The Society of Food Hygiene and Technology

Hazard Analysis and Critical Control Points

INTRODUCTION

Hazard Analysis Critical Control Point (HACCP) is an internationally recognised and recommended system of food safety management. It focuses on identifying the 'critical points' in a process where food safety hazards could arise and putting steps in place to prevent things going wrong.

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.

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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 BRC Global Standard For Food Safety V5 and ISO 9000 series, and is the system of choice in the management of food safety within such systems.

The HACCP technique was originally developed to assure the micro¬biological safety of foods. It can also be applied to other categories of hazards, such as avoidance of chemical contamination and foreign bodies. It can be used to ensure consistent product quality and improved production efficiency.

With regard to current legislation in the EU, Regulation (EC) No 852/2004, which became applicable on 1 January 2006, Regulation 1 requires:

- General Implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;

- Guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles.

Regulation 2 (a) to (g) defines those HACCP principles. An EU Regulation has immediate force on the due date in all Member States. Provisions for enforcement and penalties in the UK are contained in the Food Hygiene (England) Regulations 2005 and similar Regulations for Scotland, Wales and Northern Ireland.

Regulation (EC) No 852/2004 states that HACCP requirements should take account of the principles contained in the Codex Alimentarius. The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organisations. Codex Alimentarius HACCP principles have become the global benchmark for HACCP system development. Details of the Codex principles are provided within this document.

BACKGROUND

The HACCP system was developed in the 1960s in the USA as a result of a joint effort within the US Space Program of the Pillsbury Company, the National Aeronautics and Space Administration (NASA) and the US Army Natick Laboratories to apply a zero defects philosophy to food production for astronauts. It is based on an engineering system, the Failure, Mode and Effect Analysis, which consists of examining the product and all of the components and processes used to make that product and assessing what could potentially go wrong at each stage in an operation, along with the possible causes and the likely effect, before employing effective control mechanisms.

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HACCP DEFINITIONS

Corrective Action	Procedure to be followed when a deviation occurs from a critical limit.
Critical Control Point (CCP)	A location, stage, operation or raw material which if not controlled provides a threat to consumer safety or product acceptability. A CCP should, if established, eliminate or reduce a hazard to an acceptable level.
CCP Decision Tree	A means by which CCP's can be determined, based upon a logical series of questions to be asked, for each hazard at each process step.
Critical Limit	An absolute tolerance value which must be met for each control measure at a CCP. Critical limits separate acceptability from unacceptability.
Deviation	Failure to meet a required critical limit for a CCP.
Flow Diagram	A detailed, stepwise, diagrammatic sequence of operations in the process under study.
Hazard	Any biological, chemical or physical occurrence that may cause an unacceptable consumer health risk (e.g. unacceptable contamination, toxin levels, growth and/or survival of pathogenic organisms).
HACCP Plan	The document which defines the procedures to be followed to assure the control of product safety for a specific process.
Monitoring	A planned sequence of observations or measurements of critical limits designed to ensure that critical control points are under control and therefore maintain product safety.
Risk	The probability that a hazard will occur, based on previous experience, physical data or expert opinion.
Verification	Assessments which ensure that the implemented HACCP Plan continues to truly reflect the actual process which is occurring.

PREPARATION FOR HACCP

Assembly of a HACCP Team

The formal method of HACCP requires a multi-disciplinary team approach. This should include representatives from a range of disciplines and have personnel who have expertise in areas such as Production, Technical/Quality, Engineering/Maintenance, Hygiene, and NPD. The team should have specific knowledge of HACCP and relevant knowledge of product, processes and associated hazards.

This formal team approach is not always practical in a smaller business, as these experts may not exist within the company. In these instances it is advisable to have at least 2 people involved, one who understands the business and how it operates and someone who understands the principles of HACCP and has practical experience of documenting and implementing HACCP plans. External expertise should be sought where appropriate.

The HACCP Team should have a qualified team leader who shall demonstrate competence and experience of HACCP.

The company' s senior management shall demonstrate commitment and support the HACCP team.

Training

The HACCP team members should have training in HACCP. It is recommended that at least one team member (preferably the Team Leader) holds a recognised HACCP qualification and other team members have received internal HACCP training. Records should be maintained to demonstrate the HACCP team has knowledge and understanding of HACCP.

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Describe the 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 (heat-treatment, freezing, brining, smoking, etc.), packaging, durability and storage conditions and method of distribution.

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.

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.

On site Verification 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.

HACCP PRINCIPLES

The Codex Alimentarius HACCP approach to food safety consists of seven key principles:

1. Conduct a Hazard Analysis
2. Determine the Critical Control Points CCP(s).
3. Establish critical limits.
4. Establish procedures to monitor the CCP(s).
5. Establish corrective actions to be taken when monitoring indicates a CCP is not under control.
6. Establish procedures for verification to confirm the HACCP system is working effectively.
7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

Taking each principle step in detail:

Principle 1: Conduct a hazard analysis
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:

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- 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.

A flow diagram of the process is put together, itemising all the steps in the process, from the acquisition of raw materials to consumption by the final consumer. The flow diagram must then be verified by the HACCP team.

A hazard analysis is then undertaken, consisting of an evaluation of all procedures concerned with the production, distribution and use of raw materials and food products to:

- Identify potentially hazardous raw materials;
- Identify potential hazards throughout the process, or points at which acceptable hazards could increase to an unacceptable level;
- Determine the likelihood of the hazards occurring;
- Assess the risks and severity of the hazards identified.

Ingredient specifications, recipe formulation, processing and packaging criteria must all be known. Management routines, process details and general factory operations will also need to be taken into consideration in order for all the potential hazards to be assessed.

Principle 2: Determine Critical Control Points (CCP' s)

At this point, the stages in the process which must be controlled adequately to assure product safety are identified. Example of common CCPs are:

- Time/temperature conditions required to destroy given pathogens (e.g. pasteurisation);
- Freezing and time to freezing before pathogens can multiply;
- Formulation where the ingredients affect pH or aw.

There are various ways of identifying CCPs. For a CCP to occur:

i. a preventative measure must exist; and
ii. the process step should be specifically designed to eliminate or reduce a hazard; or
iii. if ii. is not applicable but the hazard could increase to unacceptable levels without the preventative measure; and
iv. a subsequent step will not eliminate or reduce the hazard.

A "CCP decision tree" can also be used, whereby a series of questions ena¬bles the CCPs to be established.

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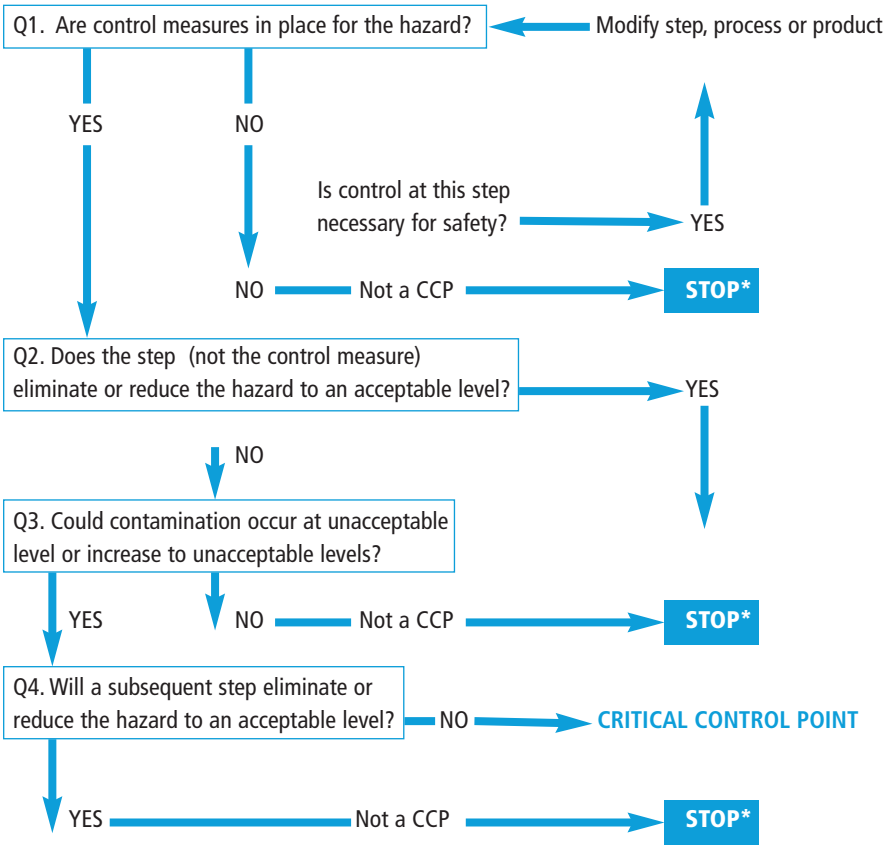
CCP Decision Tree

Step.....Hazard No.....

Answer each question in sequence at each step for each identified hazard:



* Proceed to the next step in the described process

The determination of CCPs will depend upon the food being prepared, the process involved and the equipment used. The same process might not have the same CCPs if there are differences in operation or a particular step might be intended to do different things.

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Principle 3: Establish critical limits

Once the critical control points have been identified, appropriate control measures should be implemented. For all hazards, critical limits must be established and meet with specified tolerances to ensure the safety of the product. For example, critical limits may need to be set for: temperature time ratios, the pH or aw of the final product; temperatures during cooling.

Principle 4: Establish Procedures to monitor CCP' s

Procedures must be implemented to monitor each CCP to check that it is under control and within the set critical limits. The procedures should accurately measure the chosen factors which control a CCP and usually depend on observations and physical or chemical measurements (e.g. temperature, pH, salt concentration). Results should be obtained immediately so that the process can be quickly adjusted if necessary. Microbial results are generally not satisfactory at this stage as too much time is required for results, although rapid testing methods are now available. Records of the results should be taken as part of an assurance of safety and for subsequent review.

Principle 5: Taking corrective action

If monitoring indicates that a process is out of control, or that critical limits are not being met, immediate action must be taken. The course of action taken will depend upon the process being monitored, and may include reheating or reprocessing, decreasing pH, adjusting the concentration of certain ingredients or discarding the product. The decision will be based on the hazards, their severity, the risks involved and on the expected use of the product. The person responsible for making the decision as to the course of action must be clearly defined.

Principle 6: Establish procedures for verification to confirm the HACCP system is working effectively.
It is essential to keep records that supplement the HACCP system. These will help to ensure that CCP' s are regularly monitored and may highlight weaknesses in the process. The records will demonstrate whether the HACCP system is operating correctly and if the product is being manufactured safely.

Principle 7: Establish documentation concerning all procedures and records appropriate to these principles and their application.
In order to verify that the HACCP system is working, supplementary information is often used. This is where microbiological examination of the product during and/or after processing has its place in the HACCP system.

Verification includes a review of the HACCP plan to determine whether all hazards have been detected, all critical control points identified, critical limits are appropriate and monitoring procedures are effective. Checks should also be made to ensure that the flow diagram is still valid. Records should be reviewed to check the effectiveness of the monitoring. A planned, regular auditing programme is also advisable.

VALIDATION

Validation - the process of confirming that all the elements of a HACCP plan have been considered and will be effective. This is usually carried out before implementation of the plan or as part of an annual review to ensure that the HACCP plan is still relevant and up-to-date.

A validation exercise involves the examination of each HACCP principle or step and should include the following questions:

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- Was the correct mix of skills included in the HACCP team and are they trained in HACCP?
- Does the scope of the HACCP plan(s) include all parts of the operation?
- Are all plans up-to-date and has an annual review been conducted?
- Have all plans been authorised by appropriate personnel?
- Does the scope include the appropriate groups of hazards e.g. microbiological, physical and chemical hazards?
- Is the flow diagram accurate?
- Have all significant hazards been considered during CCP identification? This requires a technical understanding of hazards as related to the process under consideration.
- Is the risk assessment process and CCP decision-tree suitable for all products and processes?
- Have practical CCP' s been identified to control significant hazards?
- Have suitable critical limits been set?
- Will the monitoring system ensure that the control measures are effective?
- Have suitable corrective actions been identified?
- Has HACCP awareness been communicated to the workforce?

The HACCP plan should also be reviewed and validated when any of the following changes are made:

- A new product is added to the range (as part of the product development procedure)
- Change in raw material / product formulation
- Change in processing system
- Change in factory layout
- Modification to process equipment
- Receipt of information from the market place indicating a health or spoilage risk associated with the product
- Emergence of food borne pathogens with public health significance

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The objective of this exercise is to ensure that the HACCP plan remains relevant and effective.

Verification (or Audit)

Verification - An examination of the HACCP system to ensure it has been correctly implemented and that all predicted hazards are being controlled.

HACCP system verification should be completed at regular and scheduled intervals as part of an overall auditing plan. Often individual control points or products are audited at different times during the course of the year. This results in full verification on an annual basis and will ensure that the system is continually, correctly operated regardless of product, process and personnel changes.

A HACCP plan will consist of a number of critical control points. Effective verification is therefore achieved by checking that the systems are in place to control these critical hazards, the controls are being consistently applied and monitoring confirms that they are working effectively.

During a verification audit it is important to investigate any anomalies or non-conformances to the system found during the audit, note any concerns that cannot be resolved and ensure that any problems are clearly understood and supported by evidence. It is equally important that these anomalies or non-conformances are corrected and action is taken to prevent re-occurrence.

Verification or audit procedures may include the following questions:
- Are there instructions and control documents for the CCP at the monitoring point?
- Are these up-to-date?
- Are any indicated targets and tolerances correct?

- Is any measuring equipment calibrated?
- Is the procedure being correctly followed?
- Are records clear, completed and to specified frequencies?
- Is there any evidence of corrective action where required?
- Is the operator trained?
- Are records signed and dated?

Other Verification/Audits

Other non-critical control points or generic/"foundation" controls, such as pest control or hygiene, may be verified/audited as part of an overall auditing plan. Such controls are often documented in a similar way to HACCP but may be referred to as Quality Critical Control Points or even Business Critical Control Points.

A smaller business with no formal quality system in place may find it useful to include these areas in their audit schedule or as part of their HACCP Verification/Auditing Procedure.

These controls, whilst not usually individually critical in terms of food safety, can have a significant effect on critical controls and should therefore not be overlooked. Examples of other audits and some of the areas to consider are given on the following page:

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Pest Control
- Is the pest control contract in place?
- Are the visits up-to-date?
- Have the recommendations been actioned?
- Have any other problems been found?

Personnel
- Has the relevant staff received specific training for the work they are expected to do?
- Has induction training being completed?
- Is the hygiene awareness training up-to-date?
- Has refresher training been completed?
- Are staff complying with hygiene rules?

Buildings & Equipment
- Are buildings still in good repair?
- Are proofing measures still in place?
- Are glass or other foreign body controls still in place and adhered to?

Cleaning
- Are the approved chemicals being used?
- Are the correct concentrations and contact times being used?
- Are the approved cleaning procedures being adhered to?
- Do staff still have the correct equipment?
- Are the results of microbiological swabs or tests within the standards?
- Have the appropriate visual checks been completed?

Suppliers
- Are ingredient specifications for critical ingredients on file?
- Are they current and up-to-date?
- Have the agreed supplier audits / questionnaires been completed?
- Have any corrective actions been completed?
- Are any non-approved suppliers being used?

Intake
- Is the agreed sampling / testing of ingredients being adhered to?
- Have any problems been found?
- Have out of specification ingredients been rejected / suppliers informed?

Storage
- Have ingredients been stored under the correct conditions e.g. temperature?
- Are shelf life stock rotation procedures being adhered to?

Traceability
- Are traceability codes recorded as specified in the quality system?
- Can ingredients be traced back from a finished product?
- Can finished products be traced forwards from a specific ingredient?

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Frequency of Audits

How often should HACCP verification audits be completed? This depends on the type/size of a business and the relative importance of a CCP, with some checks for critical issues such as storage temperature; cooking and cooling often audited daily or weekly as part of routine QA checks. Other points may be checked every few weeks or months. Verification of the complete HACCP system should be undertaken annually as a minimum.

Summary

Validation of a HACCP plan:

- Ensures that the elements of the HACCP plan are relevant and are capable of being effective.

Verification audits:

- Provide evidence that the HACCP plan is effective.
- Maintain confidence in the HACCP system through confirming its effectiveness.
- Provide documented evidence of due diligence.
- Identify areas for improvement.
- Provide confirmation that what is actually happening complies with the documented HACCP plan.
- Helps to meet the requirements of the BRC standard and other customer standards.

Auditors should therefore examine a HACCP plan (validation) and then assess if critical control points are being effectively controlled by a combination of observation and examination of records (verification)

CONCLUSION

The successful application of HACCP requires the full commitment and involvement of management and the work force, resulting in improved assurances of product safety, fewer customer complaints and greater production efficiencies. By focusing attention on the factors that directly affect the safety of any food, it eliminates the wasteful use of resources on irrelevant considerations.

The data collected throughout hazard analyses can also be used for training and educational purposes. The HACCP system and approaches similar to it have been valued to such an extent that they are included in EU Regulations (EC) No 852/2004. The application of HACCP is also compatible with the implementation of quality management systems, such as the BRC Global Standard For Food Safety V5 and ISO 9000 series, and is the system of choice in the management of food safety within such systems.

A HACCP system is not static but will evolve as new products are made and equipment purchased. A formal annual review must be carried out to ensure that all changes have been captured, assessed and appropriate action taken.