

**FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972 (ACT NO. 54
OF 1972) REGULATIONS RELATING TO THE APPLICATION OF THE
HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM
(HACCP SYSTEM)**

The Minister of Health intends, in terms of section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No 54 of 1972), to make the regulations in the Schedule.

Interested persons are invited to submit any comments on the proposed regulations, or any representations they may wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Food Control), within three months of the date of publication of this notice.

SCHEDULE

Definitions

1. In these regulations, "the Act" means the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) and any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and in these regulations

"Department" means the national Department of Health;

"food chain" means all the stages through which food is handled from primary production to processing, manufacturing, distribution and retail, to the point of consumption;

"food handler" means a person who in the course of his or her normal duties comes into contact with food not intended for his or her own use;

"food handling enterprise" means a business which during its operations produces, processes, manufactures, stores, transports, distributes or sells foodstuffs or is engaged in any activity which may impact on the safety of such foodstuffs;

"food safety" means the assurance that food will not cause harm chemically, microbiologically or physically, to the consumer when prepared or eaten according to its intended use;

"Good Manufacturing Practice (GMP)" means methods or manufacture procedures applied taking into account the most basic principle of hygiene, that food must not be contaminated or spoilt during the manufacturing process;

"HACCP system" means a system which identifies, evaluates and controls hazards which are significant for food safety;

"HACCP plan" means a plan, in a document form, which outlines the control of hazards which are significant for food safety in a segment of the food chain under consideration;

"External HACCP auditing" means a process aimed at verifying whether or not a HACCP system implemented by a food handling enterprise is in accordance with the requirements laid down by regulations 12 and 16 in relation to the handling of the foodstuffs under consideration;

"HACCP certification" means the issuing of documentary evidence by a person accredited to do so by the South African National Accreditation System ("SANAS", a nonprofit organisation registered in terms of section 21 of the Companies Act, 1973 (Act No. 61 of 1973), registration No. 199600354108) based on the results of an external HACCP auditing;

"representative body" means a group of persons or an organization mandated to represent persons in a specific sector or specific food handling enterprise responsible for handling 60% or more of the foodstuff(s) under consideration; and

"sector" means a classification of the food industry in South Africa in categories based on the foodstuffs handled and the food handling enterprises normally associated with that within the food chain;

HACCP system: requirements

2. No owner of a food handling enterprise as specified in column 2 of Annex A is allowed to handle food without
 - (i)a HACCP system fully implemented to the satisfaction of the Director General in relation to the foodstuffs under consideration, on or after the date specified in column 3 of Annex B as applicable to such a food handling enterprise; and
 - (ii) a valid certificate referred to in regulation 14.
3. The Minister may by notice list the name of a sector as specified in column 1 of Annex A regarding a specific category of food handling enterprise as specified in column 2 of the same Annex; in column 2 of Annex B; in which case the restriction included in regulation 2 will come into affect on the date as specified in such notice.
4. The listing referred to in regulation 3 shall be made only after
 - (a) considering a request made by a representative body of a specific sector,

- including that of a specific category of food handling enterprise, to be listed in column 2 of Annex B on a specified date to be listed in column 3 of the same Annex; or
- (b) after consultation with the representative body considering a recommendation made by the Director-General to list such a sector regarding a specific category food handling enterprise in column 2 of Annex B on a date specified in column 3 of the same Annex.
5. A request referred to in regulation 4 (a) shall be in writing and only if such sector or specific category of food handling enterprise is of the opinion that it is in a position to comply with the restrictions specified in Regulation 2.
 6. A recommendation referred to regulation 4 (b) may only be made if the Director-General is of the opinion that it is in the interest of the safety of food handled by a specific sector or category of food handling enterprise, and also the health of the consumer, that such a sector or food handling enterprise must comply with the restrictions specified in Regulation 2.
 7. The owner of a food handling enterprise listed in Annex B is responsible for ensuring that
 - (a) prior to the implementation of a HACCP system as required in Regulation 2, the enterprise already operates good manufacturing practices as well as health and safety measures applicable to the food handling operation under consideration; and,
 - (b) foodstuffs received from a producer or supplier for further handling by the food handling enterprise in question comply with all the requirements for safety applicable to the foodstuffs under consideration.
 8. The owner of a food handling enterprise, when implementing a HACCP system must ensure that the system is in accordance with the principles as provided for by the Joint Food and Agricultural Organisation / World Health Organisation ("FAO / WHO") Food Standards Programme Codex Alimentarius Commission's general requirements (food hygiene), entitled:
"Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application", published in the Supplement to Volume 113-1997 document of the Commission.
 9. The owner of a food handling enterprise may apply a system equivalent to the one referred to in regulation 8 if such equivalent system includes at least the principles and process of the HACCP system.

Application of the HACCP system to a specific sector or category of food handling enterprise

10. A HACCP plan for a specific sector or category of food handling enterprise must be compiled by a representative body or the Director-General and the plan shall contain the requirements for a HACCP system applicable to its members.
11. The HACCP plan referred to in regulation 10 must accompany a request referred to in regulation 4(a).

Verification of the HACCP system

12. The external HACCP auditing must be carried out by a person suitably qualified and experienced in the application of the HACCP system and who is employed by a certifying body that is accredited by SANAS.
13. Information related to the external HACCP auditing activities conducted by certifying bodies referred to in regulation 12 must be submitted to the relevant provincial Department of Health and to the Director-General in a format as determined by the Director-General.
14. A HACCP certification must be conducted by a certifying body referred to in regulation 12 based on the results of an external HACCP audit and in a format as determined by the Director-General and the certificate is valid for a period not exceeding one calendar year, starting on the date of issuance.

Requirements for a HACCP system applicable to imported foodstuffs

15. The requirements for the application of the HACCP system become applicable to imported foodstuffs on the same date per sector or a specific category of food handling enterprise as specified in column 3, Annex B.
16. The Director-General may request documentary evidence of the country of origin for the external HACCP auditing and certification with regard to imported foodstuffs.

General requirements

17. The owner of a food handling enterprise must take steps to ensure that all the food handlers involved in its operation are sufficiently trained on an ongoing basis regarding the application of the requirements of the HACCP system and the level of training shall be as determined by the Director-General.

(signed)

**ME TSHABALALA-MSIMANG
MINISTER OF HEALTH**

ANNEX A

CATEGORIES OF FOOD HANDLING ENTERPRISES AS PER SECTOR BASED ON FOODSTUFFS HANDLED

SECTOR	FOOD HANDLING ENTERPRISE
1) MEAT AND EDIBLE MEAT OFFAL PREPARATIONS AND PRODUCTS	<p>WHOLESALERS (FRESH MEAT)</p> <p>PROCESSORS (CANNED MEAT)</p> <p>PROCESSORS (CHILLED, FROZEN MEATS)</p> <p>PROCESSORS (DRIED MEATS)</p> <p>RETAILERS (FRESH MEAT) (INCLUDING THOSE ON SUPERMARKET PREMISES)</p>
2) FISH, CRUSTACEANS, MOLLUSCS AND OTHER AQUATIC INVERTEBRATES PREPARATIONS AND PRODUCTS	<p>WHOLESALERS (FRESH PRODUCTS)</p> <p>PROCESSORS (CANNED PRODUCTS)</p> <p>PROCESSORS (CHILLED, FROZEN PRODUCTS)</p> <p>PROCESSORS (DRIED PRODUCTS)</p> <p>RETAILERS (FRESH PRODUCTS) (INCLUDING THOSE ON SUPERMARKET PREMISES)</p>
3) SUGARS, HONEY AND SUGAR CONFECTIONARIES	<p>PROCESSORS</p> <p>RETAILERS</p>
4) EDIBLE OILS AND FATS	<p>EXPRESSERS</p> <p>PROCESSORS</p>
5) VEGETABLES, FRUIT, NUTS OR OTHER PARTS OF PLANTS PREPARATIONS AND PRODUCTS	<p>WHOLESALERS (FRESH PRODUCTS)</p> <p>PROCESSORS (CANNED PRODUCTS)</p> <p>PROCESSORS (FROZEN PRODUCTS)</p> <p>PROCESSORS (DRIED PRODUCTS)</p> <p>RETAILERS (FRESH PRODUCTS) (INCLUDING THOSE ON SUPERMARKET PREMISES)</p>
SECTOR	FOOD HANDLING ENTERPRISE
6) GRAINS, CEREALS, COCOA, STARCH AND PASTRY-COOK PREPARATIONS AND PRODUCTS	<p>MILLERS</p> <p>WHOLESALERS</p>

	PROCESSORS (DRIED PRODUCTS) PROCESSORS (CHILLED, FROZEN PRODUCTS) PROCESSORS (INDUSTRIAL BAKERIES) RETAILERS (FRESH PRODUCTS) (INCLUDING THOSE ON SUPERMARKET PREMISES)
7) BEVERAGES, BEER, WINE AND SPIRITS PREPARATIONS AND PRODUCTS	PROCESSORS (CONCENTRATES) PROCESSORS (SOFT DRINKS) PROCESSORS (FRUIT JUICES) PROCESSORS (BOTTLED WATERS) BREWERIES DISTILLERS CELLARS
8) MILK AND DAIRY PREPARATIONS AND PRODUCTS	MILKING SHEDS (PARLOURS) SUPPLIERS (FRESH MILK) PROCESSORS (CHEESES) PROCESSORS (CHILLED PRODUCTS) PROCESSORS (DRIED, LONG LIFE PRODUCTS) RETAILERS (FRESH MILK) (INCLUDING THOSE ON SUPERMARKET PREMISES)
9) FOOD PREPARATION AND CATERING (EXCLUDING STREET-VENDORS)	RESTAURANTS DELICATESSENS (INCLUDING THOSE ON SUPERMARKET PREMISES) HOTELS CAFE'S CATERERS (INDUSTRIAL) CATERERS (RETAIL)
SECTOR	FOOD HANDLING ENTERPRISE
10) STREET VENDED FOODS	CATERERS PERISHABLE PRODUCTS
11) COFFEE, TEA, SALT, HERBS AND SPICES	PROCESSORS PACKERS
12) POULTRY PREPARATIONS AND PRODUCTS	WHOLESALEERS (FRESH MEAT) WHOLESALEERS (FRESH EGGS)

	PROCESSORS (CANNED MEAT) PROCESSORS (CHILLED, FROZEN MEAT) PROCESSORS (EGG PRODUCTS) RETAILERS (INCLUDING THOSE ON SUPERMARKET PREMISES)
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ANNEX B

**NAME AND DATE OF A SECTOR OF THE FOOD INDUSTRY OR A FOOD HANDLING
 ENTERPRISE ASSOCIATED WITH SUCH A SECTOR LISTED
 BY THE MINISTER OF HEALTH IN TERMS OF REGULATION 3 (1) OR (2)**

SECTOR	FOOD HANDLING ENTERPRISE	DATE LISTED

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

Annex to CAC/RCP 1-1969, Rev. 3 (1997)

Preamble

The first section of this document sets out the principles of the Hazard Analysis and Critical Control Point

(HACCP) system adopted by the Codex Alimentarius Commission. The second section provides general

guidance for the application of the system while recognizing that the details of application may vary

depending on the circumstances of the food operation. **1**

The HACCP system, which is science based and systematic, identifies specific hazards and measures for

their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems

that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable

of accommodating change, such as advances in equipment design, processing procedures or technological

developments.

HACCP can be applied throughout the food chain from primary production to final consumption and its

implementation should be guided by scientific evidence of risks to human health. As well as enhancing food

safety, implementation of HACCP can provide other significant benefits. In addition, the application of

HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing

confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the

work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include,

when appropriate, expertise in agronomy, veterinary health, production, microbiology, medicine, public

health, food technology, environmental health, chemistry and engineering, according to the particular study.

The application of HACCP is compatible with the implementation of quality management systems, such as

the ISO 9000 series, and is the system of choice in the management of food safety within such systems.

While the application of HACCP to food safety was considered here, the concept can be applied to other

aspects of food quality.

Definitions

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

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.

Critical limit: A criterion which separates acceptability from unacceptability.

Deviation: Failure to meet a critical limit.

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

1 The Principles of the HACCP System set the basis for the requirements for the application of HACCP, while the Guidelines for the Application provide general guidance for practical application.

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HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

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.

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

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.

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

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

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

Principles of the HACCP System

The HACCP system consists of the following seven principles:

PRINCIPLE 1

Conduct a hazard analysis.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish critical limit(s).

PRINCIPLE 4

Establish a system to monitor control of the CCP.

PRINCIPLE 5

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

PRINCIPLE 6

Establish procedures for verification to confirm that the HACCP system is working effectively.

PRINCIPLE 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

Guidelines for the Application of the HACCP System

Prior to application of HACCP to any sector of the food chain, that sector should be operating according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation. Management commitment is necessary for implementation of an effective HACCP

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system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must 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. The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found. HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step. It is important when applying HACCP to be flexible where appropriate, given the context of the application taking into account the nature and the size of the operation.

Application

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

1. ASSEMBLE HACCP TEAM

The food operation should assure 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. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

2. DESCRIBE PRODUCT

A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including Aw, pH, etc.), microcidal/static treatments (heattreatment, freezing, brining, smoking, etc.), packaging, durability and storage conditions and method of distribution.

3. IDENTIFY INTENDED USE

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

4. CONSTRUCT FLOW DIAGRAM

The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

5. ON-SITE CONFIRMATION OF FLOW DIAGRAM

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.

6. LIST ALL POTENTIAL HAZARDS ASSOCIATED WITH EACH STEP, CONDUCT A HAZARD ANALYSIS, AND CONSIDER ANY MEASURES TO CONTROL IDENTIFIED HAZARDS (SEE PRINCIPLE 1)

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The HACCP team should list all of the hazards that may be reasonably expected to occur at each step from

primary production, processing, manufacture, and distribution until the point of consumption.

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:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of microorganisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents; and,
- conditions leading to the above.

The HACCP team must then consider what control measures, if any, exist which can be applied for each hazard.

More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

7. DETERMINE CRITICAL CONTROL POINTS

(SEE PRINCIPLE 2)²

There may be more than one CCP at which control is applied to address the same hazard. The determination

of a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g. Diagram 2),

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.

Other approaches may be used. Training in the application of the decision tree is recommended.

If a 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.

8. ESTABLISH CRITICAL LIMITS FOR EACH CCP

(SEE PRINCIPLE 3)

Critical limits must be specified and validated if possible for each Critical Control Point. In some cases more

than one critical limit will be elaborated at a particular step. Criteria often used include measurements of

temperature, time, moisture level, pH, Aw, available chlorine, and sensory parameters such as visual

appearance and texture.

9. ESTABLISH A MONITORING SYSTEM FOR EACH CCP

(SEE PRINCIPLE 4)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. 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

² Since the publication of the decision tree by Codex, its use has been implemented many times for training

purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding

needed to determine CCPs, it is not specific to all food operations, e.g. slaughter, and therefore it should be

used in conjunction with professional judgement, and modified in some cases.

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towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived

from monitoring must be evaluated 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.

10. ESTABLISH CORRECTIVE ACTIONS

(SEE PRINCIPLE 5)

Specific corrective actions must be developed for each CCP in the HACCP system 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. Deviation and product disposition procedures must be

documented in the HACCP record keeping.

11. ESTABLISH VERIFICATION PROCEDURES

(SEE PRINCIPLE 6)

Establish procedures for verification. Verification and auditing methods, procedures and tests, including

random sampling and analysis, can be used to determine if the HACCP system is working correctly. The

frequency of verification should be sufficient to confirm that the HACCP system is working effectively.

Examples of verification activities include:

- Review of the HACCP system and its records;
- Review of deviations and product dispositions;
- Confirmation that CCPs are kept under control.

Where possible, validation activities should include actions to confirm the efficacy of all elements of the

HACCP plan.

12. ESTABLISH DOCUMENTATION AND RECORD KEEPING (SEE PRINCIPLE 7)

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.

Documentation examples are:

- Hazard analysis;
- CCP determination;
- Critical limit determination.

Record examples are:

- CCP monitoring activities;
- Deviations and associated corrective actions;
- Modifications to the HACCP system.

An example of a HACCP worksheet is attached as Diagram 3.

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Training

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.

Cooperation between primary producer, industry, trade groups, consumer organizations, and responsible

authorities is of vital importance. Opportunities should be provided for the joint training of industry and

control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in

the practical application of HACCP.

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DIAGRAM 1

LOGIC SEQUENCE FOR APPLICATION OF HACCP

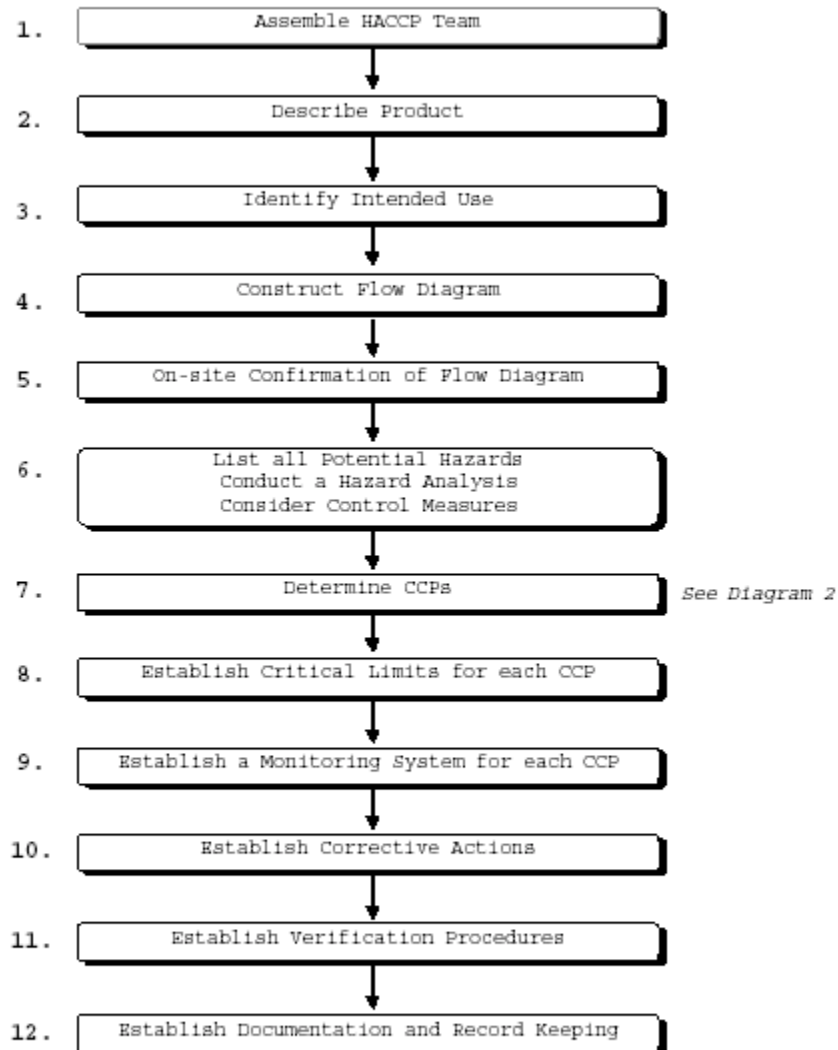
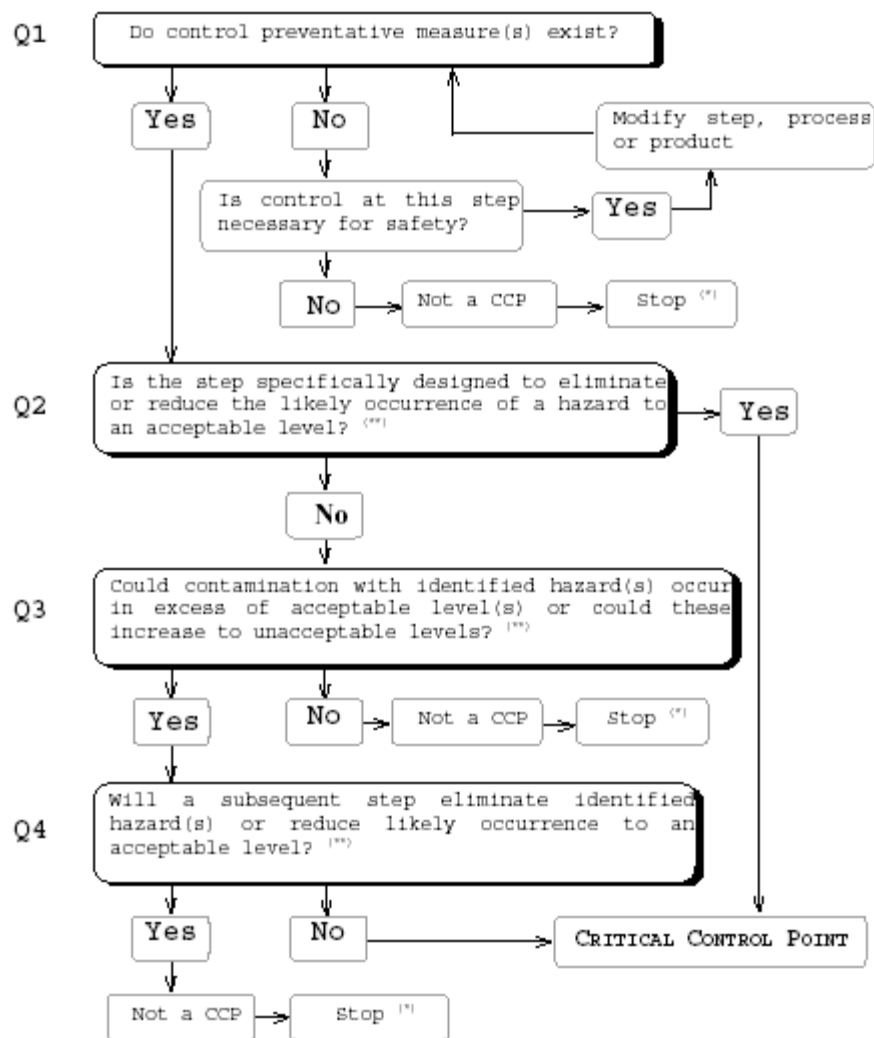


DIAGRAM 2

EXAMPLE OF DECISION TREE TO IDENTIFY CCPs

(answer questions in sequence)



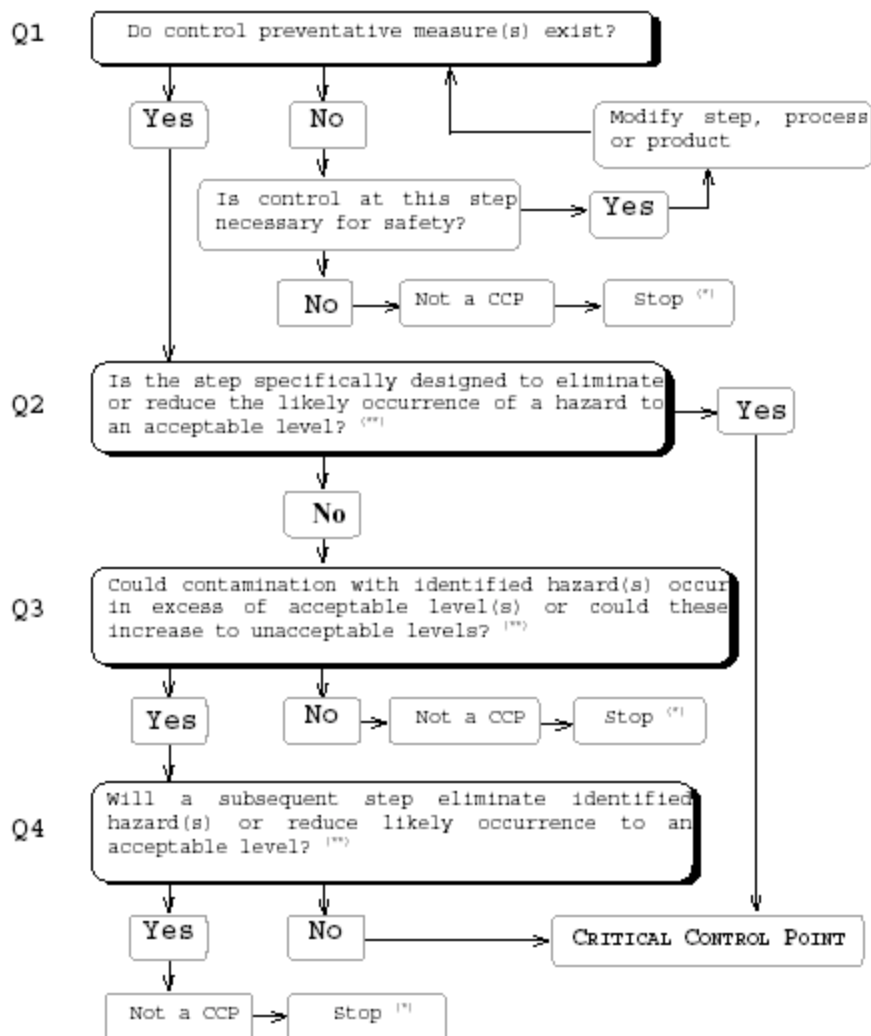
(*) Proceed to the next identified hazard in the described process.

(**) Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of HACCP plan.

DIAGRAM 2

EXAMPLE OF DECISION TREE TO IDENTIFY CCPs

(answer questions in sequence)



^(*) Proceed to the next identified hazard in the described process.

^(**) Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of HACCP plan.

DIAGRAM 3**EXAMPLE OF A HACCP WORKSHEET**

1.

Describe Product
2.

Diagram Process Flow

LIST							
Step	Hazard(s)	Control Measure(s)	CCPs	Critical Limit(s)	Monitoring Procedure(s)	Corrective Action(s)	Record(s)

4.

Verification