UNIT 11 PRINCIPLES AND IMPLEMENTATION OF HACCP

Structure

11.0 OBJECTIVES

After reading this unit, we shall be able to:

- outline the steps for implementation of HACCP;
- construct decision charts and decide a critical control point;
- develop a system to implement HACCP; and
- formulate ways to ensure the critical points are in check.

11.1 INTRODUCTION

The HACCP system is a scientific, rational and systematic approach for identification, assessment and control of hazards during production, processing, manufacturing, preparation and use of food to ensure that food is safe when consumed (i.e. it does not present a risk to health). With the HACCP system, food safety control is integrated into the design of the process rather than the present ineffective system of end-product testing. Therefore, the HACCP system provides a preventive and thus a cost-effective approach to food safety. The main responsibility for the implementation of a HACCP-based approach to food safety lies with industries involved in all stages of the food chain, policy makers and planners who have the mandate to facilitate the adoption of HACCP systems, and government authorities, including legislators, regulatory food control officials and health education bodies.

The prerequisites for implementation of HACCP include Good Manufacturing Practices (GMP) and other requirements as per Good Hygienic Practices (GHP). These have already been discussed in the previous Unit. Henceforth we shall elaborate the implementation of HACCP in any industry/ establishment.

11.2 IDENTIFICATION OF HAZARDS AND CONTROL MEASURES

11.2.1 Assemble HACCP Team

The food operation should assure that the product specific knowledge and expertise is available for the development of an effective HACCP plan. Usually, a multidisciplinary team is preferred to ensure that informed unbiased assessments with each aspect of hazard analysis are made. Where such expertise is not available on site, expert advise should be obtained from other sources such as trade and industry associations, independent experts, regulatory authorities, HACCP literature and HACCP guidance (including sector specific guidelines).

Each team member should have been trained in HACCP and have a working knowledge of the process/ product under study. A typical HACCP team consists of:

i) a manager or supervisor responsible for the process under study,

ii) an engineer,

iii) a Quality Assurance manager, and

iv) a microbiologist.

This team will be the core group; other experts can be called in as required. A team leader should be appointed to guide the discussions, and a secretary to record the decisions. The conclusions reached by the team can be summarized on a HACCP data sheet (see Table 11.2).

Defining the scope

The scope of HACCP plan should be identified, such that the segment of the food chain involved is properly defined and the general classes of the hazards to be addressed.

The potential food safety concerns of the study, including the types of microorganisms, chemicals and foreign materials of concern must be defined. It is important to limit the extent of each HACCP study in order to keep it manageable. Each study should examine specific pathogens, chemicals and physical contaminants that may affect the safety of a particular product or group of products. In this way, it can be precisely defined for which hazards controls have to be established. For example, the scope of four different studies might be:

- *Listeria* and *Salmonella* species, which are infectious pathogens, as potential hazards in soft cheese,
- Allergens in residues of other products in shared processing lines,
- Pesticides as contaminants in raw materials and in the line environment, and
- Foreign material in finished products.

Often, several studies are needed to establish a complete HACCP plan.

11.2.2 Describe Product

A very essential part of each HACCP study is the collection and evaluation of data concerning the raw materials, the formulation of the product, the processing, storage, distribution, sales, preparation and use conditions. This involves an in-depth study of the processing and supply chain and expected use by the consumer. 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 such as heat treatment, freezing, brining, smoking etc.; packaging, shelf life and storage conditions, and method of distribution.

The major points to be considered are:

1) **Formulation**: the raw materials and ingredients to be used and the parameters which may influence the product's safety or stability.

2) **Processing:** the process parameters and conditions which affect or may create the hazards.

3) **Packaging**: protection against contamination with chemicals or (re)contamination and growth of microorganisms (permeability, integrity, tamper protection are relevant aspects).

4) **Storage/handling**: the time and temperature conditions and handling in distribution centres, retail outlets and kitchens.

5) **Customer practices**: use by the consumers, caterers or professional cooks (cooking, reheating, thawing, reconstitution, storage, re-use).

6) **Target groups**: the end user (infants, adults, the elderly, immuno-compromised or sick people).

All of these factors must be taken into account to determine the probability of the presence of unacceptable levels of hazards at the moment of consumption if they are insufficiently controlled.

11.2.3 Construct Flow Diagram

The next task is to produce a process flow diagram to serve as a guide for the study. The diagram should cover all steps in the operation for a specific product i.e., it should describe all the raw materials and the processing and packaging steps. It should include the data needed for microbiological, chemical and physical hazard analysis; for example, information on the likelihood of contamination with chemicals and foreign materials, as well as microorganisms and their toxins. Data are needed on time and temperature throughout the process and distribution, as well as on acidity (pH) and water activity (aw) conditions.

Table 11.1: Examples of technical data that may be required for a HACCP study

Epidemiological and legal data on microbial pathogens, toxins and chemicals	Incidence of food borne illness (especially if related to similar product).
	Results of surveillance programmes and sentinel studies.
	Legal microbiological food safety criteria and Maximum Residue Limits.
Food Safety data	Likely presence of microbiological and chemical hazards in raw materials.
	Growth rates of pathogens in food products.
	Death rates of pathogens under a range of conditions.
	Fate of chemicals and toxins during processing, storage, distribution and use.
Raw material, intermediate and final product data	Formulation
	Acidity (pH)
	Water activity (aw)
	Packaging materials
	Product structure
	Processing conditions
	Storage and distribution conditions
	Shelf life
	Consumer use instructions, package labelling, including code dating practices.
Processing data	Number and sequence of all processing stages including storage.
	Range of product time/temperature conditions.
	Handling of rework (recycled material from the manufacturing process).
	High/low risk area separation.
	Flow conditions (for liquids).
	Presence of void spaces in processing equipment.
	Efficacy of cleaning and disinfecting.

Hygienic design, equipment characteristics, intermediate storage conditions and instructions for consumer use (Table 11.1). The same flow diagram may be used for a number of products manufactured using similar processing steps. When applying HACCP to a particular operation, considerations should be given to steps preceding and following the specified operation.

Check Your Progress Exercise 1

Note: a) Use the space below for your answers.

b) Compare your answers with those given at the end of the unit.

1) Name the specialisations of people in HACCP implementation team?

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2) List the points to be considered for describing the product for HACCP implementation.

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3) With whom does the responsibility for HACCP implementation lie?

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4) What type of data is required for microbial pathogens, toxins and chemicals' evaluation of food?

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On-site confirmation of the flow diagram

The team should confirm the flow diagram by examination at the production site of all stages and hours operation or the manufacturing process, e.g. inspecting processing lines and storage facilities. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

11.3 DETERMINATION OF SIGNIFICANT HAZARDS

First, the HACCP team should list all the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption. Then, to identify significant hazards, a number of questions, such as those in the decision tree of Fig. 11.1, have to be answered for each hazard that could be of concern at each food production step. One of the first questions would be: is it probable that the potential hazard is present in the raw material? When the answer is NO, this potential hazard in this raw material is of no concern (indicated with "no hazard" in Fig. 11.1). This is also the case when the hazard under study is not likely to be in the processing line or environment. Equally, if the hazard may be present, but the product itself will not be contaminated, it is not a significant hazard. However, if contamination was possible, further questions would have to be considered at each process step. For instance is the presence at an unacceptable level probable or is survival, persistence or increase possible that leads to an unacceptable level of the hazard? Again the potential hazard does not need to be addressed in the HACCP plan at this step if the answer is NO. When the answer is YES, the next question would be is the reduction, if any, at a later step adequate to reduce the hazard to the acceptable level? If YES, the potential hazard is not further considered at this step (but the reduction step becomes a CCP). If the answer is NO, a significant hazard has been identified, for which control measures have to be established.

11.3.1 Determination of Acceptable Levels

For many agents of a biological or chemical nature, a potential hazard is not always a significant hazard with regard to the safety of the food. Many chemicals may only have an effect when ingested in a "high dose". Acceptable Daily Intake (ADI) and Maximum Residue Levels (MRL) have been established for these. Even for certain potential carcinogens tolerable/acceptable levels have been set; often the "as low as reasonably achievable" (ALARA) concept is used in practice when no limits have been established. For microorganisms the concept of acceptable levels is less applied, but here also the ALARA concept is practiced; different levels are accepted as tolerable for different pathogens, mainly depending on the severity of the potential health impact. For instance, it is widely accepted that pathogens such as *B. cereus* and *C. perfringens* cause only illness when present at high levels in a food (about 105-106 CFU/g). For *L. monocytogenes* many countries apply an acceptable level of <100 CFU/g at the moment of consumption. A similar reasoning may apply to physical hazards. The concept of acceptable levels is crucial for HACCP, as is clear from the definitions of control measures and CCP. It is also inherent to the definition of hazard: the potential to cause an adverse health effect. Whether it is causing harm will, amongst other factors, depend on the level.

11.3.2 Consideration of Control Measures

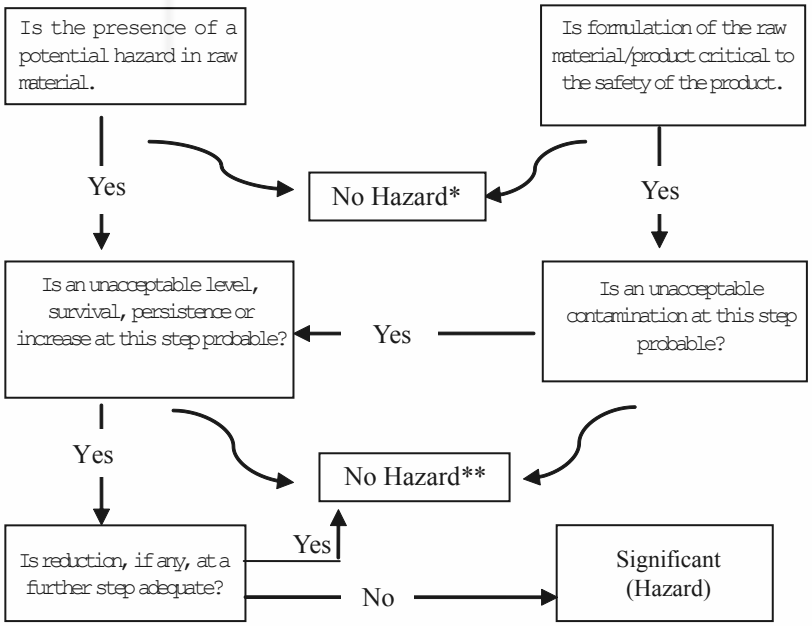
Hazards can be controlled in many ways. Heating can kill micro-organisms and their growth can be prevented or limited by low or high temperatures, low water activity, by preservatives, etc. Residues of veterinary drugs and pesticides can often be controlled by keeping a certain time between application and slaughter, milking or harvest which would reduce the residue to an acceptable level. Strict separation between raw materials and processed foods is a control measure that prevents or limits cross-contamination with pathogens. Cross-contamination in processing lines with allergens can be eliminated through appropriate validated cleaning procedures and/or sensitive consumers can be informed by appropriate labelling. Visual inspection, sieving, metal detectors etc. may be effective in controlling physical hazards. The various options for control measures have to be considered for each significant hazard.

11.4 DETERMINATION OF CRITICAL CONTROL POINTS

Once the significant hazards have been identified and control measures considered, the study team must determine the Critical Control Points (CCPs). The team should examine the entire process, and ask for each identified hazard, at each step, questions such as:

- Can the hazard be introduced into the product via the raw material under study? If this is the case, is it likely to be at, remain at, or increase to, unacceptable levels?
- Is the formulation/ composition of the raw material/ product critical to the safety of the product?
- Does the process under study make the final product safe by reducing the hazard to an acceptable level, or by keeping it from increasing to dangerous levels?
- At this step, can the hazard be introduced into the product from the processing line or the environment, and if so, is it likely to be at, remain at, or increase to, unacceptable levels?

Questions to be answered for each potential hazard at each step



* Not a hazard to be controlled at this step.

** Reduction step thus becomes a CCP.

Fig. 11.1: Hazard determination

The decision tree in Fig. 11.2 can be helpful to identify CCPs. Questions 1 and 2 in Fig. 11.2 apply to the raw materials, and questions 3 to 6 apply to the process stages. Clearly, some of the questions are similar to the ones used to identify the significant hazards because of the conceptual link between hazards and CCPs. Hazard determination emphasises identification of hazardous agents which may reach the consumer when not properly controlled; during the determination of CCPs, the emphasis is on the identification of the sources of, or conditions leading to, the hazards, and on the measures to control them. At each process step, the team should consider the possible consequence of a deviation from the "normal". Good manufacturing practices (GMP) procedure, whether such a consequence could be unacceptable with regard to food safety, and the probability that it will occur. Moreover, the team must consider what happens to the product later on, to determine whether the process step is critical. A large amount of technical data may be needed for making decisions (Table 11.1). If the analysis suggests that it is not possible to control the hazard at a certain step, and that the hazard (or product) should be modified to eliminate the point. HACCP may be a raw material, formulation, location, practice or process stage, but it must be specific, for example:

- a raw material with regard to the "absence" of specified contaminants,
- acidification of a food to a specified pH,
- drying a food under conditions that prevent pathogen increase,
- the chlorination step of can cooling water, or
- product pasteurisation step.

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.

11.5 ESTABLISHING THE CRITICAL LIMITS

The team must define the critical limits that assure that a hazard is under control. The critical limit is the value that separates acceptability from unacceptability for each CCP. They are the maximum values that should never be exceeded. In order to assure this, target values may be established. They take into consideration the variability of control measures. By making these target values more stringent they ensure that critical limits are always met. This can be seen in Table 11.2, which illustrates how a HACCP data sheet might be compiled. These target values are the process parameters necessary to achieve the required performance criteria that need to be validated.

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, water activity (aw), available chlorine and sensory parameters such as visual appearance and texture.

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

Check Your Progress Exercise 2

Note: a) Use the space below for your answers.

b) Compare your answers with those given at the end of the unit.

1) Elaborate:

ADI ……

ALARA ……..

2) How are critical limits for any hazard determined?

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3) If a hazard is present in raw material, what is the next question to be asked for decision making in HACCP decision tree?

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11.6 ESTABLISHMENT OF A MONITORING SYSTEM

A monitoring system must be established, to ensure that each CCP is always under control, that is, that the critical limits or target values are met. This is illustrated in Table 11.2, which identifies the CCPs (what must be controlled and where control is achieved) and describes the associated control procedures (how the hazard will be controlled). Data derived from monitoring must be sufficient to guarantee that the CP is in control. Monitoring methods should be rapid to be effective. Physical/ chemical tests and observations are preferred, even for microbiological purposes, because microbiological methods tend to be time consuming. Ideally, they should allow adjustments to be made before the situation becomes unacceptable. In practice this means that the frequency of monitoring is linked to the volume of a product that is produced between two monitoring measurements. If a monitoring result shows that an unacceptable deviation occurred (i.e. the critical limit was exceeded), the product should not reach the consumer. The amount of product to be rejected, reworked or further investigated depends on the time passed since the last monitoring result showed that the situation was under control. Full records must be kept of all monitoring data for management, audits, trend analysis and scrutiny by inspectors.

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.

11.7 ESTABLISH CORRECTIVE ACTIONS

When critical limits are not met, the "out of control" situation should be rectified immediately and appropriate follow-up actions taken. These 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. All these actions should be planned and described during the HACCP study.

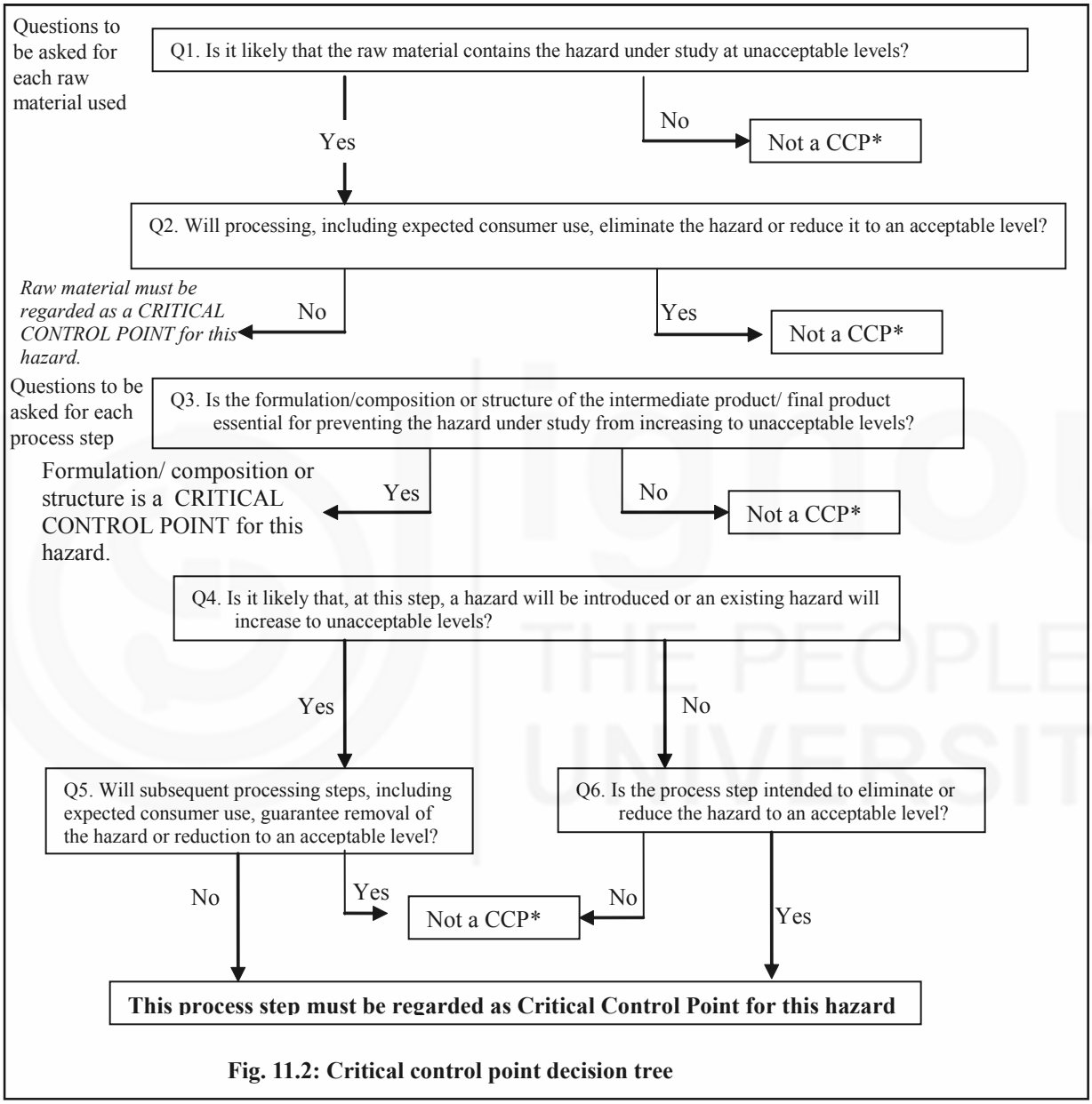

Fig. 11.2: Critical control point decision tree

From Table 11.2 two examples are taken, chlorination of cooling water and pasteurisation of milk. At the CCP where the chlorine level of the cooling water is critical, a concentration of less than 1 ppm should lead to an immediate adjustment of the chlorine dosing. If chlorine is absent, the batch should not be released until further examination has demonstrated that the product is safe.

At pasteurisation, a temperature drop below 71.7°C should result in re-pasteurisation (via a flow diversion valve), adjustment of the heating equipment and an examination of the pasteurisation operation to find out why it happened. Once the cause of the problem has been identified, further corrective actions should be taken to prevent it from happening again.

Monitoring data should be examined systematically to identify the points where controls should be improved or where other modifications are needed. In this way, the system can adapt to changes by constant fine-tuning.

11.8 ESTABLISH VERIFICATION PROCEDURES

Verification is a very important element of HACCP and should always be included. 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. Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP system. Example of verification activities include:

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

It is intended to provide additional information to reassure the producer (and the inspector) that application of HACCP results in the production of safe foods. It comprises two distinct activities, i.e. demonstrating conformity with the HACCP plan (are we doing what we planned to do?) and data gathering (did we meet our objectives, can things be improved?). It includes activities such as inspections and audits as well as the use of classical microbiological and chemical contaminant tests to confirm that the control measures operate as designed. Samples examined by inspection services and reviews of customer complaints can in certain cases also provide insight into the proper design and implementation of the system. Verification is different from monitoring. The gathered data may indicate, for instance, that certain things were overlooked in the HACCP plan or that the monitoring procedure is not good enough to assess the level of control. It may also indicate that the quantity of product that is kept on hold for further investigation, to determine release or no release, is too large, indicating that the frequency of monitoring should be increased. It may provide information that, in practice, the product is used in a manner other than was foreseen during the HACCP study. As a consequence, changes in the HACCP plan need to be made. Verification is an ongoing activity, some aspects, e.g. environmental and product sample testing, may be specified in the HACCP plan, others may be done whenever there is a need. Certification is a specific form of verification. It is performed by independent third parties; it deals with checking that a certain HACCP system, as described in a "HACCP Standard", was applied. An auditor from a certification body will report on the business' performance in relation to the standard, but will normally not provide a judgement concerning the product's safety.

11.9 ESTABLISH DOCUMENTATION AND RECORD KEEPING

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 assist the business to verify that HACCP controls are in place and being maintained. This ensures that information gathered during the installation, modification and operation of the system would be readily

accessible to everyone involved in the process as well as to outside auditors. It also helps to ensure the long-term continuity of the system. Records should include explanations of how the CCPs have been defined, descriptions of control procedures and modifications to the system, monitoring and verification data, a file of deviations from normal practice and corrective actions.

Documentation examples are:

- Hazard analysis,
- CCP determination, and
- Critical limit determination.

Record examples are:

- CCP monitoring activities,
- Deviations and associated corrective actions,
- Verification procedures performed, and
- Modifications of the HACCP plan.

An example of a HACCP worksheet for the development of a HACCP plan is provided in Table 11.2. A simple record-keeping system can be effective and easily communicated to the employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperature.

11.10 VALIDATION

Before the HACCP plan can be finalised and implemented essential elements need to be validated. Evidence must be obtained that the control measures indeed achieve what was intended. For example, does the heat treatment carried out to render a canned product safe achieve the 12 decimal reduction (12D) of *C. botulinum* spores as required? Is the description on the label for preparing a frozen meal in a microwave oven sufficient for the purpose? Does the formulation of the product keep growth of the hazard under control? In simple terms, validation means: does the evidence show the hazard(s) will be controlled? This is different from verification where the question is: were the things done correctly? Validation is in principle carried out before control measures or changes in control measures are implemented and as such it is putting the proverb "look before you leap" into practice.

11.11 GENERAL ERRORS IN HACCP PLANS

Some common anomalies were pointed out during one study carried out in Italy*, in HACCP systems in various retail, hospitality and food industry sectors. These included:

Voluminosity: Well-packaged self-monitoring plans were examined with good typographical layout and coloured sheets, but that were filled with superfluous elements such as the legislation, philosophy and the history of HACCP. These elements invalidated rapid consultation of the plan, making the plan lack in the

***Panunzio1 M.F., Antoniciello1 A., Pisano1, A. and Rosa G. (2007).** *Int. J. Environ. Res. Public Health 4(3): 228*

inspiring motto "only write what you have to do, do what you have written".

Redundancy: A few plans did not follow a precise table of contents for their subjects but rather many things were repeated in different parts of the plan. This resulted in rather difficult specific, immediate and unambiguous comprehension of the procedures to be followed.

Besides **Confusion of critical limits**, hazard non-specificity and lack of a time plan for the control were also observed.

The sheets were not drawn up following the production flow chart but rather by homogeneous phases of the production process. The application of the **decision tree** in identifying the CCP was ignored. The decision tree is a diagram indicating a few questions/answers, built on the flow of the production activity. Its use is an essential tool to remove the inherent subjectivity in self-monitoring.

Non-specificity of the hazard refers to the generic wording such a biological, physical or chemical contamination. If the hazard is non-specific, it goes without saying that the rest of the plan can only be generic and therefore useless.

Finally, a few plans did not indicate a **time plan** for the controls to carry out, therefore there was no precise agenda to follow for hazard self-monitoring measures.

11.12 QUANTITATIVE APPROACH IN HACCP

HACCP is quantitative by nature, and in its simplest form descriptors are used to determine the probability/ likelihood that something may happen. Such descriptors are, for instance, found in the hazard determination tree: is the presence of a potential hazard in a raw material probable? The same question could be worded as: is presence possible or likely? Using these three different descriptors, often different answers will be obtained. For example, the presence of *Salmonella* in sugar is possible, but normally not likely. Examination of raw materials may provide numerical values that can be used to decide whether presence will be possible, probable or likely.

Another example deals with the selection of significant hazards from the list of potential hazards. This selection is based on the likelihood of their occurrence in the final product at levels that are unacceptable. Thus, judgements have to be made and decisions have to be taken based on quantitative considerations.

When determining CCPs, for example, the seriousness of a deviation from the normal Good Manufacturing Practices has to be estimated. If the deviation would have little or no impact on a product's safety, the process step would remain to be covered by GMP. However, if the deviation would have a major impact on the product's safety, the process or handling would become a CCP. Inherent to this decision is that the magnitude of this impact is related to the size or the seriousness of the deviation. Furthermore, at each CCP, the critical limits that have to be established are of a quantitative nature.

However, at present, the implementation of a truly quantitative approach to HACCP in relation to defined food safety goals is difficult because the indication

of what is acceptable and what is not with regard to the safety of a food is not specified in most regulations or guidance documents. This hampers are the clear definition of the level of control that is needed to ensure that the appropriate level of protection of the consumers is achieved. In practice, a "benchmarking" approach often provides a useful indication of product safety. Most foods that have been processed to assure safety have an excellent record.

Thus the level of a hazard obtained with GMP and HACCP can, based on the epidemiological evidence, be considered to be acceptable without expressing explicitly in quantitative terms what this level is. New products or changes in raw materials, processes, formulation, commercialisation, preparation and use, can be evaluated using such a benchmarking approach.

Recently, the concept of Food Safety Objectives (FSOs) has been introduced to provide a more formal guidance on the level of control necessary.

11.12.1 Food Safety Objectives

A Food Safety Objective (FSO) is a statement of the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection. Although, the FSO concept is relatively new and is still evolving, it offers a practical means to convert public health goals into quantitative values that can be used by regulatory authorities and by food producers and manufacturers to manage food safety all along the food chain.

FSOs are established according to a participative, interactive and transparent process involving the regulatory authorities, the industry at large, the consumers and other interested parties. The limits indicated in an FSO reflect the best available scientific information, as well as technical and societal considerations from other sources. In particular, it should be evidenced that FSOs can be met by adequate GMP and HACCP systems.

As an example, an FSO could be expressed as: "the level of *Listeria monocytogenes* in ready-to-eat foods must not exceed 100 CFU/g at the time the foods are consumed". FSOs can be used by health authorities to communicate clearly to producers/manufacturers what is expected of foods produced in properly managed processes. The FSOs form the basis on which these authorities can establish standards and guidelines. These should form the basis of assessments whether an operation is producing safe foods, i.e. whether the food does not exceed, under normal conditions of commercialisation and use, the established FSO.

The food industry at large (primary food producers, processors, retailers, caterers etc.) can use FSOs as a basis to manage food safety throughout the food production chain. This is done by translating the FSOs into a set of quantitatively stated requirements that would assist in the appropriate design of products, processes and control measures, i.e. compliance with the appropriate level of protection as expressed through the FSOs, while providing for flexibility of operation. FSOs also provide the necessary basis for validation.

11.12.2 Numerical Calculations in HACCP

An FSO (or a benchmark) indicates the maximum level of a hazard at the time of consumption that should not be exceeded. In order to achieve this, it is necessary to consider the possible initial level of a hazard in a (semi-) raw product from primary production, and how this level may change (potential for growth, inactivation and recontamination) during the different steps in production, distribution, storage, preparation and final use of a product.

The hazard level which is acceptable at a specified step earlier in the food chain (which is called Performance Objective, PO) can be established using FSO as a guide. Knowing the contamination level at the start of a particular step, the effect (for example in terms of number of decimal reductions of a given pathogen) required in order to meet the acceptable level at the end of the step can be determined. One or more control measures may need to be applied at one or more steps in the food chain, or within a given process, in order to achieve this effect. The required effect of the control measure(s) that need to be applied (for example in terms of number of decimal reductions of a given pathogen) in order to meet the acceptable level can be determined. Within the framework of HACCP, the determined effect of the control measure is used as a guide to establish the critical limits at the relevant CCPs.

For example, if an FSO for *Listeria monocytogenes* in a ready-to-eat product that does not support growth of this pathogen were to be set at 100 CFU *L. monocytogenes*/g at the moment of consumption, the acceptable level (PO) at the moment of commercialisation should be the same or targeted lower. An example is given in Fig. 11.3. It is assumed that:

a) The initial number is around 1 CFU/g of the raw material;

b) The heat treatment achieves a 3-decimal reduction;

c) Re-contamination of the product cannot be prevented, but does not reach a level of more than 1 CFU/100g of product when GHP is effectively applied, and

d) The condition of the product does not allow multiplication of *Listeria* during commercialisation and use.

In this situation, the PO could be set at 1 CFU of *L. monocytogenes*/100g to restrict the recontamination as much as possible. Clearly, with this PO, the FSO will not be exceeded. When such calculations are made, the critical limits needed to achieve the required acceptable levels can be determined and validated.

11.12.3 Validation of Numerical Values

The expression of the result of control measures in quantitative terms greatly facilitates their validation, i.e. obtaining evidence that they are effective. In principle all requirements that have been set to assure that a safe product is obtained should be validated. For example, if the initial number of *Listeria monocytogenes* in a raw product should be less than 1 CFU/gram, this must be validated. If the re-contamination of a product with *Listeria monocytogenes* should be less than 1 CFU/100 gram, this must be validated. If the maximum increase of *Listeria monocytogenes* in a certain product that supports growth should be no more than a factor of 1000 before the food is eaten, this should be validated.

Data providing evidence on the performance of control measures can be found in historical data, scientific literature, codes of GMP, generic HACCP plans, growth models, small scale tests, etc. but it must be made sure that these are pertinent for the specific product and manufacturing or preparation conditions. Experimental studies such as challenge and storage tests may need to be carried out to obtain this pertinent information.

Recently, much progress has been made in applying microbial modelling and computer simulation techniques to quantify the behaviour of microbial hazards associated with certain specific process steps used in the food industry. When properly validated, these techniques are of value in the development of numerical calculations for validation of control measures and the effectiveness of HACCP plans.

11.12.4 HACCP and Microbiological Risk Assessment (MRA)

Microbial growth and inactivation models and computer simulations of the fate of pathogens in the food chain are also applied in the framework of Microbiological Risk Assessment (MRA). MRA is a procedure used by regulatory authorities to understand the likelihood of adverse effects as a consequence of the consumption of a certain pathogen/food combination.

There are many similarities between an MRA and the hazard analysis which is a part of a HACCP study. Both procedures identify hazards, study where and how they appear in the food chain, what the effect of potential control measures will be and determine the seriousness of potential health effects. The result of a MRA is primarily utilized by public authorities to decide whether the estimated risk would be acceptable or, if not, what would be the best options for its management. It is also one of the scientific bases that the public authorities would consider when establishing FSOs.

In this way, MRA may be indirectly linked with HACCP: outcomes of MRA and/or FSOs can be used to target the control measures at CCPs in a HACCP study. However, MRA is not needed to conduct a HACCP study.

Check Your Progress Exercise 3

Note: a) Use the space below for your answers.

b) Compare your answers with those given at the end of the unit.

1) What are the requirements for monitoring systems recommended for detecting hazard?

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2) What is the difference between verification and validation?

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11.13 WHEN TO IMPLEMENT HACCP PLAN

Ideally, a HACCP study should be carried out as part of product and process development, so that potential hazards can be "designed out" at the earliest stage. In any case, a HACCP study results in a HACCP plan that should be correctly implemented to ensure that the appropriate control measures are put in place before products are put on the market. A HACCP plan is the result of a HACCP study carried out for a specific product at a specific production site and is thus to be used for that product only. So-called generic or model HACCP plans can be used, however, to give guidance to the study team. After industrialisation or scaling up of the processing line, the HACCP study should be reviewed and the HACCP plan complemented when necessary. The study should consider all the differences in conditions between the pilot plant and factory.

For products currently manufactured without a HACCP plan, a HACCP study should be best carried out according to the guidelines described in this document. This ensures that no critical point has been overlooked, that appropriate control measures have been identified and implemented and that the required monitoring procedures and record keeping systems have been put in place.

A HACCP study should be carried out again prior to implementing any significant changes in, for example, raw materials and packaging materials, production line layout, product formulation or product use. Evidently, the existing HACCP plan should be updated to reflect the findings of the new study. Ideally, a HACCP study should be carried out as part of product and process development, so that potential hazards can be "designed out" at the earliest stage. In any case, a HACCP study results in a HACCP plan that should be correctly implemented to ensure that the appropriate control measures are put in place before products are put on the market. A HACCP plan is the result of a HACCP study carried out for a specific product at a specific production site and is thus to be used for that product only. So-called generic or model HACCP plans can be used, however, to give guidance to the study team. After industrialisation or scaling up of the processing line, the HACCP study should be reviewed and the HACCP plan complemented when necessary. The study should consider all the differences in conditions between the pilot plant and factory. For products currently manufactured without a HACCP plan, a HACCP study should best be carried out according to the guidelines described in this document. This ensures that no critical point has been overlooked, that appropriate control measures have been identified and implemented and that the required monitoring procedures and record-keeping systems have been put in place. A HACCP study should be carried out again prior to implementing any significant changes in, for example, raw materials and packaging materials, production line layout, product formulation or product use. Evidently, the existing HACCP plan should be updated to reflect the findings of the new study.

Table 11.2: HACCP Data sheet (Data in table are presented as examples only)

Point of Control (Raw material or process step)	Hazards or condition leading to hazards	Control measures	CCP Parameters	Critical Limits	Target values	Monitoring	Corrective Actions
Egg product (ingredient in mayonnaise)	Salmonella	Supplier's Quality Assurance	"Absence" of Salmonella in eggs	Negative in 5 random samples of 25 g	No target value	Supplier certification with shipping records, supplier audits, microbiological testing	Rejection of suspected lots
Incoming raw milk	Mycotoxins	Farmer's education, feed, supplier's QA	Aflatoxin M	Less than 0.1 ppb	No target value	Testing	Reinforcement of prevention programmes
Pasteurizer (in milk plant)	Salmonella, Listeria, Campylobacter etc.	Correct design and operation of the pasteurizer	Temperature and Time of pasteuri-sation	Not less than 71.7°C for 15 secs	73°C for 15 secs	Temperature/ flow rate recording; record of plant sensor calibration and diversion system operation	Repasteurisation
Chlorination of can cooling water	Recontamination with pathogenic microbes	Correct functioning of chlorine doser and monitor	Free available chlorine	1 ppm after cooling	1-3 ppm	Continuous chlorine monitor	Doser adjustment (Blocking of batch and investigation)
Endpoint of Jam	Inconsistency in heating system	Correct design and operation of heater and heating agent (steam)	TSS	68° Brix	68-70° Brix	Testing for TSS, or product temperature	Steam/ heating duration adjustment

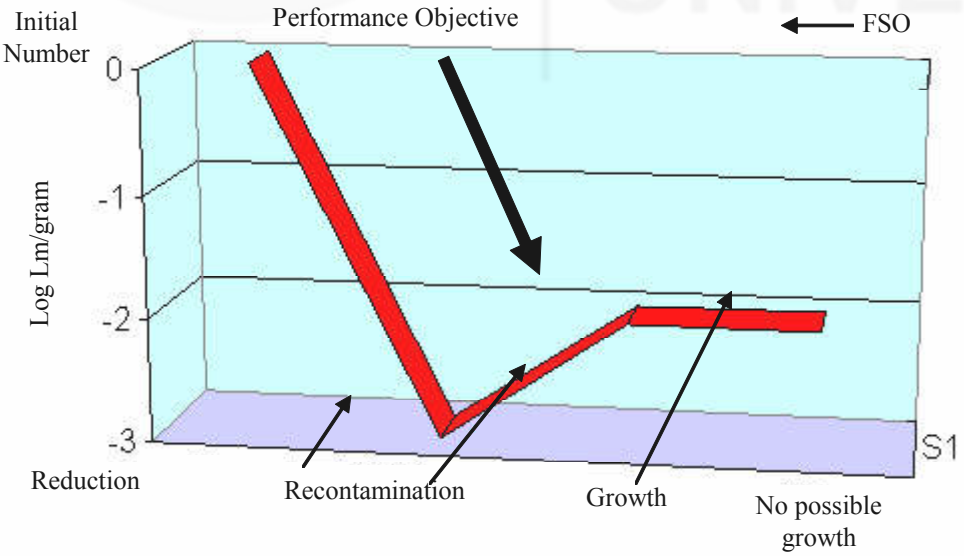

Fig. 11.3: This figure represents the fate of *Listeria monocytogenes* in a ready to eat shelf-stable food. The initial level of the pathogen in the raw material is around 1 CFU/g and a heat treatment is applied which achieves a 3-decimal reduction. Unfortunately, recontamination of the product cannot be prevented, but does not reach a level of more than 1 *L. monocytogenes*/100g of product which is set as the Performance Objective. The condition of the product does not allow multiplication of *Listeria* during commercialisation and use, therefore the situation described is consistent with an FSO of 100 *Listeria monocytogenes*/g

11.14 LET US SUM UP

HACCP is a scientific, rational and systematic approach for identification assessment and control of hazards during production, processing, manufacturing preparation and use of food to ensure that it is safe when consumed. It include assembling of HACCP team, describing the product and construction of flow diagram. It also include of determinate of hazards their acceptable limits and control measures and also the critical control points, their limit and monitoring system corrective actions for the hazards and verification procedures and creating documents and their record keeping is also a part of HACCP.

11.15 KEY WORDS

ADI : The acceptable daily intake (ADI) for man, expressed on a body weight basis, is the amount of a food additive that can be taken daily in the diet, even over a lifetime, without risk.

ALARA : ALARA or As Low As Reasonably Achievable; is also a concept which links risk management approaches with acceptability considerations. Both the level of risk and the severity of cases are used to categorize risk into intolerable, tolerable or acceptable regions.

Decision Tree : A logical reasoning approach to determine the CCP.

Epidemiology : Epidemiology is the study of factors affecting the health and illness of populations, and serves as the foundation and logic of interventions made in the interest of public health and preventive medicine. The work of epidemiologists range from outbreak investigation to study design, data collection and analysis including the development of statistical models to test hypotheses and the documentation of results.

Food Safety Objective : "The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)". It transforms a public health goal to a concentration and/or frequency (level) of a hazard in a food. The FSO sets a target for the food chain to reach, but does not specify how the target is to be achieved.

GHP : Good Hygienic Practices.

GMP : Good Manufacturing Practices.

Microbiological Risk Assessment : It has as its objective a characterisation of the nature and likelihood of harm resulting from human exposure to agents in food. The

characterisation of risk typically contains both qualitative and quantitative information and is associated with a certain degree of scientific uncertainty.

There are four very distinct steps in the risk assessment process. The first step is hazard identification, which involves the collection, organisation, and evaluation of all information pertaining to a pathogen or a nutrient. Second is hazard characterisation, which determines the relationship between a pathogen and any adverse effects. Third is exposure assessment, which involves determining how much of pathogen might be ingested in a serving of food. The fourth, and last step, is risk characterisation, which involves evaluating the risk and related information.

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

Performance Objective : The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or an appropriate level of health protection, as applicable.

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.

11.16 ANSWERS TO CHECK YOUR PROGRESS EXERCISES

Your answer should include the following points:

Check Your Progress Exercise 1

1) (i) a manager or supervisor responsible for the process under study, (ii) an engineer, (iii) a Quality Assurance manager, (iv) a microbiologist (v) team leader, and (vi) a secretary.

2) Formulation, Processing, Packaging, Storage/handling, Customer practices, Target groups.

3) Food industries involved in all stages of the food chain; Policy makers and Planners; Government authorities, including legislators, regulatory food control officials; and Health education bodies.

4) Incidence of food borne illness; Results of surveillance programmes and studies; Legal microbiological food safety criteria and Maximum Residue Limits.

Check Your Progress Exercise 2

1) Acceptable Daily Intake; As Low As Reasonably Achievable.

2) For chemical hazards, Acceptable daily intake (ADI) and Maximum residue levels (MRL), for certain potential carcinogens tolerable/acceptable levels have been set; often the "as low as reasonably achievable" (ALARA) concept is used. For biological hazards, ALARA concept is practiced; different levels are accepted as tolerable for different pathogens, mainly depending on the severity of the potential health impact. Similar reasoning is applied to physical hazards.

3) Is the presence at an unacceptable level probable or is survival, persistence or increase possible that leads to an unacceptable level of the hazard?

Check Your Progress Exercise 3

1) Monitoring methods should be rapid Physical/ chemical tests and observations are preferred, even for microbiological purposes. The frequency of monitoring should be linked to the volume of a product that is produced between two monitoring measurements.

2) Validation is obtaining evidence that the elements of the HACCP plan are effective while verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

11.17 SUGGESTED READING

HACCP Introducing the Hazard Analysis and Critical Control Points System (1997) Food Safety Series, Food Safety Unit, World Health Organisation.

Inteaz Ali (2004). *Food Quality Assurance: Principles and Practice*. CRC Press LLC, Florida, USA.

Jogeneel Susan (Ed.) (1999). *HACCP Principles and Practices: A WHO/ ICD Training Manual in collaboration with WHO*.