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भारतीय मानक *मसौदा*

खतरे का विश्लेषण और महत्वपूर्ण नियंत्रण बिन्दु (एचएसीसीपी) —
खाद्य श्रृंखला में किसी भी संगठन के लिए अपेक्षाएँ
(IS 15000 *का द्वितीय पुनरीक्षण*)

Draft ***Indian Standard***

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) — REQUIREMENTS FOR ANY ORGANIZATION IN THE FOOD CHAIN

(*Second Revision of* IS 15000)

ICS No. 67.020

Food Hygiene, Safety Management and Other Systems Sectional, FAD 15	Last Date of Comments **22 April 2024**

FOREWORD
(Formal clause will be added later)

The HACCP system, which is a science based and systematic tool, identifies specific hazards and establish measures for their control to ensure the safety of food on a preventive basis rather than relying mainly on end-product testing. Development of a HACCP system may identify the need for changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of distribution, in the intended use or in the GHPs applied. Any HACCP system is capable of accommodating change, such as, advances in equipment design, processing procedures or technological developments.

HACCP principles 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. Although it is not always feasible to apply HACCP at primary production, some of the principles can be applied and may be incorporated into good practices programmes (For example, Good Agricultural Practices (GAPs), etc.). It is recognised that implementation of HACCP may be challenging for some businesses. However, HACCP principles can be applied flexibly in individual operations, and businesses may use external resources (or example, consultants) or adapt generic HACCP plan provided by the competent authority, academia or other competent bodies (for example, trade or industry associations) to the specific site circumstances. Beside enhancing food safety, implementation of HACCP can provide other significant benefits, such as more efficient processes based on a thorough analysis of capability, more effective use of resources by focusing on critical areas, and fewer recalls through identification of problems before product is released. In addition, the application of HACCP systems can aid review by competent authorities and promote international trade by increasing confidence in food safety.

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 multi-disciplinary 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.

The application of HACCP is compatible with the implementation of quality management systems, such as, the IS/ISO 9000 series and IS/ISO 22000 and is a system of choice in the management of food safety. While the application of HACCP to food safety has been considered here, the concept can be applied to aspects of food quality also.

Keeping in view the above, this standard was first published in 1998 based on the Guidelines for the Application of the Hazard Analysis and Critical Control Point (HACCP) System (CAC/GL 18-1993) brought out by the Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Rome and was identical to it. The first revision of the standard was brought out in 2013 to align with the Annex of CAC/RCP 1-1969, Rev. 4- 2003 which covered the HACCP guidelines. In the first revision, guidelines for small and/or less developed businesses which did not have the resources and the necessary expertise on site for the development of HACCP plan were included facilitating them with the implementation of an effective HACCP plan.

The fifth revision of Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev. 5-2020) has prompted the need for the second revision of this standard aligning it with the Codex document. In this revision, HACCP Principles have been rephrased, guidelines for flexibility for small and/or less developed food businesses have been elaborated, general guidelines for application of HACCP system has been further explained to ensure better understanding and effective implementation of HACCP System. Examples of decision tree have been revised and examples of hazard analysis worksheet and HACCP worksheet have been added. Annex A provides a comparison of control measures applied as GHPs and those applied at critical control points (CCPs) with examples. The application of the HACCP system has been described in 12 successive steps in Annex B.

In the formulation of this standard, due consideration has been given to the provisions of the Food Safety and Standards Act, 2006, the Legal Metrology Act, 1985 and the Rules and Regulations framed thereunder. However, this standard is subject to the restrictions imposed under these, wherever applicable

Draft Indian Standard

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) — REQUIREMENTS FOR ANY ORGANIZATION IN THE FOOD CHAIN

(*Second Revision*)

SCOPE

This standard sets out the principles of the hazard analysis and critical control point (HACCP) system and provides general guidelines for the application of these principles, while recognizing that the details of application may vary depending on the circumstances of the food operation.

2 REFERENCES

The standard listed below contains provision which through reference in this text, constitutes provision of this standard. At the time of publication, the edition indicated was valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below:

IS No.	*Title*
IS 2491 : 2013	Food hygiene — General principles — Code of practice (*third revision*)

3 DEFINITIONS

For the purpose of this standard, the following definitions shall apply.

3.1 Acceptable Level - A level of hazard in a food at or below which the food is considered to be safe according to its intended use.

3.2 Allergen Cross-contact - the unintentional incorporation of an allergenic food, or ingredient, into another food that is not intended to contain that allergenic food or ingredient.

3.3 Cleaning - The removal of soil, food residues, dirt, grease or other objectionable matter.

3.4 Competent Authority - The government authority or official body authorized by the government that is responsible for the setting of regulatory food safety requirements and/or for the organization of official controls including enforcement.

3.5 Contaminant - Any biological, chemical or physical agent, foreign matter or other substances not intentionally added to food that may compromise food safety or suitability.

3.6 Contamination - The introduction or occurrence of a contaminant in the food or food environment.

3.7 Control (Noun) - The state wherein correct procedures are being followed and any established criteria are being met.

3.8 Control (Verb) - To take all necessary actions to ensure and maintain compliance with established criteria and procedures.

3.9 Control Measure: Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.

3.10 Corrective Action: Any action taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product if any and prevent or minimize reoccurrence of the deviation.

3.11 Critical Control Point (CCP): A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system.

3.12 Critical Limit: A criterion, observable or measurable, relating to a control measure at a CCP which separates acceptability from unacceptability of the food.

3.13 Deviation: Failure to meet a critical limit or to follow a GHP procedure.

3.14 Disinfection: Reduction by means of biological or chemical agents and/or physical methods in the number of viable microorganisms on surfaces, in water or air to a level that does not compromise food safety and/or suitability.

3.15 Flow Diagram: A systematic representation of the sequence of steps used in the production or manufacture of food.

3.16 Food Business Operator (FBO): The entity responsible for operating a business at any step in the food chain.

3.17 Food Handler: Any person who directly handles packaged or unpackaged food, equipment and utensils used for food, or surfaces that come into contact with food and that is expected, therefore, to comply with food hygiene requirements.

3.18 Food Hygiene: All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

3.19 Food Hygiene System: Prerequisite programmes, supplemented with control measures at CCPs, as appropriate, that when taken as a whole, ensure that food is safe and suitable for its intended use.

3.20 Food Safety: Assurance that food will not cause adverse health effects to the consumer when it is prepared and/or eaten according to its intended use.

3.21 Food Suitability: Assurance that food is acceptable for human consumption according to its intended use.

3.22 Good Hygiene Practices (GHPs): Fundamental measures and conditions applied at any step within the food chain to provide safe and suitable food.

3.23 HACCP Plan: Documentation or set of documents, prepared in accordance with the principles of HACCP to ensure control of significant hazards in the food business.

3.24 HACCP System: The development of a HACCP plan and the implementation of the procedures in accordance with that plan.

3.25 Hazard: A biological, chemical or physical agent in food with the potential to cause an adverse health effect.

3.26 Hazard analysis: The process of collecting and evaluating information on hazards identified in raw materials and other ingredients, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards.

3.27 Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.

3.28 Primary Production: Those steps in the food chain up to and including storage and, where appropriate, transport of outputs of farming. This would include growing crops, raising fish and animals, and the harvesting of plants, animals or animal products from a farm or their natural habitat.

3.29 Prerequisite Programme: Programmes including Good Hygiene Practices, Good Agricultural Practices and Good Manufacturing Practices, as well as other practices and procedures such as training and traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of a HACCP system.

3.30 Significant Hazard: A hazard identified by a hazard analysis, as reasonably likely to occur at an unacceptable level in the absence of control, and for which control is essential given the intended use of the food.

3.31 Step: A point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption.

3.32 Validation of Control Measures: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

3.33 Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

4 PRINCIPLES OF THE HACCP SYSTEM

The HACCP system is designed, validated and implemented in accordance with the following seven principles:

a) Principle 1 — Conduct a hazard analysis and identify control measures.

b) Principle 2 — Determine the critical control points (CCPs).

c) Principle 3 — Establish validated critical limit(s).

d) Principle 4 — Establish a system to monitor control of the CCPs.

e) Principle 5 — Establish the corrective action to be taken when monitoring indicates a deviation from a critical limit at a CCP has occurred.

f) Principle 6 — Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended.

g) Principle 7 — Establish documentation concerning all procedures and records appropriate to these principles and their application.

5 GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

5.1 Prior to application of a HACCP system by any FBO in the food chain, that FBO should be operating according to prerequisite programs of Food Hygiene – General Principle (Code of Practice) as mentioned in IS 2491, the appropriate product and sector-specific Indian Standards on codes of hygienic practices, and in accordance with relevant food safety requirements recommended under Food Safety and Standards Act, 2006 and regulations framed thereunder. Prerequisite programmes should be well-established, fully operational and verified, where possible, in order to facilitate the successful application and implementation of the HACCP system. HACCP application will not be effective without prior implementation of prerequisite programmes including GHPs.

5.2 For all types of food business, management awareness and commitment to food safety are necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and personnel having the appropriate HACCP training and competency. Therefore, ongoing training is necessary for all levels of personnel, including managers, as appropriate to the food business.

5.3 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, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

5.4 A HACCP system identifies and enhances control of significant hazards, where necessary, over that achieved by the GHPs that have been applied by the establishment. The intent of the HACCP system is to focus control at Critical Control Points (CCPs). By specifying critical limits for control measures at CCPs and corrective actions when limits are not met, and by producing records that are reviewed before product release, HACCP provides consistent and verifiable control beyond that achieved by GHPs.

5.5 The intent of the HACCP system is to focus 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.

5.6 A HACCP approach should be customized to each food business. Hazards, control measures at CCPs and their critical limits, CCP monitoring, CCP corrective actions and verification activities can be distinctive for a particular situation and those identified in specific hygienic codes or other appropriate guidelines might not be the only ones identified for a specific application or might be of a different nature.

5.7 The HACCP system should be reviewed periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (for example, new process, new ingredient, new product, new equipment) associated with the food business. Periodic review should also be conducted when the application of the HACCP principles has resulted in a determination that no CCPs are needed, in order to assess whether the need for CCPs has changed.

5.8 Annex A provides a comparison of control measures applied as GHPs and those applied at critical control points (CCPs) with examples.

5.9 Flexibility for Small and/or Less Developed Food Businesses

5.9.1 The application of the HACCP principles to develop an effective HACCP system should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by individual food businesses. This is particularly relevant in small and/or less developed food businesses. Barriers to the application of HACCP in small and less developed businesses (SLDBs) have been acknowledged and flexible approaches to the implementation of HACCP in such businesses are available and encouraged. Some approaches may provide ways to adapt the HACCP approach to assist competent authorities in supporting SLDBs, for example, development of a HACCP-based system which is consistent with the seven principles of HACCP but does not conform to the layout or steps described in this chapter. While it is recognized that flexibility appropriate to the business is important when applying HACCP, all seven principles should be considered in developing the HACCP system. This flexibility should take into account the nature of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food. Applying such flexibility, for example, recording only monitoring results when there is a deviation instead of every monitoring result to reduce unnecessary burden of record keeping for certain types of FBOs, is not intended to impact negatively on the efficacy of the HACCP system and should not endanger food safety.

5.9.2 Small and/or less developed food businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP system. In such situations, expert advice should be obtained from other sources, which may include trade and industry associations, independent experts and competent authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. HACCP guidance developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing a HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration. A comprehensive explanation of the basis for the HACCP plan should be provided to the FBO. The FBO is ultimately responsible for elaboration and implementation of the HACCP system and the production of safe food.

5.9.3 The efficacy of any HACCP system will nevertheless rely on management and personnel having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of personnel, including managers, as appropriate to the food business.

6 APPLICATION OF HACCP PRINCIPLES

6.0 Application of HACCP principles consists of the following tasks as identified in the logical sequence for application of HACCP (*see* Annex B).

6.1 Assemble HACCP Team and Identify Scope (Step 1)

6.1.1 The FBO should ensure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. responsible for different activities within the operation, for example, production, maintenance, quality control, cleaning and disinfection. The HACCP team is responsible for developing the HACCP plan.

6.1.2 Where relevant expertise is not available in- house, expert advice should be obtained from other sources, such as trade and industry associations, independent experts, competent authorities, HACCP literature and HACCP guides (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement a HACCP System in-house. A generic HACCP plan developed externally may be used by FBOs where appropriate but should be tailored to the food operation.

6.1.3 The HACCP team should identify the scope of the HACCP system and applicable prerequisite programmes. The scope should describe which food products and processes are covered.

6.1.4 The scope of the HACCP plan should be identified, alongwith pre-requisite programs. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (for example, does it cover all classes of hazards or only selected classes?).

6.2 Describe Product (Step 2)

A full description of the product should be developed, including relevant safety information such as composition (i.e. ingredients), physical/chemical characteristics (for example, a_w, *p*H, preservatives, allergens), processing methods/technologies (for example, heat treatment, freezing, drying, brining, smoking, etc.), packaging, durability/shelf life, storage conditions and method of distribution. Within businesses with multiple products, it may be effective to group products with similar characteristics and processing steps for the purpose of development of the HACCP plan. Any limits relevant to the food product already established for hazards should be considered and accounted for in the HACCP plan, for example, limits for food additives, regulatory microbiological criteria, maximum allowed veterinary medicines residues, and times and temperatures for heat treatments prescribed by competent authorities.

6.3 Identify Intended Use and users (Step 3)

Describe the use intended by the FBO and the expected uses of the product by the next FBO in the food chain or the consumer; the description may be influenced by external information, for example, from the competent authority or other sources on ways in which consumers are known

to use the product other than those intended by the FBO. In specific cases (for example, hospitals), vulnerable groups of the population may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to enhance process controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.

6.4 Construct Flow Diagram (Step 4)

A flow diagram that covers all steps in the production of a specific product, including any applicable rework, should be constructed. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. The flow diagram should indicate all inputs, including those of ingredients and food contact materials, water and air if relevant. Complex manufacturing operations can be broken down into smaller, more manageable modules and multiple flow diagrams that link together can be developed. The flow diagrams should be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of hazards. Flow diagrams should be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams should, as appropriate, include but not be limited to the following:

i) the sequence and interaction of the steps in the operation;
ii) where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;
iii) any outsourced processes;
iv) where applicable reworking and recycling take place;
v) where end products, intermediate products, waste and by-products are released or removed.

6.5 On-Site Confirmation of Flow Diagram (Step 5)

The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

6.6 List all Potential Hazards that are Likely to Occur and Associated with Each Step, Conduct A Hazard Analysis to Identify the Significant Hazards, and Consider Any Measures to Control Identified Hazards (Step 6/ Principle 1)

6.6.1 Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which of them are significant for the specific food business operation. An example of a hazard analysis worksheet is provided at Annex C. The HACCP team should list all potential hazards. The HACCP team should then identify where these hazards are reasonably likely to occur at each step (including all inputs into that step) according to the scope of the food business operation. Hazards should be specific, for example, metal fragments, and the source or reason for presence should be described, for example, metal from broken blades after chopping. The hazard analysis can be simplified by breaking down complex manufacturing operations and analysing steps in the multiple flow diagrams described in step 4.

6.6.2 The HACCP team should next evaluate the hazards to identify which of these hazards are such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food (i.e., determine the significant hazards that have to be addressed in the HACCP plan).

6.6.3 In conducting the hazard analysis to determine whether there are significant hazards, wherever possible the following should be considered:

i) hazards associated with producing or processing the type of food, including its ingredients and process steps (for example, from surveys or sampling and testing of hazards in the food chain, from recalls, from information in the scientific literature or from epidemiological data);
ii) the likelihood of occurrence of hazards, taking into consideration prerequisite programs, in the absence of additional control;
iii) the likelihood and severity of adverse health effects associated with the hazards in the food in the absence of control;
iv) identified acceptable levels of the hazards in the food, for example, based on regulation, intended use, and scientific information;
v) the nature of the facility and the equipment used in making the food product;
vi) survival or multiplication of pathogenic microorganisms;
vii) production or persistence in foods of toxins (for example, mycotoxins), chemicals (for example, pesticides, drug residues, allergens) or physical agents (for example, glass, metal);
viii) the intended use and/or probability of product mishandling by potential consumers that could render the food unsafe; and
ix) conditions leading to the above.

6.6.4 The hazard analysis should consider not only the intended use, but also any known unintended use (for example, a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. (*see* Annex C for an example of a hazard analysis worksheet.)

6.6.5 In some cases, it may be acceptable for a simplified hazard analysis to be carried out by FBOs. This simplified process identifies groups of hazards (biological, physical, chemical) in order to control the sources of these hazards without the need for a comprehensive hazard analysis that identifies the specific hazards of concern. There can be drawbacks to such an approach, as the controls can differ for hazards within a group, for example, controls for pathogenic spore-formers versus vegetative cells of microbial pathogens. Generic HACCP-based tools and guidance documents provided by external sources, for example, by industry or competent authorities, are designed to assist with this step and mitigate concerns about different controls needed for hazards within a group.

6.6.6 Hazards which are such that their prevention, elimination or reduction to acceptable levels is essential to the production of safe food (because they are reasonably likely to occur in the absence of control and reasonably likely to cause illness or injury if present) should be identified and controlled by measures designed to prevent or eliminate these hazards or reduce them to an acceptable level. In some cases, this may be achieved with the application of good hygiene practices, some of which may target a specific hazard (for example, cleaning equipment to control contamination of ready-to-eat foods with *Listeria monocytogenes* or to

prevent food allergens being transferred from one food to another food that does not contain that allergen). In other instances, control measures will need to be applied within the process, for example, at critical control points.

6.6.7 Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard. For example, to control *L. monocytogenes*, a heat treatment may be needed to kill the organism in the food and cleaning and disinfection may be needed to prevent transfer from the processing environment. More than one hazard may be controlled by a specified control measure. For example, a heat treatment can control both *Salmonella* and *E. coli* O157:H7 when they are present as hazards in the food.

6.7 Determine Critical Control Points (CCPs) (Step 7/ Principle 2)

6.7.1 The FBO should consider which among the available control measures listed during step 6, Principle 1 should be applied at a CCP. Critical Control points are to be determined only for hazards identified as significant as of the result of a hazard analysis. CCPs are established at steps where control is essential and where a deviation could result in the production of a potentially unsafe food. The control measures at CCPs should result in an acceptable level of the hazard being controlled. There may be more than one CCP in a process at which control is applied to address the same hazard (for example, the cook step may be the CCP for killing the vegetative cells of a pathogenic spore-former, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (for example, cooking can be a CCP that addresses several microbial pathogens). Determining whether or not the step at which a control measure is applied in a CCP in the HACCP system can be helped by using a decision tree or a CCP determination worksheet (*see* Annex D, Figure 1 and Table 1). A decision tree should be flexible, given whether it is for use in production, slaughter, processing, storage, distribution or other processes. Other approaches such as expert consultation may be used.

6.7.2 To identify a CCP, whether using a decision tree or other approach, the following should be considered:

i) Assess whether the control measure can be used at the process step being analysed:

   a) If the control measure cannot be used at this step, then this step should not be considered as a CCP for the significant hazard.

   b) If the control measure can be used at the step being analysed, but can also be used later in the process, or there is another control measure for the hazard at another step, the step being analysed should not be considered as a CCP.

ii) Determine whether a control measure at a step is used in combination with a control measure at another step to control the same hazard; if so, both steps should be considered as CCPs.

6.7.3 The CCPs identified could be summarized in tabular format, for example, the HACCP worksheet presented in Annex D, Table 2, as well as highlighted at the appropriate step on the flow diagram.

6.7.4 If no control measures exist at any step for an identified significant hazard, then the product or process should be modified.

6.8 Establish Validated Critical Limits for Each CCP (Step 8/ Principle 3)

6.8.1 Critical limits establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (for example, heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, *p*H, a_w, available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting. A deviation from the critical limit indicates that it is likely that unsafe food has been produced.

6.8.2 Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented. Validation of critical limits may include conducting studies (for example, microbiological inactivation studies). FBOs may not always need to conduct or commission studies themselves to validate critical limits. Critical limits could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party, for example, studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts. Validation of control measures is further described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69 - 2008).

6.9 Establish a Monitoring System for Each CCP (Step 9/ Principle 4)

6.9.1 Monitoring of CCPs is the scheduled measurement or observation at a CCP relative to its critical limits. The monitoring procedures should be able to detect a deviation at the CCP. Further, the monitoring method and frequency should be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product. Where possible, process adjustments should be made when monitoring results indicate a trend towards a deviation at a CCP. The adjustments should be taken before a deviation occurs.

6.9.2 The method and frequency of monitoring should take into account the nature of the deviation (for example, a drop in temperature or a broken sieve, rapid drop in temperature during pasteurization, or a gradual increase in temperature in cold storage). Where possible, monitoring of CCPs should be continuous. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously. Other measurable critical limits such as moisture level and preservative concentration cannot be monitored continuously. Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously. If monitoring is not continuous, then the frequency of monitoring should be sufficient to ensure to the extent

possible the critical limit has been met and limit the amount of product impacted by a deviation. Physical and chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and can often indicate the control of microbial hazards associated with the product and/or the process.

6.9.3 The personnel doing the monitoring should be instructed on appropriate steps to take when monitoring indicates the need to take action. Data derived from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

6.9.4 All records and documents associated with monitoring CCPs should be signed or initialled by the person performing the monitoring.

6.10 Establish Corrective Actions (Step 10/ Principle 5)

6.10.1 Specific corrective actions should be developed for each CCP in the HACCP system in order to deal with deviations when they occur. When critical limits at CCPs are monitored continuously and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe. When a deviation in meeting a critical limit occurs and monitoring was not continuous, then the FBO should determine what product may have been impacted by the deviation.

6.10.2 The corrective actions taken when a deviation occurs should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers. Actions taken should include segregating the affected product and analysing its safety to ensure proper disposition.

6.10.3 External experts may be needed to conduct evaluations regarding the safe use of products when a deviation occurs. It may be determined that the product could be reprocessed (for example, pasteurized) or the product could be diverted to another use. In other situations, the product may need to be destroyed (for example, contamination with *Staphylococcus* enterotoxin). A root cause analysis should be conducted where possible to identify and correct the source of the deviation in order to minimize the potential for the deviation to reoccur. A root cause analysis could identify a reason for the deviation that limits or expands the amount of product impacted by a deviation.

6.10.4 Details of the corrective actions, including the cause of the deviation and product disposition procedures, should be documented in the HACCP records. Periodic review of corrective actions should be undertaken to identify trends and to ensure corrective actions are effective.

6.11 Validation of the HACCP Plan and Verification Procedures (Step 11/ Principle 6)

6.11.1 Validation of the HACCP Plan

6.11.1.1 Before the HACCP plan can be implemented, its validation is needed; this consists of making sure that the following elements together are capable of ensuring control of the significant hazards relevant to the food business: identifying the hazards, critical control points,

critical limits, control measures, frequency and type of monitoring of CCPs, corrective actions, frequency and type of verification and the type of information to be recorded.

6.11.1.2 Validation of control measures and their critical limits is performed during the development of the HACCP plan. Validation could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources.

6.11.1.3 Where HACCP guidance developed by external experts, instead of the HACCP team, 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.

6.11.1.4 During the initial implementation of the HACCP system and after verification procedures have been established, evidence should be obtained in operation to demonstrate that control can be achieved consistently under production conditions.

6.11.1.5 Any changes having a potential impact on food safety should require a review of the HACCP system, and when necessary a revalidation of the HACCP plan.

6.11.2 Verification Procedures

6.11.2.1 After the HACCP system has been implemented, procedures should be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are effectively controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.

6.11.2.2 Verification activities should be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively. Verification, which includes observations, auditing (internal and external), calibration, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly and as planned. Examples of verification activities include:

i) reviewing monitoring records to confirm that CCPs are kept under control;
ii) reviewing corrective action records, including specific deviations, product disposition and any analysis to determine the root cause of the deviation;
iii) calibrating or checking the accuracy of instruments used for monitoring and/or verification;
iv) observing that control measures are being conducted in accordance with the HACCP plan;
v) sampling and testing, for example, for microorganisms (pathogens or their indicators), chemical hazards such as mycotoxins, or physical hazards such as metal fragments, to verify product safety;
vi) sampling and testing the environment for microbial contaminants and their indicators, such as *Listeria*; and
vii) reviewing the HACCP system, including the hazard analysis and the HACCP plan (for example, internal and/or third-party audits).

6.11.2.3 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.

6.11.2.4 The frequency of verification activities should be sufficient to confirm that the HACCP system is working effectively. Verifications of the implementation of control measures should be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly.

6.11.2.5 Verification should include a comprehensive review (for example, re-analysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that monitoring, and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. This review can be carried out by individuals within a food business or by external experts. The review should include confirmation that various verification activities have been executed as intended.

6.12 Establish Documentation and Record Keeping (Step 12/ Principle 7)

6.12.1 Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. 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.

6.12.2 Examples of documentation include:

a) HACCP Team Composition;
b) Hazard analysis and the scientific support for the hazards included or excluded from the plan;
c) CCP determination;
d) Critical limit determination and the scientific support for the limits set;
e) validation of control measures; and
f) modifications made to the HACCP plan

6.12.3 Examples of records include:

a) CCP monitoring activities;
b) Deviations and associated corrective actions;
c) Verification procedures performed; and

6.12.4 An example of a HACCP worksheet is given in Annex D, Table 2 for guidance.

6.12.5 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. Where appropriate, records can also be maintained electronically.

6.13 Training

6.13.1 Training of personnel in industry, government and academia in HACCP principles and applications, and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each critical control point. Training programmes should be designed to address the concepts at a level appropriate for the knowledge and skill level of the personnel being trained. Training programmes should be reviewed periodically and updated where necessary. Re-training may be needed as part of corrective actions for some deviations.

6.13.2 Cooperation between food business operations, trade groups, consumer organisations, and competent authorities is vitally important. Opportunities should be provided for the joint training of food business operators and competent authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

Annex A
(*Clause* 5.8)

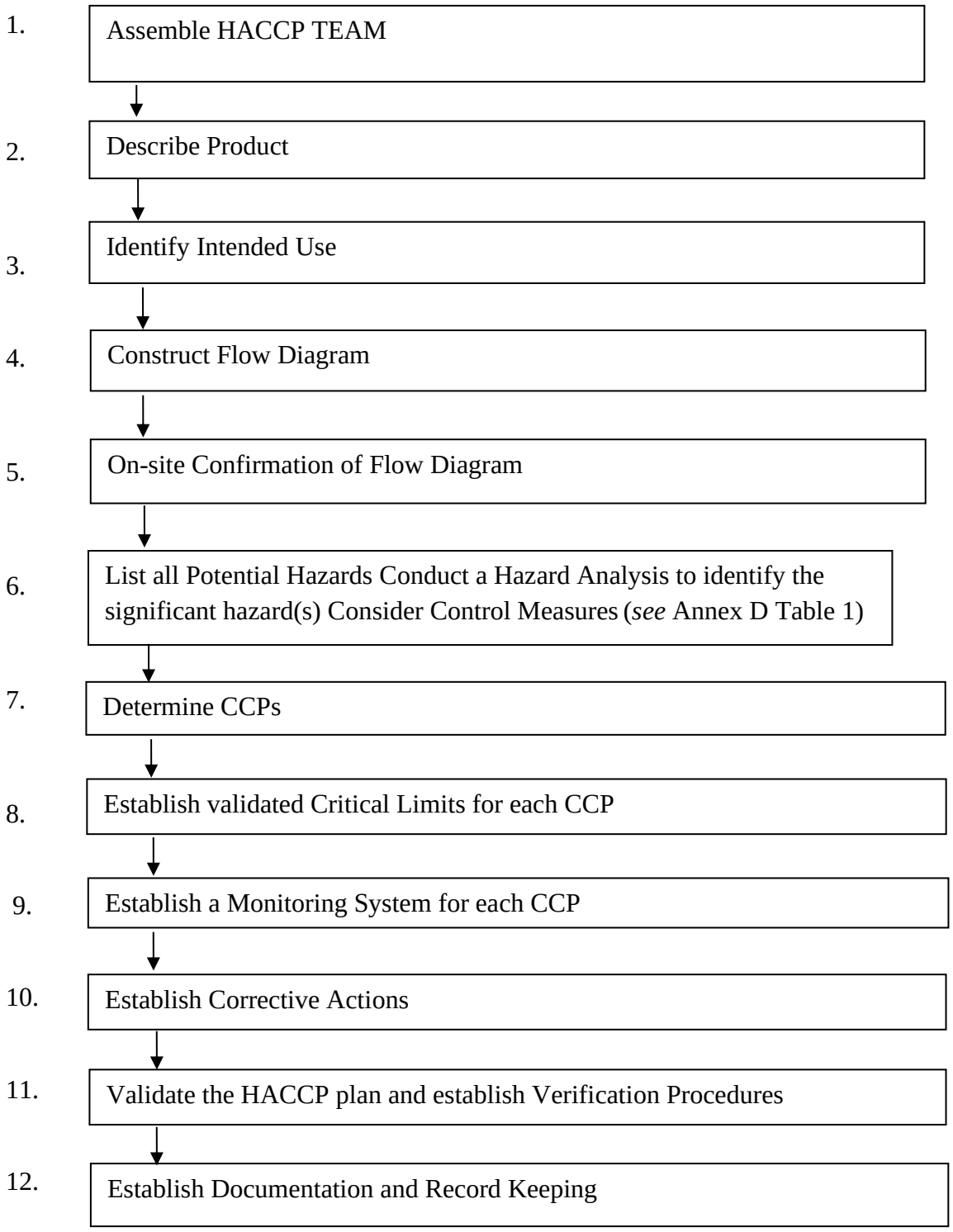
Comparison of Control Measures Applied as GHPs and CCPs with Examples

	Control Measures Applied as Good Hygiene Practices (GHPs)	**Control Measures Applied at Critical Control Points (CCPs)**
Scope	General conditions and activities for maintaining hygiene, including creating the environment (inside and outside the food business) so as to ensure production of safe and suitable food. Generally, not specific to any hazard but results in reduction of likelihood of hazards occurring. Occasionally a GHP activity may target a specific hazard, and this may be a GHP that requires greater attention (for example, cleaning and disinfection of food contact surfaces for control of *Listeria monocytogenes* in a ready-to-eat food processing environment).	Specific to production process steps and a product or group of products, and necessary to prevent eliminate or reduce to acceptable level a hazard determined as significant by the hazard analysis.
When identified?	After consideration of the conditions and activities necessary to support the production of safe and suitable food.	After a hazard analysis has been completed, for each hazard identified as significant, control measures are established at steps (CCPs) where a deviation would result in the production of a potentially unsafe food.
Validation of the control measures	Where necessary, and generally not carried out by FBOs themselves (*Guidelines for the Validation of Food Safety Control Measures* CXG 69-2008). Validation data provided by competent authorities, published scientific literature, information provided by manufacturers of equipment/food processing technology etc. is adequate, for example, cleaning compounds/products/equipment should be validated by the manufacturer and it is generally sufficient for the FBO to use cleaning compounds/ products/equipment according to manufacturers' instructions.	Validation should be carried out (*Guidelines for the Validation of Food Safety Control Measures* CXG 69-2008).

	The FBO should be able to demonstrate it can follow manufacturers' instructions.	
Criteria	GHPs may be observable (e.g. visual checks, appearance) or measurable (e.g. ATP tests of equipment cleaning, concentration of disinfectant), and deviations may require an evaluation of the impact on safety of the product (e.g. whether the cleaning of complex equipment such as meat slicers is adequate).	Critical limits at CCPs which separate acceptability from unacceptability of the food: • measurable (e.g. time, temperature, pH, aw); or • observable (e.g. visual checks of conveyor belt speed or pump settings, ice covering product).
Monitoring	When appropriate and necessary, to ensure procedures and practices are applied properly. Frequency dependent on the impact on the product's safety and suitability.	Necessary to ensure critical limit is met: • continuously during production; or • if not continuous, at appropriate frequency that ensures to the extent possible the critical limit has been met.
Corrective actions when deviation has occurred	• For procedures and practices: necessary • For products: usually not necessary. Corrective action should be considered on a case- by-case basis, as failure to apply some GHPs, such as failure to clean between products with different allergen profiles, not rinsing after cleaning and/or disinfecting (where needed) or post maintenance equipment checks indicating missing machinery parts, may result in action on product.	• For products: necessary pre-determined actions. • For procedures and practices: necessary corrective actions to restore control and prevent reoccurrence. • Specific written corrective actions should be developed for each CCP in the HACCP plan in order to effectively respond to deviations when they occur. • The corrective actions should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers.
Verification	When appropriate and necessary, usually scheduled (e.g. visual observation that equipment is clean before use).	Necessary: scheduled verification of implementation of control measures, e.g. through record review, sampling and testing, calibration of measuring equipment, internal audit.
Record keeping (e.g. monitoring records)	When appropriate and necessary, to allow the FBO to assess whether GHPs are operating as intended.	Necessary to allow the FBO to demonstrate ongoing control of significant hazards.
Documentation (e.g. documented procedures)	When appropriate and necessary to ensure GHPs are properly implemented.	Necessary to ensure the HACCP system is properly implemented.

Annex B
(*Clause* 6.0)

Logical Sequence for Application of HACCP



Annex C
(*Clause* 6.6.1)

Example of Hazard Analysis Worksheet

(1) **Step***	**(2)** **Identify potential hazards introduced, controlled or enhanced at this step** **B = biological** **C = chemical** **P = physical**		**(3)** **Does this potential hazard need to be addressed in the HACCP plan?**		**(4)** **Justify your decision for column 3**	**(5)** **What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level?**
			Yes	**No**		
	B					
	C					
	P					
	B					
	C					
	P					
	B					
	C					
	P					

*A hazard analysis should be conducted on each ingredient used in the food; this is often done at a "receiving" step for the ingredient. Another approach is to do a separate hazard analysis on ingredients and one on the processing steps.

Annex D
(Clause *6.7.1, 6.7.3, 6.12.4*)

Tools to Determine the Critical Control Points (CCPs)

The following are examples of a decision tree and CCP worksheet tools that can be used in the determination of a CCP. Such examples are not unique and other tools can be used as long as the general requirements as elaborated in CXC 1-1969 [that is, Step 7/Principle 2 - Determine the critical control points (CCPs)] have been met.

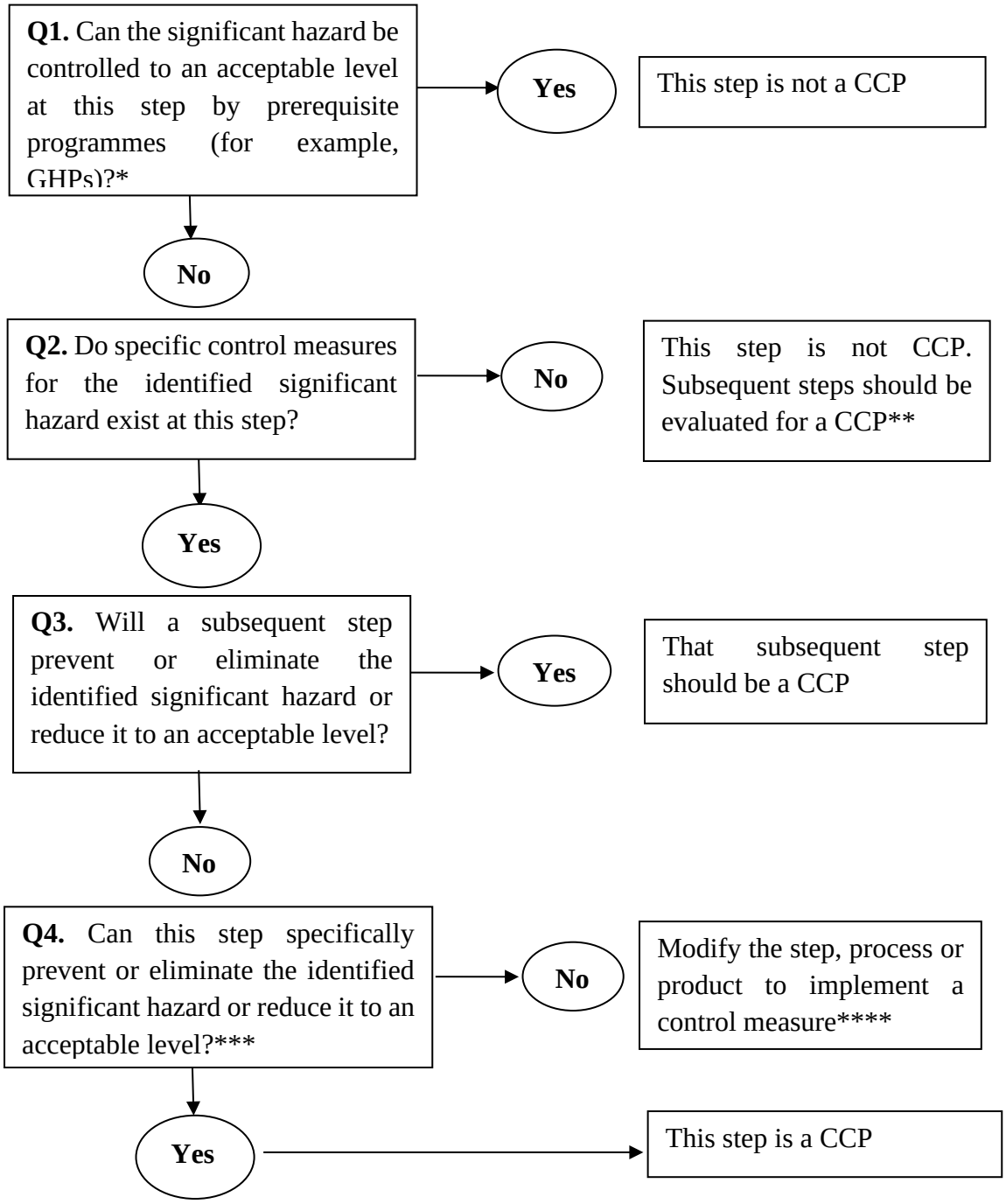


Figure 1 - Example of a CCP decision tree – Apply to each step where a specified significant hazard is identified

* 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 programmes 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.

Table D.1 Example of a CCP determination worksheet

(Clause *6.7.1*)

(apply to each step where a specified significant hazard is identified)

Process step	**Significant hazard**	**Q1.** **Can the significant hazard be controlled to an acceptable level at this step by prerequisite programs (e.g. GHPs)?**[a]	**Q2.** **Do specific control measures for the identified significant hazard exist at this step?**	**Q3.** **Will a subsequent Step prevent or eliminate the identified significant hazard or reduce it to an acceptable level?**	**Q4.** **Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?**[c]	**CCP number**
Identify process step	Describe hazard and cause	**If yes**, this step is not a CCP.	**If yes,** proceed to Q3.	**If yes,** that subsequent step should be a CCP.	**If yes,** this step is a CCP.	Number the CCP and include in HACCP worksheet.
		If no, proceed to Q2.	**If no,** this step is not a CCP. Subsequent steps should be evaluated for a CCP.[b]	**If no,** proceed to Q4.	**If no,** modify the step, process or product to implement a control measure.[d]	

[a] Consider the significance of the hazard (that is, 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 (for example, monitoring and recording).

[b] 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.

[c] 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.

[d] Return to the beginning of the decision tree after a new hazard analysis.

Table D.2 – Example of a HACCP worksheet

(Clause *6.7.3, 6.12.4*)

Critical Control Points (CCPs)	Significant Hazard(s)	Critical Limits	Monitoring				Corrective Actions	Verification Activities	Records
			What	How	When (Frequency)	Who			

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