area in which food is handled and the surroundings under the control of the same management

3.25
validation
obtaining evidence to confirm that the elements of the HACCP plan are effective

3.26
verification
the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan

4 [General requirements for HACCP system]

For effective implementation of a HACCP based food safety system at any stage of the food chain:]

a) appropriate good practices shall be in place, documented, fully operational and verified; and

b) there shall be compliance to the appropriate food safety legislation

4 [Documentation requirements for implementation of HACCP system]

4.1 The HACCP manual

The organization shall establish and maintain a HACCP manual that includes:

a) the scope of the HACCP system,

b) PRP procedures or reference to them, and

c) documented procedures established for the HACCP system or reference to them. This manual may be included in another management system manual or parts of this manual may refer to other relevant management system manual(s). The interrelation shall be described appropriately.

4.2 Control of documents

The organization shall ensure the establishment and implementation of documented procedures for the control of documents. HACCP system documentation shall include documents needed by the organization to ensure effective development, implementation and updating of the HACCP system. The requirements of stage 12 of the HACCP plan shall be defined in these procedures.

4.3 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and evidence of effective operation of the HACCP system. The requirements of stage 12 of the HACCP plan shall be defined in these. Records shall remain legible, readily identifiable and retrievable. The organization shall ensure a documented procedure is established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5 Management responsibilities

5.1 Top management commitment

The responsibility for, and commitment to, a HACCP system lies on the top or highest level of management. The top management shall provide evidence of its commitment and implementation of the HACCP system.

This shall include;

a) establishment of the HACCP system policy,

b) commitment to the development and implementation of the HACCP system,

c) participation in continual improvement of the HACCP system,

d) conducting management review of the HACCP system for continued adequacy, suitability and effectiveness

e) communication and understanding of the HACCP system within the organization, and

f) establishing a means for resolving conflict within and outside the organization.

5.2 Appointment of the management representative

A management representative shall be appointed by the top management and shal, irrespective of other responsibilities and duties, act as the management representative of the HACCP system and shall have the responsibility and authority to;

a) ensure that the HACCP system is established, implemented, maintained, updated and continually improved in accordance with the requirements of this standard,

b) report on the performance of the HACCP system to top management and any need for improving the system,

c) ensure top management's commitment is visible, and

d) ensure a clear route for communication (up, down and sideways) both within and outside the organization.

5.3 Resource management

Prior to commencing of the HACCP system, the HACCP team leader shall be appointed, and shall assess which resources are needed for the HACCP plan and for the establishment, implementation, maintenance, updating and continual improvement of the HACCP system.

The organization shall provide the necessary and adequate resources. The resources shall include time, competent personnel, suitable and adequate infrastructure, work environment, equipment and funding in order to establish, implement, maintain and continually improve the HACCP system.

Training needs shall be established for all personnel involved with the establishment, implementation and maintenance of the HACCP system. Effectiveness of training shall be evaluated. Appropriate records of education, training, skills and experience shall be maintained.

5.4 Management review

The top Management shall review the HACCP system at planned intervals to ensure its continual improvement, suitability, adequacy and its effectiveness. Records of management reviews shall be maintained.

A management review shall include:

a) matters arising from previous management reviews,

b) a review of the effectiveness of CCP monitoring and failure of CCPs,

c) a review of corrective actions and product disposal,

d) HACCP plan verifications,

e) HACCP plan reviews and validation of changes to the HACCP plan,

f) a review of customer and consumer complaints,

g) a review of recall incidents,

h) recommendations for improvement,

i) resource needs,

j) a review of suitability of the HACCP policy, and

k) where applicable, interrelation with other management systems.

The top management shall be responsible for managing HACCP system. An immediate subordinate may be appointed to represent the management on managing the system. In this case the appointee shall, irrespective of other responsibilities and duties, act as the management representative of the HACCP system and shall have the responsibility and authority to;

a) ensure that the HACCP system is established, implemented, maintained, updated and continually improved in accordance with the requirements of this standard,

b) report on the performance of the HACCP system to top management and any need for improving the system,

c) ensure top management's commitment is visible, and

d) ensure a clear route for communication (up, down and sideways) both within and outside the organization.

6 Requirements for the implementation of HACCP system

6.1 Application of the HACCP system

Prior to application of HACCP system to any sector of the food chain, that sector should have in place prerequisite programmes such as good hygienic practices according to the EAS 39, the appropriate codes of practice and appropriate food safety requirements.

6.2 Application of Prerequisite Programmes (PRPs)

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programmes. The PRPs shall be appropriate to the organizational needs with regard to food safety, be appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled and be implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or operational line.

The organization shall consider the following when establishing these PRPs:

a) personal hygiene,

b) pest control,

c) cleaning, sanitizing and disinfecting,

d) measures for the prevention of cross contamination,

e) construction and lay-out of building or premises and associated facilities,

f) supplies of air, water, energy and other utilities,

g) supporting services including waste and sewage disposal,

h) the suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance,

i) management of purchased materials (for example raw materials, ingredients, chemicals and packaging), supplies (e.g. water, air, steam and ice), disposals (for example waste and sewage) and handling of products (for example storage, distribution and transportation), and

j) relevant training programmes and relevant records.

Additional to the PRPs, the following shall be done by any organization before implementation of HACCP system: a) a complete investigation to determine the suitability of the facility and the equipment to be used with regards to design, construction and maintenance, b) identification of shortcomings that might complicate the implementation of the HACCP plan. Suitable food handling equipment and facilities shall be available to handle the intended product safely, and c) evidence of progress made with the correction of the shortcomings identified during the investigation. Responsibilities and appropriate time limits shall be set for the completion of the intended corrections.

These prerequisite programmes to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system.

6.3 Development of corrective action system

The organization shall ensure the development of a documented corrective action system.

The system shall define the requirements for:

a) review of non-conformities,

b) determination of the cause of the non-conformity,

c) evaluation of the need for action to ensure that the non-conformity does not recur,

d) determination and implementation of the action needed,

e) recording of the results of the action taken (correction), and

f) reviewing the effectiveness of the corrective action taken.

The corrective action system shall, as a minimum, address the following:

a) customer and consumer complaints,

b) internal audit reports,

c) non-conformity reports,

d) outcome of management reviews,

e) outcome of HACCP plan reviews,

f) results from HACCP plan validations and verifications, and

g) failure of CCPs.

The intent of the HACCP system is to focus on control at CCPs. Re-design of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found.

During hazard identification, evaluation and subsequent operations in designing and applying HACCP system, consideration should be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, end-use of the product, categories of consumers of concern and the epidemiological evidence relative to food safety.

HACCP should be applied to each specific operation separately. CCPs identified in any given code of practice might not be the only ones identified for a specific application or might be of a different nature. Therefore, HACCP application should be reviewed and necessary changes made when any modification is made in the product, process or any step.

When applying HACCP, it is important to be flexible, where appropriate, taking into account the nature and size of the operation.

7 Development and application of the HACCP plan

The HACCP team shall develop the HACCP plan document in accordance with the principles of HACCP. The application of the HACCP plan consists of the twelve (12) stages as identified in Annex A (the logical sequence for application of the HACCP plan). The seven HACCP principles have been listed and shall be applied in the stages below;

7.1 Stage 1: Assemble the HACCP Team and Identify Scope

7.1.1 Assemble the HACCP Team

Top management shall ensure the establishment of criteria for the selection of HACCP team members to assist with the plan, establishment, implementation, maintenance and continual improvement of the HACCP system. Every team member shall accept, in writing, his/her assignment and commitment to the HACCP team.

The HACCP team shall be multidisciplinary and consist of personnel with specific knowledge of and expertise appropriate to the product under consideration, its production processes (manufacture, handling process, storage and distribution), its consumption and associated food safety hazard categories.

The HACCP team may consist of:

a) a quality control specialist who understands the biological, chemical, physical and allergenic hazards associated with a particular product group,

b) a production specialist who has responsibility for or is closely involved with, the technical process of manufacturing the product under study,

c) a technician who has a working knowledge of the hygiene and operation of the process plant and equipment,

d) any other person with specialist knowledge of microbiology, hygiene and food technology.

One person may fulfil several of these roles, provided all relevant information is available to the team and is used to ensure that the HACCP system developed is reliable. Where such or necessary, skills or knowledge or expertise are not available within the food handling organization, advice should be obtained from other sources such as individual experts, regulatory authorities, consultant, etc. The services of a consultant may be used on condition that the consultant acts only as an expert advisor to the team.

The team's activities should include establishing rules and guidelines for team meeting, the criteria used for decision making processes, methodology to be used by the team to determine food safety hazards and CCPs, reporting on the status of the HACCP system and the methodology for the establishment of procedural requirements or integration with other relevant management system procedures.

7.1.2 Identify Scope

The HACCP team shall establish defined and documented scope of the HACCP plan and the team's activities. The scope shall describe the segment of the food chain involved, the products and processes of the food business organization.

7.2 Stage 2: Describe the product

A full description of the product shall be given in terms of relevant safety information such as:

a) type and composition (for example raw materials, ingredients, additives, etc.),

b) structure and physical – chemical characteristics (for example solid, liquid, gel, emulsion, water activity Aw, pH, etc.),

c) microbiocidal/static treatments (for example heat - treatment, freezing, drying, salting, smoking, etc. and the extent of the processing),

d) packaging (e.g. hermetic, vacuum, modified atmosphere),

e) durability and storage conditions,

f) method of distribution,

g) required shelf life (for example sell by date and best before date),

h) instructions for use,

i) any allergens, microbiological, chemical or physical properties/criteria applicable.

7.3 Stage 3: Identify intended use of the product

The intended use should be based on the expected uses of the product by the end user or consumer. The normal or the expected use of the product by the consumer, consumer target groups or customers for which the product is intended shall be defined. In specific cases, the suitability of the product for particular groups of consumers, such as institutional caterers, travellers, vulnerable groups of the population may have to be considered. Attention shall be focused on the likely uses and abuses of the product after it has left the control of the food handling organization.

7.4 Stage 4: Construct a flow diagram

The HACCP team shall prepare a detailed flow diagram for the specified food products or process categories relevant to the defined scope of the HACCP plan. The flow diagram should cover all steps in the operation for a specific product. Whatever the format chosen all steps involved in the process including delays during or between steps, from receiving the materials to placing the end product on the market, through preparation, processing, packaging, storage and distribution, should be studied in sequence and presented in a detailed flow diagram with sufficient technical data. The same flow diagram may be used for a number of products that are manufactured using similar processing steps.

When preparing the flow diagram, the following should be considered:

a) the selection of raw material,

b) equipment layout and characteristics,

c) sequence of all processing steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps),

d) rework cycles,

e) technical parameters of operations (in particular time and temperature, including delays),

f) flow of products (including potential cross contamination),

g) segregation of clean and dirty areas (or high/low risk areas),

h) hygienic environment of the facility, including cleaning and disinfecting programmes,

i) personnel routes and hygienic practices,

j) packaging and storage conditions,

k) distribution, retail and customer handling of the product,

l) any outsourced processes, and

m) removal of intermediary products, by-products and waste.

When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

7.5 Stage 5: Arrange an on-site confirmation of the flow diagram

The HACCP team shall confirm the processing operation against the flow diagram on-site during all stages and hours of operation, so as to ensure that the flow diagram and technical data as described in clause 7.4 gives an accurate representation of the operation. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation. Thereafter, the flow diagram shall be amended to take into account any deviations from the original diagram. Reports shall be kept and maintained.

7.6 Stage 6: Conduct a hazard analysis (Principle 1)

The HACCP team should list all potential food safety hazards (such as biological, chemical physical and/or allergenic hazards) associated with each step, conduct a hazard analysis and consider any measures to control the identified hazards.

The HACCP team shall use the confirmed flow diagram, including all the technical data as a guide to identify all the potential food safety hazards (inherent and introduced) that may be reasonably expected to occur at each step from primary production, processing, manufacture, storage and distribution until the point of consumption. Relevant legislation related to the food safety hazards and their control shall also be considered.

After identification of the food safety hazards, the HACCP team should next conduct a hazard analysis to identify for the HACCP plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included: a) the likely occurrence of hazards and severity of their adverse health effects, b) the qualitative and/or quantitative evaluation of the presence of hazards, c) survival or multiplication of micro-organisms of concern, d) production or persistence in foods of toxins, chemicals or physical agents, and e) conditions leading to the above.

The HACCP team should consider and describe what control measures, if any exist, can be applied for each food safety hazard.

More than one control measure may be required to control a specific identified hazard(s) and more than one hazard may be controlled by a specified control measure. Also more than one hazard and control measure might be applicable to one step in the process.

Records shall be kept and maintained

7.7 Stage 7: Determine the Critical Control Points (CCPs) (Principle 2)

The HACCP team shall determine whether a particular process step identified in the flow diagram is a CCP. The method by which a CCP is determined shall be recorded, kept and maintained.

There may be more than one CCP at which control is applied to address the same food safety hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree (see Annex B), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used

for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations, therefore, other approaches may be used. Training in the application of the decision tree is recommended.

If a food safety hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

7.8 Stage 8: Establish critical limits for each CCP (Principle 3)

The HACCP team shall establish critical limits that can be measured quickly and easily and should be appropriate for each CCP.

Critical limits must be specified and validated for each CCP. In some cases, more than one critical limit will be elaborated at a particular process step. Criteria often used include measurements of temperature, time, moisture level, pH value, water activity, available chlorine, chemical analyses and sensory parameters such as visual appearance and texture.

Where HACCP guidance developed by experts has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration.

These critical limits should be measurable and records shall be kept and maintained.

7.9 Stage 9: Establish a monitoring system for each CCP (Principle 4)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The HACCP team shall establish a monitoring system to ensure that control of the CCP is effective. The control measures established as part of the monitoring system shall be such that they can confirm that all CCPs are under control.

During establishment of the monitoring system the following shall be addressed:

Responsible person or equipment. Responsibilities and authorities for the monitoring of a specific CCP shall be identified. This person or equipment shall have the knowledge or capability respectively to ensure effective monitoring of the CCP. A person shall be given the responsibility and authority to take all the necessary corrective action when the specified critical limit of the CCP is exceeded. Equipment used for the monitoring of a CCP shall be calibrated.

Frequency of monitoring. The frequency of monitoring shall be specified. The frequency shall be adequate to ensure the control of the CCP.

Monitoring methodology. A detailed description shall be given to indicate precisely how the monitoring shall be done.

The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits.

Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs.

Data derived from monitoring must be evaluated and verified by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control.

Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product.

All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

Records shall be kept and maintained to prove effectiveness of the monitoring system.

7.10 Stage 10: Establish corrective action plans (Principle 5)

The HACCP team shall establish corrective action plans for each CCP identified in the HACCP system when monitoring of the critical limits indicates deviation from the limits.

Specific corrective actions must be developed for each identified CCP in order to deal with deviations when they occur.

The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product and/or unsafe product. Deviation and product disposition procedures must be clearly identified and documented in the HACCP record keeping.

Records of all corrective actions shall be kept and maintained.

7.11 Stage 11: Establish verification procedures (Principle 6)

The HACCP team shall establish procedures for validation, verification and review of procedures to confirm that the HACCP system is working effectively.

7.11.1 Validation

Validation activities shall include actions and/or evidence to confirm that the established critical limit(s) for each identified CCP is effective for all elements of the HACCP system and capable of achieving the intended control of the identified food safety hazard(s).

If validation results show that one or more of the above elements cannot be confirmed, the relevant elements shall be modified and reassessed.

7.11.2 Verification

The HACCP team shall establish procedures for verification of all HACCP procedures and records. Verification and auditing methods, procedures and tests, including random sampling and analysis, shall be used, as appropriate to determine the effectiveness of the HACCP system. The frequency of verification should be sufficient to confirm that the HACCP system is working correctly and effectively.

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

Examples of verification activities include review of the HACCP system and plan and its records; review of deviations and product dispositions; and confirmation that CCPs are kept under control.

Regular internal audits shall be scheduled and conducted to ensure that the HACCP system conforms to the planned arrangements and the CCP monitoring system(s) and that the corrective action plans are effective. All processes relevant to the HACCP system shall be audited.

The audit criteria, scope, frequency and methods that form part of the audit programme shall be defined and documented. Selection of auditors and conduct of audits shall be such that objectivity and impartiality are ensured during the audit process.

7.11.3 Review of the HACCP plan

The HACCP team shall establish a procedure for the review of the HACCP plan. This procedure shall include events that will automatically trigger a HACCP plan review (internal and external factors should be considered). The HACCP plan shall be updated after such a review. The review may lead to a reduction in or the addition of CCPs or the inclusion of additional critical limits in order to improve the HACCP plan.

The following potential events can influence or automatically trigger a HACCP plan review: a)customer and consumer complaints, b)any report from the marketplace that indicates a health risk associated with the product, c)an anticipated change in customer and consumer use, d)a change in raw materials or product formulation, e)a change in the food handling process activities, f) a change in the food handling organization layout and environment, g)any modification to food handling equipment, h)a change in the cleaning and disinfection programme, i) a change in the packaging, storage and distribution system, j) changes to staff levels and responsibilities, k)changes in legislation, l) results of validation and verification activities, and m) any changes pertaining to PRPs.

Records of validations, verifications, audits and HACCP plan reviews shall be kept and maintained, and the results shall be discussed at management reviews.

7.12 Stage 12: Establish Documentation and record keeping (Principle 7)

The HACCP team shall establish documentation concerning all procedures and records appropriate to these principles and their application.

7.12.1 Documentation and document control

HACCP procedures should be documented. The HACCP team shall ensure that procedures for documentation and document control are established and maintained. The controls shall ensure that all proposed changes are reviewed prior to implementation to determine their effects on the food safety and impact on the HACCP system. A method of control for identification of the latest versions of all documents shall be established.

Documentation examples are Hazard analysis, CCP determination, Critical limit determination, etc.

The document control procedure shall address at least the following:

a) approval of documents for adequacy before being issued,

b) review and update of documents as necessary and re-approval of these documents,

c) identification of changes to documents and the current revision status,

d) ensure that the current versions of applicable documents are available at points of use

e) ensure that documents are legible and readily identifiable,

f) ensure that documents of external origin are identified and their distribution controlled, and g) prevention of the unintended use of obsolete documents and application of suitable identification to them if retained for any purpose.

7.12.2 Record keeping and record control

Efficient and accurate record keeping is essential to the application of a HACCP system. The HACCP team shall ensure the establishment of a procedure for the record keeping and control of records. The documented

procedure shall be established to define the controls needed for the identification, collection, storage, protection, retrieval, retention times and disposition of records.

Records shall be legible, readily identifiable, easily retrievable and accessible, and shall be maintained to provide evidence of conformity to the requirements and evidence of the effective operation of the HACCP system.

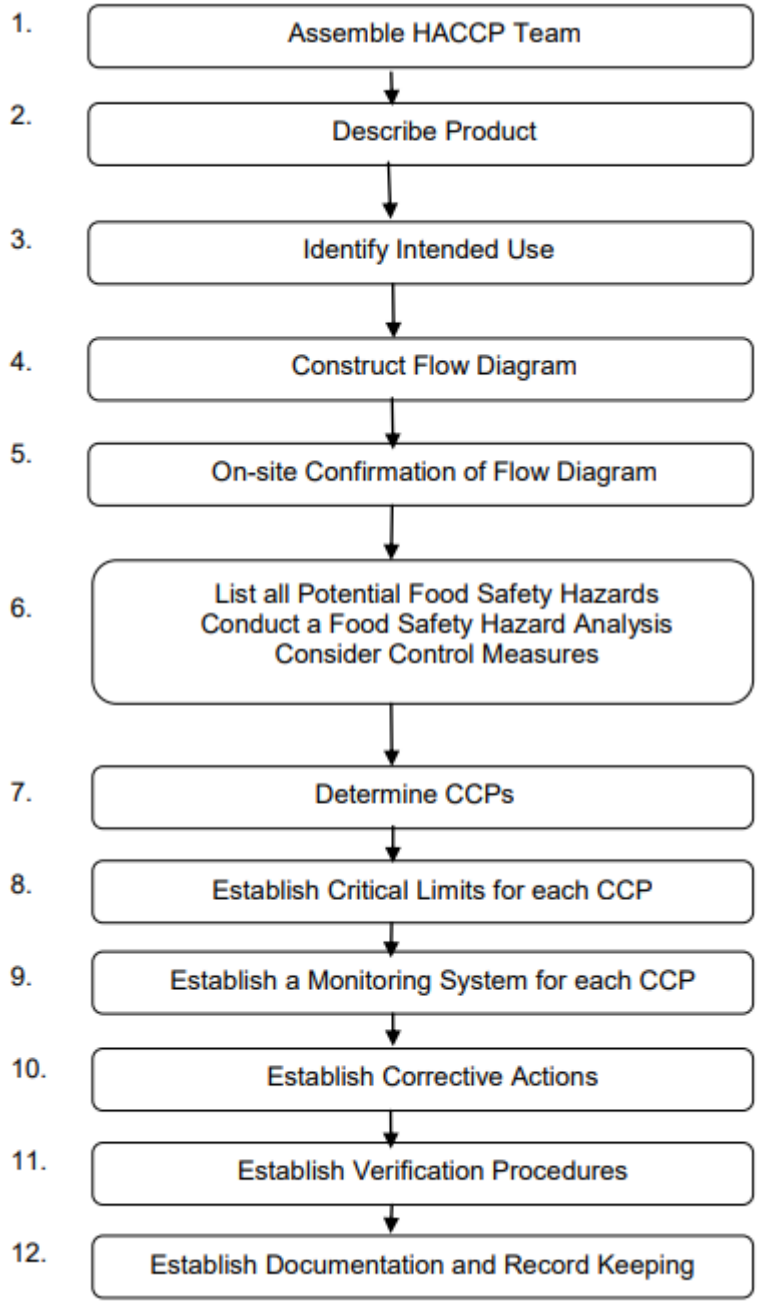
Records examples are CCP monitoring activities, deviations and associated corrective actions, verification procedures performed modifications to the HACCP plan, etc.

A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (for example. sector-specific HACCP guides) may be utilized as part of the documentation, provided that those materials reflect the specific food operations of the business.

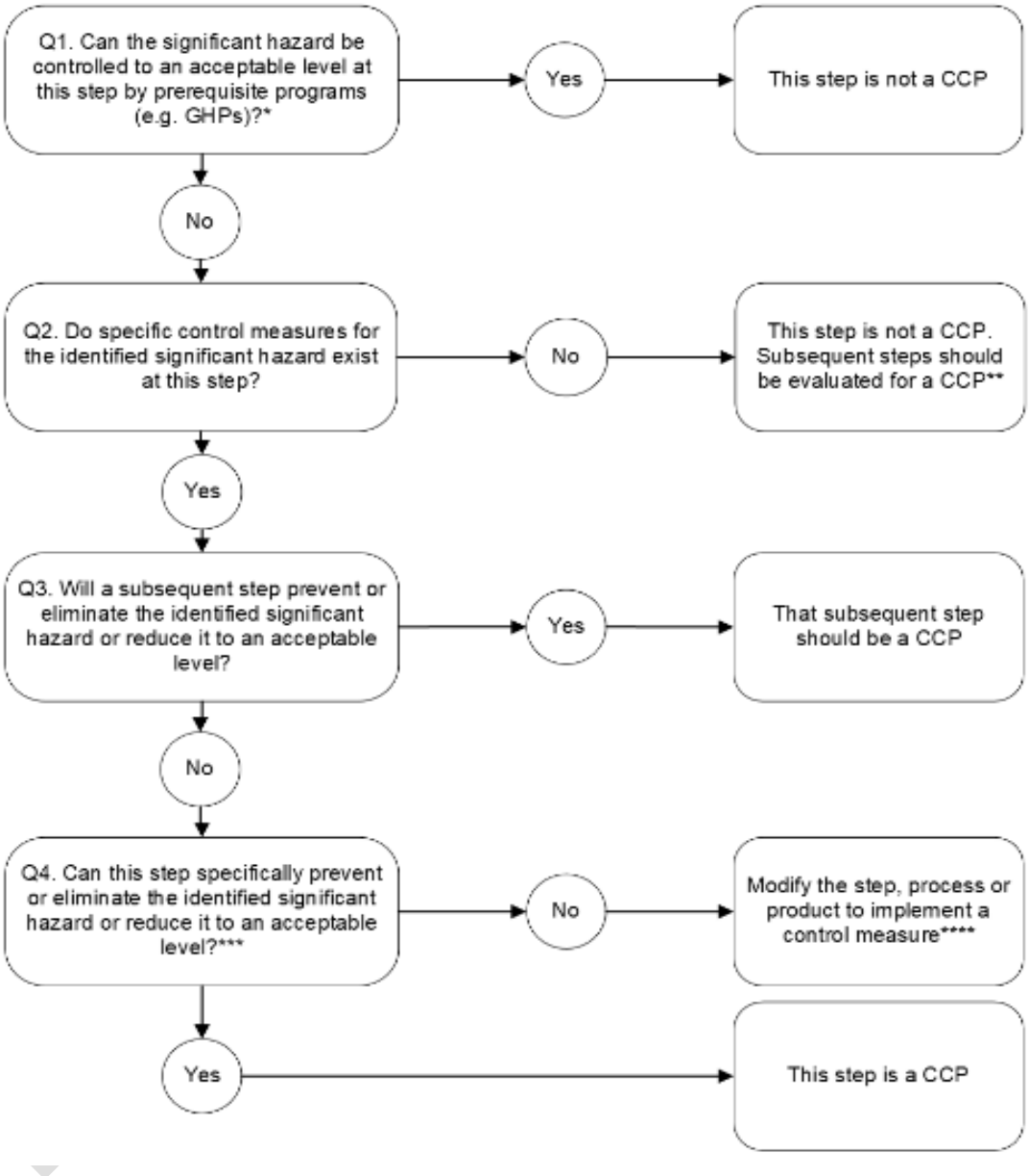
Annex A
(informative)

The logical sequence for application of the HACCP plan



Annex B
(informative)

Example of a CCP decision tree -Apply to each step where a specified significant hazard is identified



* Consider the significance of the hazard (i.e., the likelihood of occurrence in the absence of control and the severity of impact of the hazard) and whether it could be sufficiently controlled by prerequisite programs such as GHPs. GHPs could be routine GHPs or GHPs that require greater attention to control the hazard (e.g. monitoring and recording).

** If a CCP is not identified at questions 2-4, the process or product should be modified to implement a control measure and a new hazard analysis should be conducted.

***Consider whether the control measure at this step works in combination with a control measure at another step to control the same hazard, in which case both steps should be considered as CCPs.

****Return to the beginning of the decision tree after a new hazard analysis

Bibliography

[1] CXC 1-1969, *General principles of food Hygiene*

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