CODE OF PRACTICE
No. (6)/2011

IMPLEMENTING HACCP PRINCIPLES IN THE
FOOD MANUFACTURING SECTOR

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I. Introduction

HACCP has become synonymous with food safety. It is a worldwide-recognized systematic and preventive approach that addresses biological, chemical and physical hazards through anticipation and prevention, rather than through end-product inspection and testing. The system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food.

The HACCP system can be applied throughout the food chain from the primary producer to the consumer. Besides enhancing food safety, other benefits of applying HACCP include more effective use of resources, savings to the food industry and more timely response to food safety problems.

HACCP enhances the responsibility and degree of control at the level of the food industry. A properly implemented HACCP system leads to greater involvement of food handlers in understanding and ensuring food safety, thus providing them with renewed motivation in their work. Implementing HACCP does not mean undoing quality assurance procedures or good manufacturing practices already established by a company; it does, however, require a revision of these procedures as part of the systematic approach and for their appropriate integration into the HACCP plan.

While the application of HACCP to all segments and sectors of the food chain is possible, it is assumed that all sectors should be operating according to the Codex General Principles of Food Hygiene. The ability of an industry segment or sector to support or implement the HACCP system depends on the degree of its adherence to these practices.

The successful application of HACCP requires the full commitment and involvement of management and the workforce. It requires a multidisciplinary approach which should include, as appropriate, expertise in agronomy, veterinary health, microbiology, public health, food technology, environmental health, chemistry, engineering, etc. according to the particular situation.

This Code of Practice has been developed to give manufacturers guidance on how food businesses should comply with the internationally recognized Codex principles for the application of HACCP system. In order to meet regulatory requirements, it assumes that pre-requisite programs to ensure that premises, equipment, transport and employees do not contribute to or become food safety hazards are already in place. Without these basic principles (e.g. sanitation, pest control, personnel practices), a risk-based system such as HACCP will fail. As described by Codex ‘prerequisite programs to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system.’

II. SCOPE

This Code of Practice shall apply to the implementation of Codex based HACCP principles within the manufacturing sector. It reflects the requirements of Regulation No (6) 2010 Food Hygiene Throughout the Food Chain, which requires the implementation of a food safety management system in all food businesses:

The food business operator shall develop, implement and maintain food safety management systems based on the Hazard Analysis and Critical Control Point (HACCP) principles. (Article 100, Regulation 6)

The Code specifically excludes guidance on pre-requisite programs. It assumes these are already in place and have been validated, documented and verified routinely. Regulatory requirements for pre-requisites can be found in other sections of Regulation 6 and related documents.

III. RELATED DOCUMENTS

The following legislation issued by ADFCA are relevant to this Code of Practice and recommended to be read in conjunction with:

- Regulation No. (1) for the year 2008 Description of Violations Related to Food & its Handling
- Regulation No. (6) for the year 2010 Food Hygiene throughout the Food Chain
IV. DEFINITIONS
In addition to the definitions stated in the Food Law no. (2) for the year 2008 and its regulations, the terms and expressions indicated below shall apply unless the text indicates otherwise:

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

Control (noun): To 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

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 loading 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 a control measure, if properly implemented, is capable of controlling the hazard to a specified outcome.

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

Prerequisite programs: Steps or procedures that control the general operational conditions within a food establishment and promote environmental conditions that are favorable for the production of safe food.

1. HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) SYSTEM

1.1 THE CODEX HACCP REFERENCE STANDARD
HACCP is a system based on seven well-defined, theoretical risk management principles. However, during the first four decades of its development, there were many different opinions and confusion as to how these principles should be applied in practice. At the request of member nations, the Codex Alimentarius Commission established, in 1993, definitive guidelines for the application of HACCP principles to be used in conjunction with the existing Codex Guidelines for the application of pre-requisite programs. This "classical method" has become the definitive standard for the application of HACCP principles. As can be seen in Figure (2) below, it involves a twelve-step process that incorporates the seven principles.

2. THE CODEX TWELVE STEPS FOR THE APPLICATION OF HACCP
Figure (2): The Codex Protocol for the Application
2.1 STEP 1: IDENTIFY THE HACCP TEAM

2.1.1 INTRODUCTION

Prior to proceeding to HACCP team selection, it is extremely important to have full commitment to the HACCP initiative from management at all levels. Without a firm commitment, it may be difficult or impossible to implement the HACCP plan. Before the study is begun, management should inform all staff of the intention to implement HACCP. Both the company and the personnel involved in the development of the HACCP plan must be totally committed to its implementation.

The first task in the application of HACCP is to assemble a team having the knowledge and expertise to develop an HACCP plan. The team should be multidisciplinary and could include plant personnel from production/sanitation, quality assurance, laboratory, engineering and inspection. It should also involve representation from all levels of the organization for example, managers, supervisors and workers from the factory floor. It is essential to assemble the right blend of expertise and experience, as the team will collect, collate and evaluate technical data and identify hazards and critical control points. In smaller establishments, one person may fulfill several roles or even constitute the whole team. In the latter case the use of external consultants or advice may be necessary.

The team should also include personnel who are directly involved in daily processing activities, as they are more familiar with the specific variability and limitations of the operations. Their representation will foster a sense of ownership among those who will have to implement the plan. The HACCP team may require independent outside experts to advice on identified issues or problem areas; for example, an expert in public health risks associated with the product or process may be hired. However, complete reliance on outside sources is not recommended in developing the HACCP plan, as such an approach may lack the support of the plant personnel.

Ideally the team should be small enough to work effectively. However, for some stages of the study it may be necessary to enlarge the team temporarily with personnel from other departments, e.g. marketing, research and development or purchasing and finance.

2.1.2 TEAM COMPOSITION

When selecting the team it is important to involve members who will have expertise of the technology and equipment used on the processing lines, practical aspects of the food operations, the flow and technology of the process, applied aspects of food microbiology, and understanding of Codex methodology. The selection of a team coordinator (chairperson) is vital role as it will include the following activities:

- Ensure that the composition of the team meets the needs of the study
- Ensure that team members are trained in the application of Codex methodology
- Suggest changes to the team if necessary
- Coordinate the team’s work
- Ensure that the agreed established plan is followed
- Share the work and responsibilities
- Ensure that a systematic approach is used
- Ensure that the scope of the study is met
- Chair meetings so that team members can freely express their ideas
- Represent the team before management
- Provide management with an estimate of the time, money and labor required for the study
- Ensure that the rationale for all decisions is documented.

2.1.3 SCOPE

One of the first tasks of the HACCP team should be to identify the scope of the HACCP plan. The team should identify the specific product or process to be studied.

2.1.4 RESOURCES

The number of meetings will depend on the scope of the study and the complexity of the operation. For efficiency, each meeting should have a specific objective, a planned agenda and a limited duration.

Meetings should be of sufficient frequency to maintain momentum, but spaced out enough so there will be time between meetings for the gathering of any necessary information. It is advantageous to keep the study proceeding at a reasonable pace to maintain the enthusiasm of the team. A time-line should be developed and goals set for the accomplishment of team and individual assignments.

To ensure success and demonstrate commitment, it is important for senior management to allocate the necessary resources for the HACCP study. These may include:

- Time for team meetings and administration
- Costs of initial training
- Necessary documents
- Access to analytical laboratories
- Access to information sources to answer questions raised by the team (e.g. universities, public and private research authorities, government and public authorities, scientific and technical literature, databases)

2.2 STEP 2: DESCRIBE THE PRODUCT

The HACCP team must make a complete description of each food product – including all ingredients/processing methods/packaging materials/etc. used in the formulation of the product – to assist in the identification of all possible hazards associated with the product. In brief, the product description should include the name of the product, ingredients and composition, potential to support microbial growth (water activity [Aw], pH, etc.), brief details of the process and technology used in production, appropriate packaging. To complete this description as accurately as possible it is important that the team be familiar with the properties, destination and use of the product. It is important, for example, to take into consideration whether sensitive segments of the population may consume the product.

The HACCP team needs to have as complete an understanding of the product as possible. All details of the product’s composition and processing should be known and understood. For example, in the case of microbiological hazards the product’s composition needs to be assessed in relation to the ability of different pathogens to grow. Before arriving at the specific details of the product description to be included in the forms, the HACCP team should address the questions outlined below:

a. Formulation of product
b. What raw materials or ingredients are used?
c. Are microorganisms of concern likely to be present in or on these materials, and if so what are they?
d. If food additives or preservatives are used, are they used at acceptable levels, and at those levels do they accomplish their technical objective? Will the pH of the product prevent microbial growth or inactivate particular pathogens?
e. Will the Aw of the product prevent microbial growth?
f. What is the oxidation/reduction potential (Eh) of the product?
g. Processing and preparation checklist
h. Can a contaminant reach the product during preparation, processing or storage?
i. Will microorganisms or toxic substances of concern be inactivated during cooking, reheating or other processing?
j. Could any microorganisms or toxins of concern contaminate food after it has been heated?
k. Would more severe processing be acceptable or desirable?
l. Is the processing based on scientific data?
m. How does the package or container affect survival and/or growth of microorganisms?
n. How much time is taken for each step of processing, preparation, storage and display?
o. What are the conditions of distribution?
A typical set of information to place together in order to describe a certain food product would include:

- Product name (common name) or group of product names (the grouping of like products is acceptable as long as all hazards are addressed)
- Important end-product characteristics: properties or characteristics of the food under review that are required to ensure its safety (e.g. Aw, pH/preservatives)
- How the product is to be used (i.e. ready-to-eat/further processing required, heated prior to consumption)
- Type of package, including packaging material and packaging conditions (e.g. modified atmosphere)
- Shelf-life, including storage temperature and humidity if applicable
- Where the product will be sold (e.g. retail, institutions, further processing)
- Labeling instructions (e.g. handling and usage instructions)
- Special distribution control (e.g. shipping conditions)

(See Example in Appendix 3)

2.3 STEP 3: IDENTIFY THE INTENDED USE

The HACCP approach allows flexibility in terms of the level of control required within food businesses. This will be dependent on the position of the company in the food chain and also the end user. For example, whilst vegetables which are to be eaten raw may undergo chlorination to reduce the risk of pathogens, this would be a totally unnecessary step if the vegetables were intended to be eaten cooked. It is also accepted that some hazards pose a greater risk to 'vulnerable' groups within the community such as the elderly, the very young or those with low immunity to infection. For example, a factory producing dried milk to be sold for further processing including heat treatment (e.g. canned rice pudding) may have a lower level of control than a factory producing dried infant milk formula.

2.4 STEP 4: CONSTRUCT THE FLOW DIAGRAM

2.4.1 INTRODUCTION

The development and control of HACCP systems is aided by a clear vision of the complex sets of relationships and processes involved. This is achieved through the construction of a 'picture' or flow diagram of the steps involved in the production process. It is easier to identify routes of potential contamination, to suggest methods of control and to discuss these among the HACCP team if there is a flow diagram. The review of the flow of raw materials from the point at which they enter the plant, through processing to departure is the feature that makes HACCP a specific and important tool for the identification and control of potential hazards.

A process flow diagram must be constructed following interviews, observation of operations and other sources of information such as blueprints. The process flow diagram will identify the important process steps (from receiving to final shipping) used in the production of the specific product being assessed. There should be enough detail to be useful in hazard identification, but not so much as to overburden the plan with less important points.

2.4.2 GENERAL REQUIREMENTS OF THE FLOW DIAGRAM

The process flow diagram needs to chart every step in the production of the specific foodstuff being assessed. It is therefore 'operation specific' and it is therefore unique to the business. Whilst the design of the chart is not prescribed in the Codex guidelines, the following factors apply in most situations:

1. Each process step should be included in the correct sequence of the operation.
2. All ingredients should be tracked including water, ice and steam.
3. Processing aids and packaging should be included.
4. Numbering of steps should be encouraged to aid communication in team meetings and reduce paperwork.
5. There should be no loose ends, for example the route out of the factory for waste material and rejected stock should be clearly identified.
6. Product recycle/re-work loops should be included.

2.4.3 FLOOR PLAN

It is useful to prepare a floor plan (plan schematic) to show product flow and employee traffic patterns within the plant for the specific product. This should include the flow of all ingredients and packaging materials from the moment they are received at the plant, through storage, preparation, processing, packaging, finished product holding and shipping. The personnel flow should indicate employee movement through the plant, including changing rooms, washrooms and lunchrooms. The location of hand-washing facilities and footpaths (if applicable) should also be noted.

This plan should aid in the identification of any areas of potential cross-contamination within the establishment, and the floor and equipment layout should be considered in detail and assessed. Data may include but is not restricted to:

- Personnel routes
- Routes of potential cross-contamination
- Area segregation
- Flow of ingredients and packaging materials
- Location of changing rooms, washrooms, lunchrooms and hand-washing stations

2.5 STEP 5: ON-SITE CONFIRMATION OF THE FLOW DIAGRAM

Once the process flow diagram has been drafted, it must be confirmed by an on-site inspection for accuracy and completeness. This will ensure that all the major process operations have been identified. It will also confirm the assumptions made with respect to the movement of product and employees on the premises.

The flow diagram should also be compared with the operation it represents on site. The process should be reviewed at various times throughout the hours of operation to verify that the flow diagram is valid throughout all operational periods. All members of the HACCP team should be involved in the flow diagram confirmation. Adjustments should be made to the flow diagram, as necessary based on the actual operations observed.

2.6 STEP 6: CONDUCT A HAZARD ANALYSIS (PRINCIPLE 1)

2.6.1 INTRODUCTION

Hazard analysis is the first HACCP principle. As the name HACCP implies, hazard analysis is one of the most important tasks. An inaccurate hazard analysis would inevitably lead to the development of an inadequate HACCP plan. Hazard analysis is a complex process where a series of technical, practical and operation decisions have to be made. It requires technical expertise and a scientific background in various domains for proper identification of all hazards. Knowledge of food science and HACCP methodology is necessary for the performance of a satisfactory hazard analysis.

The hazard analysis is necessary to identify for a specific process/product the hazards that (1) are not controlled through pre-requisites and (2) are of such a nature that their elimination or reduction to an acceptable level is essential to the production of a safe food. In summary, it involves the following activities:

- Conduct a detailed evaluation of the process steps to identify any step where there is potential for the introduction, increase or survival of the hazard. The important question is - if something went wrong at this step, could the hazard in question be introduced, increased or survive/persist?
- Design control measures for those steps.

2.6.2 HAZARDS

Hazard will vary among businesses making the same products because of differences in:

- Sources of ingredients
- Formulations
- Processing equipment
- Processing and preparation methods
- Duration of processes
Hazard analysis must therefore be done on all existing and new products. Changes in raw materials, product formulations, processing or preparation procedures, packaging, distribution and/or use of the product will require review of the original hazard analysis. All biological, chemical and physical hazards should be considered and the following sections highlight some of the key issues of concern.

Food borne biological hazards include microbiological organisms such as bacteria, viruses, fungi and parasites. These organisms are commonly associated with humans and with raw products entering the food establishment. Many of these microorganisms occur naturally in the environment where foods are grown. Most are killed or inactivated by cooking, and numbers can be minimized by adequate control of handling and storage practices (hygiene, temperature and time).

The majority of reported food borne disease outbreaks and cases are caused by pathogenic micro-organisms. A certain level of these microorganisms can be expected with some raw foods. Improper storage or handling of these foods can contribute to a significant increase in the level of these microorganisms. Cooked foods often provide fertile media for rapid growth of microorganisms if they are not properly handled and stored.

Viruses can be food borne/water-borne or transmitted to food by human, animal or other contact. Unlike bacteria, viruses are unable to reproduce outside a living cell. They cannot therefore replicate in food, and can only be carried by it.

Parasites are most often animal host-specific and can include humans in their life cycles. Parasitic infections are commonly associated with undercooked meat products or contaminated ready-to-eat food. Parasites in products that are intended to be eaten raw, marinated or partially cooked can be killed by effective freezing techniques.

Fungi include moulds and yeasts. Fungi can be beneficial, as they can be used in the production of certain foods (e.g. cheese). However, some fungi produce toxic substances (mycotoxins) which are toxic for humans and animals.

Chemical contaminants in food may be naturally occurring or may be added during the processing of food. Harmful chemicals at high levels have been associated with acute cases of food borne illnesses and can also be responsible for chronic illness at lower levels. They include naturally occurring chemicals, processing aids and contaminants.

Whilst physical hazards cannot cause food borne disease, injury can result from hard foreign objects in food. For this reason they are usually included within food safety plans. These physical hazards can result from contamination and/or poor practices at many points in the food chain from harvest to consumer, including those within the food establishment.

After listing all the hazards (biological, chemical or physical) that may be reasonably expected at each step from primary production, processing, manufacturing and distribution until the point of consumption, the HACCP team should assess the potential significance or risk of each hazard by considering its likelihood of occurrence and severity. The estimate of the risk of a hazard occurring is based upon a combination of experience, epidemiological data and information in the technical literature. Severity is the degree of seriousness of the consequences of a hazard if the hazard is not controlled.

A hazard analysis must be conducted for each existing product or process type and for each new product. In addition, the hazard analysis done for a product or process type must be reviewed if any changes are made in raw material, product formulation, preparation, processing, packaging and distribution or intended use of the product.

2.6.3 HOW TO CONDUCT A HAZARD ANALYSIS.

The hazard analysis process is one of the most difficult aspects of HACCP and many operational failures in food safety are caused by problems with this step in the process. It is best attempted in a structured way, as presented in the 9 step method below.

2.6.3.1 DECIDE THE SIGNIFICANT HAZARD GROUPS

Depending on the nature of the business and product, there will be a greater or less risk to public health from microbiological, chemical and physical hazards. The first step in hazard analysis is to identify which groups of hazards pose a risk to consumers if not controlled.

2.6.3.2 PRIORITIZE THE HAZARD GROUPS

If more than one group of hazards has been identified as significant, these should be ranked in order of importance. The most important group should be studied first.

2.6.3.3 IDENTIFY EACH INDIVIDUAL HAZARD

Within the hazard group in question it is necessary to consider all of the individual hazards that could occur, and decide which of them represents a significant risk to the safety of the consumer if not controlled.

2.6.3.4 PRIORITIZE THE SIGNIFICANT HAZARDS

Each individual hazard now needs to be placed in order of importance so that the most important one(s) can be identified.

By following steps 1-4 above a list of hazards will be identified in order of food safety risk. Each individual hazard can then be evaluated by the HACCP team.

2.6.3.5 STUDY INDIVIDUAL HAZARDS ONE AT A TIME

The process of hazard analysis can proceed, addressing each specific hazard in turn.

2.6.3.6 ‘DESIGN OUT’ THE HAZARD IF POSSIBLE

The next stage in the HACCP study is a process of decision making, whereby judgments are made as to whether ‘significant hazards’ can be removed by modification of the system. HACCP teams often plan elaborate, costly and misguided control strategies when the problem is more easily ‘designed out’ of the process. For example, the problems of defrosting poultry with the inherent risk of Salmonella infection due to cross contamination has led to a decline in use of frozen poultry within UK school kitchens and hospitals.

2.6.3.7 DETAILED EVALUATION OF THE PROCESS STEPS

If the hazard cannot be designed out of the process and the team are convinced that its prevention, elimination or reduction to acceptable levels is essential to the production of safe food then it needs to be addressed through the HACCP plan. This requires an examination of the flow diagram to identify any process step where there is potential for the presence, contamination, growth or survival of microbiological hazards or the presence, contamination or persistence of chemical or physical hazards.

2.6.3.8 DEVELOP CONTROL MEASURES

Each of the process steps identified above should be discussed by the team in order for preventative strategies to be implemented. These ‘control measures’ are described as ‘actions and activities which are implemented to eliminate hazards or reduce their occurrence to acceptable levels’. It is often the case that more than one control measure may be needed to control a hazard (e.g. low pH/temperature and pressure for Clostridium botulinum control in canned foods), or alternatively that more than one hazard is controlled by any one measure (e.g. infectious pathogens in cooking).

The process steps at which they are implemented are termed control points (CPs), i.e. points at which biological, chemical or physical factors can be controlled.

2.6.3.9 VALIDATE HAZARD ANALYSIS DECISIONS

A rationale for all decisions made during the hazard analysis process should be documented at this stage, with supporting scientific evidence that the controls are valid.
2.7 STEP 7: DETERMINE CRITICAL CONTROL POINTS (PRINCIPLE 2)

The determination of critical control points (CCPs) is the second principle of HACCP and this requires the identification of steps in the process where control is necessary for product safety. At these critical control points (CCPs) control measures need to be rigorously monitored and maintained to ensure that the product never fails to meet the required safety criteria.

Careful examination of the 'context' of the hazard, in relation to the complete production process will identify those steps in the process where:

- A loss of control at that step would lead to an unacceptable health risk.
- The hazard will not be controlled later in the process.

Prior to determining CCPs hazards should be reviewed to verify if any of the identified hazards are fully controlled by the Good Hygienic practices (GHP). Furthermore, an on-site verification must be carried out by the HACCP team to verify if those hazards are in fact controlled by the application of pre-requisite programs. Hazards that are not fully controlled by pre-programs should be analyzed to determine whether they are CCPs or not.

There are a number of tools that have been developed to assist HACCP teams in the identification of CCPs. These include a variety of decision trees (See Appendix 1 and 2), adapted from the original version that is illustrated within the Codex guidelines, that aims guide the team though a series of logical questions to determine criticality. Whilst decision trees can be useful (especially in training) most experienced HACCP teams can identify CCPs using their expertise and experience of their food process. Indeed, the decision trees do not apply in all situations and should be seen as only a guide to decision making.

2.8 STEP 6: ESTABLISH CRITICAL LIMITS FOR CCPs (PRINCIPLE 3)

2.8.1 CRITICAL LIMITS

At each CCP critical limits need to be specified. Critical limits are defined as criteria that separate acceptability from unacceptability. A critical limit represents the boundaries that are used to judge whether an operation is producing safe product. One or more critical limits may be used to control the identified hazards. Examples of critical limits can be found in Appendix X.

Critical limits may relate to operating procedures, for example specific cleaning procedures, parameters such as pH, water activity, salt levels, product characteristics or sensory characteristics such as color change. These parameters, if maintained within boundaries, will confirm the safety of the product.

The critical limits should meet requirements of government regulations and/or company standards and/or be supported by other scientific data. In some cases, food control regulatory authorities provide information on which to establish the critical limits based on known food hazards and the results of scientific studies (e.g. the time/temperature requirements for thermal processes such as pasteurization, cooking, retorting; maximum number and size of physical contaminants, chemical residues). Many businesses use critical limits based on ‘custom and practice’ rather than on ‘evidence’ – this Step in the HACCP is a good opportunity to validate these practices.

It is essential for the HACCP team to be aware of legal and commercial standards required for the product and obtain the necessary information on which to base decisions. Examples of useful sources of information include:

- Scientific publications/research data
- Regulatory requirements and guidelines
- Experts (e.g. thermal process authorities, consultants, food scientists, microbiologists, equipment manufacturers, sanitarians, academics)
- Experimental studies (e.g. in-house experiments, contract laboratory studies)

If the information needed to establish critical limits is not available, a conservative value should be selected or regulatory limits used. The rationale and reference materials for all decisions made concerning critical limits (i.e. validation data) should be recorded. The materials become part of the support documentation of the HACCP plan.

### Table (1): Examples on Critical limits:

<table>
<thead>
<tr>
<th>Hazard</th>
<th>CCP</th>
<th>Critical limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial pathogens (non-sporulating)</td>
<td>Pasteurization</td>
<td>72°C for at least 15 seconds</td>
</tr>
<tr>
<td>Metal fragments</td>
<td>Metal detector</td>
<td>Metal fragments larger than 0.5 mm</td>
</tr>
<tr>
<td>Bacterial pathogens</td>
<td>Drying oven</td>
<td>Aw&lt;0.85 for controlling growth in dried foods</td>
</tr>
<tr>
<td>Bacterial pathogens</td>
<td>Acidification step</td>
<td>Maximum pH of 4.6 to control Clostridium botulinum in acidified foods</td>
</tr>
<tr>
<td>Food allergens</td>
<td>Labelling</td>
<td>Label that is legible and contains correct list of ingredients</td>
</tr>
<tr>
<td>Histamine</td>
<td>Receiving</td>
<td>Maximum of 25 ppm histamine. To be evaluated by sensory tests</td>
</tr>
</tbody>
</table>

2.8.2 OPERATIONAL LIMITS

If monitoring shows a trend towards lack of control at a CCP, operators can take action to prevent loss of control of the CCP before the critical limit is exceeded. The point would trigger such action is often called the ‘target’ or ‘operating limit’. Many food manufacturers will set such limits in addition to critical limits. Whilst critical limits define the boundaries for safe food these additional limits provide the operator with an ‘early warning’ that the system is moving out of control. Operating limits should not be confused with critical limits. Often, the operating limits are more restrictive and are established at a level that would be reached before the critical limit is violated; i.e. they should prevent a deviation from critical limits.

An operator may observe a trend towards loss of control, such as the failure of a cooker to maintain the desired temperature consistently. Observing a trend towards loss of control early and acting on it can save product rework or, worse yet, product destruction. When the critical limit is exceeded, corrective action is required (see section 2.9). For this reason a processor may choose to operate a CCP at a limit more conservative than the critical limit. Such operating limits may be selected for various reasons.

### Table (2): Examples on Critical and Operating Limits.

<table>
<thead>
<tr>
<th>Process</th>
<th>Critical limit</th>
<th>Operating limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acidification</td>
<td>pH 4.6</td>
<td>pH 4.3</td>
</tr>
<tr>
<td>Drying</td>
<td>0.84 Aw</td>
<td>0.80 Aw</td>
</tr>
<tr>
<td>Hot fill</td>
<td>80°C</td>
<td>85°C</td>
</tr>
<tr>
<td>Slicing</td>
<td>2 cm</td>
<td>2.5 cm</td>
</tr>
</tbody>
</table>

2.9 STEP 9: ESTABLISH A MONITORING SYSTEM (PRINCIPLE 4)

2.9.1 INTRODUCTION

The (HACCP) system and guidelines for its application defines monitoring as “the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.” 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. Therefore, it is important to specify fully how, when and by whom monitoring is to be performed.
The purposes of monitoring include the following:

- To measure the performance level of the system’s operation at the CCP (trend analysis)
- To determine when the performance level of the system results in a loss of control at the CCP, e.g. when there is deviation from a critical limit
- To establish records that reflect the performance level of the system’s operation at the CCP to comply with the HACCP plan

Monitoring is the process that the producer relies upon to show that the HACCP plan is being followed. It provides the producer with accurate records enabling the producer to show that the conditions of production are in compliance with the HACCP plan.

Ideally, monitoring should provide information in time to allow any adjustments to the process, thus preventing loss of control of the process and critical limits being exceeded. In practice, operating limits are often used to provide a safety margin which allows extra time to adjust the process before the critical limit is exceeded.

There are many ways to monitor the critical limits of a CCP. Monitoring can be done on a continuous (100 percent) or batch basis. Where feasible, continuous monitoring is preferred as it is more reliable. Continuous monitoring is designed to detect shifts around target levels, thus allowing correction of these shifts and preventing deviation beyond the critical limits. Where monitoring is not continuous, the amount and frequency of monitoring should be sufficient to provide an acceptable level of assurance that the CCP is under control. The higher the frequency of monitoring (i.e. the less time between each instance of monitoring), the less product will be affected when there is a loss of control at the CCP.

A further consideration when establishing a monitoring system is the time taken to achieve a result from the monitoring procedure. Most monitoring procedures will need to be rapid, as they relate to on-line processes which in general do not leave time for lengthy analytical testing. For this reason physical and chemical measurements or visual observations, which may be done rapidly, are often preferred to microbiological testing. Examples of some physical and chemical measurements taken to monitor critical limits are temperature, time, pH, moisture level and water activity (Aw). It is essential that all monitoring equipment be properly calibrated for accuracy.

Monitoring procedures performed during the operation should result in written documentation which will serve as an accurate record of the operating conditions. Monitoring records provide information on conditions during the operation and allow for action to be taken in the event of a loss of control or for a process adjustment to be made if there is a trend towards a loss of control.

Accurate monitoring procedures and associated records provide information to the operator and allow for decisions to be made on the acceptability of the lot at a particular stage in the process. To complete the monitoring process, data derived from monitoring should be reviewed and evaluated by a designated person or persons with knowledge and authority to carry out corrective actions when indicated (see Section 2.10).

The worst scenario is that in which monitoring procedures indicate that any one of the critical limits is exceeded, which indicates loss of control of a CCP. This lack of control is considered to be a deviation resulting in the production of a hazardous or unsafe product. The situation requires immediate identification and control of the affected product and corrective action.

Responsibility for monitoring should be clearly defined, and individuals must be adequately trained in the monitoring procedures for the CCP for which they are responsible. They must also fully understand the purpose and importance of monitoring. The individual should have ready access to the monitoring activity, must be unbiased in monitoring and must accurately report the monitoring activity.

2.9.2 DESIGN OF A MONITORING SYSTEM

The control measures identified at Step 5 are intended to control a hazard or hazards at each CCP. The monitoring procedures will determine if the control measures are being implemented and ensure that critical limits are not exceeded.

Each monitoring procedure should be fully detailed in the form of a Standard Operating Procedure (SOP) that act as an operational and training reference for employees involved in CCP monitoring (see Section 2.12).

The monitoring SOP should include the following:

- Name/title of person responsible for the monitoring and evaluation of monitoring results
- Frequency of monitoring
- Detailed procedures to be followed (tests, measurements or observations)
- Detailed instructions for how results are to be recorded

The monitoring process may involve measuring a characteristic of the product or of the process to determine compliance with a critical limit. Examples include:

- Measurement of the time and temperature of a thermal process
- Measurement of cold-storage temperatures
- Measurement of pH
- Measurement of Aw

Alternatively it could also involve observing whether a control measure at a CCP is being implemented. Examples include:

- Visual examination of sealed cans
- Visual checks on color changes during meat cooking
- Verification of suppliers certificates of analysis

It is also important to remember at this stage that monitoring procedures may determine if operating limits are being adhered to rather than the critical limits, so that the operator has time to make any necessary process adjustment. Deviation from a critical limit should be detected in as short a time as possible to allow corrective action (see Section 5.10) to limit the amount of adversely affected product. To ensure accurate knowledge of conditions during the process, the monitoring procedures should provide rapid (real-time) results and should not involve lengthy analytical procedures. Microbiological testing is rarely effective for monitoring CCPs for this reason, and also because large sample-sizes would be needed to find microorganisms at levels that may cause illness. Instead, physical, chemical, sensory and procedural measurements (e.g. pH, Aw, time, temperature, cleaning procedures, steaming of hot food) are preferred, as they can be done rapidly. It is however, important that all measurements relate directly to the specified hazard(s) and that validation data is available.

Effective monitoring depends upon the proper selection and calibration of the measuring equipment. The equipment used for monitoring CCPs will vary depending on the attribute being monitored.

2.9.3 MONITORING FREQUENCY

Monitoring can be continuous or non-continuous. Where possible, continuous monitoring is preferred; it is possible for many types of physical or chemical methods.

Examples of continuous monitoring include:

- Measuring the time and temperature of a pasteurization or retorting process
- Checking each package of frozen, mechanically chopped spinach with a metal detector
- Monitoring the container closures on glass jars by passing them under a dud detector

For continuous monitoring to be effective, it is necessary to review the monitoring results periodically and take action when appropriate. The length of time between checks is important as it is directly related to the amount of product involved when there is a deviation from a critical limit.

Where non-continuous monitoring is the chosen system, the frequency of monitoring should be determined from historical knowledge of the product and process. When problems are detected the frequency of monitoring may need to be increased until the cause of the problem is corrected.

The following questions will help to determine the correct frequency:

- How much does the process normally vary?
- How close is the operating limit to the critical limit?
- How much product is the processor prepared to risk if there is deviation from the critical limit?
In developing the HACCP plan consideration should be given to assigning responsibility for monitoring. Individuals assigned to monitor CCPs may include:

- Line personnel
- Equipment operators
- Supervisors
- Maintenance personnel
- Quality assurance personnel

Once assigned, the individual responsible for monitoring a CCP must:

- Be adequately trained in the CCP monitoring techniques
- Fully understand the importance of CCP monitoring
- Have ready access (be close) to the monitoring activity
- Accurately report each monitoring activity
- Have the authority to take appropriate action as defined in the HACCP plan
- Immediately report critical limit deviation

### 2.10 STEP 10: ESTABLISH CORRECTIVE ACTIONS (PRINCIPLE 5)

#### 2.10.1 PROCESS OR PRODUCT DEVIATIONS

The preceding steps have outlined the methodology required to maintain rigorous control of steps in the process that are ‘critical’ to consumer safety. However, even the best plans can sometimes fail and HACCP requires an extra level of protection: the development of a series of ‘crisis management plans’ to use in the event of loss of control – or deviation – a CCP. Within the context of HACCP these plans are known as ‘corrective actions’.

All deviations must be controlled by taking corrective action(s) to control the non-compliant product and to correct the cause of non-compliance. Product control includes proper identification, control and disposition of the affected product. The control and disposition of the affected product and the corrective action(s) taken must be recorded and filed.

The diversity of possible deviations at each CCP means that more than one corrective action may be necessary at each CCP. When a deviation occurs, it will most likely be noticed during the routine monitoring of the CCP. Deviation and corrective action procedures are prescribed so that employees responsible for CCP monitoring understand and are able to perform the appropriate corrective action(s) in the event of a deviation.

Process adjustments should also be made when monitoring results indicate a trend towards loss of control at a CCP. Action should be taken to bring the process within the operating limits before a deviation occurs.

#### 2.10.2 CORRECTIVE ACTION PLANS

Since the main reason for implementing HACCP is to prevent problems from occurring, corrective action should be taken to prevent deviation at a CCP. Corrective action should be taken following any deviation to ensure the safety of the product and to prevent recurrence of the deviation.

Corrective action plans are necessary to determine the cause of the problem, take action to prevent recurrence and follow up with monitoring and reassessment to ensure that the action taken is effective. If the corrective action does not address the root cause of the deviation, the deviation could recur. Reassessment of the hazard analysis or modification of the HACCP plan may be necessary to eliminate further occurrence.

Each corrective action procedure should be fully detailed in the form of a Standard Operating Procedure (SOP) that acts as an operational and training reference for employees involved in this activity (see Section 2.12)

The corrective action procedure (SOP) should include the following:

- Name or title of person that has the responsibility and authority to take actions
- Detailed instructions for how results are to be recorded.

The detail in the corrective action procedure will vary but should always include:

- How the affected product will be isolated
- The procedure for dealing with the affected product
- How the process will be brought back under control

What must be done to prevent reoccurrence of the problem

Records should be available to demonstrate the control of products affected by the deviation and the corrective action taken. Adequate records permit verification that the producer has deviations under control and has taken effective corrective action.

The following information should be recorded in the deviation and corrective action records:

- Deviation
- Product/code
- Date produced/held/released
- Reason for the hold
- Amount of product held
- Results of evaluation: amount analyzed, analysis report, number and nature of defects
- Signature of personnel responsible for hold and evaluation
- Disposition of held product (if appropriate)
- Signed authorization for disposition
- Corrective action
- Cause of deviation identified
- Corrective action taken to correct deficiency immediately (i.e. quick fix)
- Investigation to identify why the control measure failed with a appropriate follow up action (e.g. redesign of control measure, competency assessment of employees involved)
- Date and Signature of person responsible

#### 2.10.3 ASSESSMENT FOR RELEASE

Product that fails to meet the critical limits specified in the HACCP Plan should only be released to customers when any of the following conditions apply:

- Evidence, other than monitoring data, demonstrates that the CCP has been effective.
- Evidence demonstrates that the combined action of multiple control measures has been effective in reducing the hazard to an acceptable level.
- The results of sampling, analysis and/or other verification activities demonstrate that the affected product meets acceptable levels of the hazard(s) concerned.

The assessment procedures should follow those identified in the corrective action plan and the results of the assessment shall be fully documented.

#### 2.10.4 DISPOSAL OF NON-COMPLIANT PRODUCT

If the results of the assessment for release indicates the product is not acceptable for release to customers it shall be either:

- Reprocessed within or outside the establishment (according to regulatory requirements) to ensure the hazard(s) is reduced to an acceptable level
- Destroyed and disposed of in a safe manner.
The disposition of non-compliant product shall follow procedures established in the corrective action plan and shall be fully documented.

2.11 STEP 11: ESTABLISH VERIFICATION PROCEDURES (PRINCIPLE 6)

2.11.1 INTRODUCTION

Careful preparation of the HACCP plan with clear definition of all the necessary items does not guarantee the plan’s effectiveness. Verification is necessary to assess the effectiveness of the plan and to confirm that the HACCP system adheres to the plan. Verification requires two different activities:

1. Those that are carried out to check if the system is meeting its objective to produce safe food. This is referred to as ‘validation’.
2. Those that are carried out to ensure that the HACCP plan is followed in practice. This is referred to as ‘Compliance’.

2.11.2 VERIFYING THAT THE HACCP PLAN IS VALID

Validation is necessary at various stages throughout the life of a HACCP plan. Initially validation occurs as the HACCP plan is being designed and decisions as to controls and limits are made. This validation can be termed the initial validation or validation during design. Once the HACCP plan has been implemented and established it must be subject to periodic, scheduled validation. This questions the effectiveness of the plan over time and can be termed revalidation. Validation can and may also be prompted by change. Such a change could occur in the product or process and prompt the controls in the plan to be reassessed. The key aim of these different types of validation remains the same, i.e., to challenge the elements of the plan. However, the nature and focus of the questions asked may differ depending on the type of validation. Terms used to describe these different types of validation can vary. Validation activities can be conducted both internally and externally to the operation.

2.11.2.1 DESIGNING A VALID PLAN

As decisions are made during the design of the HACCP plan it is vital that these are based on sound evidence, and not purely custom and practice, which is often the case. The controls selected must be capable of achieving the food safety objective, for example the necessary reduction in pathogen loading. If the controls and limits decided on within the plan are not capable of achieving a safe product then implementation and compliance with the plan become largely irrelevant. HACCP provides manufacturers with a unique opportunity to question their existing practices, some of which may have been established for many years and for reasons that may no longer be valid. This is not to say that these practices are necessarily incorrect. Validating the decisions made within the plan allows for ineffective practices to be exposed and correct practices to be substantiated. It is essential that all elements of the HACCP plan be initially validated. This process tends to happen simultaneously as the decisions are researched and made. Data and evidence should be collected, recorded and retained as the design stages of HACCP progress. This data will be needed to support the HACCP plan during later validations, both internal and external.

2.11.2.2 THE PROCESS FLOW DIAGRAM

Validation or confirmation of the process flow diagram is Step 5 in the Codex protocol as is described in Section 5.5. The process flow diagram largely dictates the content for the rest of the plan, and hence, the steps within it must accurately reflect the actual process being studied.

2.11.2.3 THE HAZARD ANALYSIS STAGE

The hazard analysis stage is perhaps the hardest step of HACCP to validate both during the design and subsequently. The inclusion of significant hazards must be supported by sound evidence, and this is also true for the decisions to exclude non-significant hazards. Keeping records of the hazard analysis stage is vital for future validations as it can be very difficult to recall from memory the decisions made during the design stage when the plan is subject to scrutiny some time later. If key members of the HACCP team leave and there is no or little documentation of decisions then a lot of the plan’s history and rationale can be lost. Making and justifying these decisions requires a good knowledge of the product and process, along with an understanding of food safety hazards. In some cases this may prompt the need for expertise from an external source. Sources of information / evidence for validating these decisions may come from:

- The experience of the HACCP team members,
- In-house specialists e.g. microbiologists,
- Regulations,
- Industry Guides,
- Research bodies,
- Suppliers,
- Trade organizations,
- International organizations such as Codex.

2.11.2.4 DECISIONS RELATED TO CCPs

A clear rationale must be kept for all decisions related to the identification of CCPs. Minutes of HACCP team meetings should be kept to record the discussions and decisions made at the time. These records will form valuable evidence during future validation activities.

2.11.2.5 VALIDATING THE CRITICAL LIMITS

Once the hazard analysis and CCP decisions have been justified the focus then turns to how to control these. When deciding on critical limits it must be proven that the limit selected will be capable of achieving the food safety objective, i.e. reduction in pathogen loading or cleaning routine. When the critical limits are being validated there are two issues which require consideration:

- Is the critical limit capable of achieving the required food safety objective?
- Can the critical limit be consistently achieved in practice?

Validating critical limits is essential for all CCPs but becomes of paramount importance for CCPs where continuous monitoring or monitoring of every unit produced is not possible or feasible. The validation of control measures in general and critical limits in particular, is one of the major weaknesses found in HACCP plans. Codex has developed practical guidance for food businesses on how this may be achieved. See examples in Appendix 10.

2.11.2.6 VALIDATING MONITORING PROCEDURES

Validating monitoring procedures requires evidence that the monitoring method used is capable of reliably measuring the critical limit and detecting a loss of control. The method must be repeatable and appropriate for the identified critical limit. For example, a critical limit may have been identified correctly but if the selected monitoring procedure is not adequate to detect a loss of control then food safety will not be managed. As discussed, continuous monitoring is ideal, yet this is not always a viable option. If not possible then it is essential that decisions about the frequency of monitoring must also be based on sound reasoning. The frequency must be appropriate for the throughput of the operation and monitoring method. This is usually a balance between the need for confidence in food safety and the cost of the resources required to perform the monitoring.

When using equipment to monitor critical limits, calibration must be considered. This should ideally be traceable back to national or international standards. Calibration of equipment should be carried out at a range close to that of the critical limit as this is the range where the device will normally be performing and where it is most required to be accurate.

2.11.2.7 VALIDATING CORRECTIVE ACTION PLANS

Corrective action plans need careful consideration at design in order to ensure their validity. They must be appropriate and effectively prevent any non-conforming and potentially unsafe product reaching the consumer. As well as regaining control and dealing with the potentially unsafe product the corrective action plan should consider longer-term preventative actions.
2.11.2.8 VALIDATION BEFORE IMPLEMENTATION

Even with validation of each decision made during the design of the plan it is a good idea to have a final validation immediately before the HACCP plan is implemented. This should be done by someone outside the original HACCP team with HACCP knowledge and an understanding of the product/process. A “fresh pair of eyes” can sometimes identify errors which the team has been too closely involved to see. Correcting these errors before implementation can save valuable time. This final validation stage can also give the team the reassurance and confidence they need to take the plan forward to implementation and justify the need for resources to make it work in practice. Suitable people to validate the plan at this stage would be:

- A member of a HACCP team from a sister site / head office
- Someone from within the operation who has had HACCP training but was not involved with the initial design of the plan.
- A consultant with experience in the relevant industry sector and HACCP knowledge.

2.11.2.9 ONGOING / REVALIDATION OF THE HACCP PLAN

When the plan has become established it is important that it is subject to scheduled revalidation. The purpose of the revalidation is to ensure the plans effectiveness and accuracy over time. This validation activity re-challenges the original decisions and assumptions made as to the controls within the plan. After receiving further training and advice from external sources the team may look back on their original decisions and find they could be improved. Revalidation also questions the appropriateness of the plan in the light of changes which may have occurred since the plans implementation or last revalidation. Developments in HACCP methodology and application should also be considered. In essence, revalidation provides an opportunity to reassess the controls within the plan with the valuable benefit of hindsight.

2.11.2.10 WHEN TO VALIDATE

The type and timing of validation will vary depending on the maturity of the HACCP plan and the nature of the operation. Once the initial validation has been carried out and the plan is implemented validation should then take place at regular, predetermined intervals and is commonly an annual event. Validation may happen more often than this in complex operations or those operations which experience frequent changes.

2.11.3 VERIFICATION AUDITS TO ASSESS COMPLIANCE

Verification is the term used to describe any activity that seeks to assess the level to which the controls and procedures prescribed within the HACCP plan are being adhered to in practice. In other words, verification seeks to confirm compliance with the HACCP plan. Verification usually takes place once the HACCP plan has been developed and implemented and helps to ensure that compliance with the system is assessed and improved as the HACCP plan matures and develops.

2.11.3.1 THE AUDIT

Auditing is a well-established technique used to check practical compliance against planned procedures. It is a standard tool in many areas of business including financial and quality management and has become the main verification method used by food businesses to check that they are complying with the HACCP Plan. The activity of auditing involves comparing practice with a documented standard, generally posing the question ‘are we doing what we planned to do?’ When applied to HACCP this means comparing the actual practices and activities that take place within the food operation to the documented practices and activities as set out within the HACCP plan. From such an assessment conclusions can then be drawn to enable any non-compliance to be corrected and to ensure that practices reflect the HACCP plan.

A HACCP audit is defined as an “systematic and independent examination involving on-site observations, interviews and review of records to determine whether the procedures and activities stated in the HACCP plan are implemented in the HACCP system. These examinations are usually performed by one or more independent persons who are not involved in implementation of the HACCP system. Audits may be performed for individual CCPs and/or for the overall plan. An example of a HACCP checklist is included in (Appendix 9).

On-site observation may include, for example, visual inspection to ensure that:

- The product description and flow diagram are accurate
- Monitoring required by the HACCP plan at the CCPs is performed
- Processes are operating within established critical limits
- Records are filled out accurately and at the time observations are made

Records to be reviewed during auditing of the HACCP plan include, for example, those demonstrating that:

- Monitoring activities have been performed at the locations specified in the HACCP plan
- Monitoring activities have been performed at the frequencies specified in the HACCP plan
- Affected product has been controlled and corrective actions have been taken whenever monitoring has indicated the occurrence of a deviation from critical limits
- Equipment has been calibrated at the frequencies specified in the HACCP plan

2.11.3.2 VERIFICATION FREQUENCY

Verification activities should be performed according to a pre-established schedule described in the HACCP plan or whenever there are indications that the food safety status may have changed. These indications may include:

- On-line observations that CCPs may not be operating within critical limits
- Record reviews indicating inconsistent monitoring
- Record reviews indicating that CCPs are repetitively operated outside critical limits
- Consumer complaints or product rejections by customers
- New scientific data

Verification procedures should be scheduled at a frequency that ensures that the HACCP plan is being followed continuously and that measurements remain accurate within established limits. Thus, the length of time between scheduled verification activities should match the level of confidence in the continuous and accurate performance of the HACCP plan.

The frequency of verification activities may change over time. A history of verification activities indicating that the process is consistently in control may support safe reduction of the frequency of verification activities.

2.11.4 TYPES OF AUDIT

Audits can be carried out either internally or externally and further divided into first, second or third party involvement. The third party audit is perceived to be the most effective due to the independent nature of the auditor. However, with careful selection and training the performance of the internal auditor can be increased significantly and, in some cases, match that of externals.
2.11.5 SELECTION OF AUDITOR / AUDIT TEAM.

To perform an effective HACCP audit several key skills are required and these should be taken into consideration when selecting the person(s) that will carry out the audit. HACCP audit skills include:

- Qualifications and experience in HACCP methodology
- Qualifications and experience in food science directly relevant to the product / process / industry sector
- Qualifications and experience in auditing.
- Independence

It is often the case that it is impossible to select one person who can demonstrate all these skills. This is why effective HACCP audits, especially if any aspects of technical validation are required, usually requires a team approach. It is necessary to clearly define the objective of the audit (for example: validation or compliance, individual process or whole production line) before auditors are contracted. In the case of external Certification Audits it is the business owners’ responsibility to ensure the competence of auditors contracted for this purpose. At the very least, the full profile of auditors should be requested in advance of an audit visit.

2.11.6 HACCP CERTIFICATION

HACCP certification is a procedure by which a third party gives written assurance that a product or process is in conformity with a defined standard and can be established by Governments or private organizations. The detailed requirements of such “standards” vary but usually they are based on Codex, including both pre-requisites and HACCP. Certification systems for compliance with an agreed HACCP standard are implemented in many countries as part of voluntary or mandatory programs. They can be linked to international schemes, such as British Retail Consortium (BRC), ISO 22000 or Global Gap. In many countries, the retail sector is increasingly directly involved; it has developed its own standards outlining the requirements and conditions which must be met by suppliers.

2.11.7 REGULATORY VERIFICATION AUDITS

Verification is a routine part of regularly scheduled ADFCA inspections. The reasons for regulatory verification activities include, among others: government obligation in consumer protection, support to the food industry (particularly medium- and small-scale food industry) and assistance to industry in trade opportunities where certification is required.

The inspector will document the existence and implementation of the HACCP plan. HACCP plans will be subsequently be reviewed to ensure the system is valid and that the manufacture follows the procedures identified in the HACCP plan.

In particular, the inspector will focus on the following:

- Review of the hazard analysis
- Review of the CCP determination
- Verification that the critical limits are valid and meet regulatory requirements
- Review of the deviation and corrective action procedures
- Review of the verification procedures
- Review of records to verify that the HACCP plan is being followed effectively at all times
- Verification of the accuracy of CCP monitoring equipment

2.11.8 MICROBIOLOGICAL TESTING IN HACCP VALIDATION AND VERIFICATION

Sampling and microbiological testing are usually not adequate by themselves to ensure food safety. Microbiological testing is seldom effective for monitoring CCPs and cannot be used as a means of process control because of the lengthiness of analytical procedures and the inability to provide results in real time. In addition, detection of pathogenic microorganisms can be difficult if contamination of the product at the CCP is at a low level or is unevenly distributed in the food sample, necessitating large and numerous samples.

Microbiological testing does have a role in HACCP verification, however: when critical limits are established for the elimination of pathogens or their reduction to an acceptable level, microbiological testing can be used to verify the HACCP plan’s effectiveness and to ensure that the identified microbiological limits have not been exceeded. In this instance, the length of time involved in the analytical procedures does not create operational difficulties.

2.11.9 OTHER METHODS OF VERIFICATION

A HACCP system will produce significant amounts of data that can be used to assess whether the HACCP system is being complied with over time, in addition to audit results. This exercise may highlight trends towards a loss of control at certain CCPs, and can be a prompt for investigation or corrective action. Types of data that may be useful include:

- CCP records
- Process control charts
- Audit reports
- Finished product test results
- Consumer & Customer complaints
- Pest control records
- Minutes of HACCP team meetings

2.12 STEP 12: ESTABLISH DOCUMENTATION AND RECORD KEEPING (PRINCIPLE 7)

2.12.1 HACCP DOCUMENTATION

HACCP documents include information and support data used to establish the system. This collection of documents is usually referred to as the HACCP Plan. The HACCP plan should include a list of the HACCP team members and their responsibilities and relevant training, as well as all the documents produced during the preparation of the HACCP plan, showing:

- Product description and intended use
- Flow diagram
- Hazard analysis
- Identification of CCPs
- Identification of the critical limits for each CCP. including data from experimental studies or information collected to support the critical limits
- Documented deviation and corrective action plans
- Planned verification activities and procedures
- Identification of the control measures for each hazard
HACCP documents also include correspondence with consultants/external experts, as well as documents detailing how the HACCP plan was developed, minutes of team meetings and most importantly, the rationale for all decisions made.

2.12.2 HACCP CONTROL CHARTS

The process of identification of CCPs and plans for their control are usually documented in the form of a Control Chart – a table containing all the key information related to the CCPs. The template outlined in the Codex HACCP guidelines has become a standard for industry, with adaptation to meet local government requirements or industry preference. (See Appendices 5 & 6).

A Codex style example can be seen in Figure 3 below. This is a simplified HACCP Control Chart of the manufacture of potato crisps. The complete chart would have a lot of extra detail (e.g. SOPs, justification, record sheets) to support it. It would also be necessary to cross-reference the process steps against the flow diagram and control measures, monitoring procedures and corrective actions would be required to be documented as SOPs.

Figures (3): HACCP Chart example (Hazard: Metal)

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Hazard</th>
<th>Control Measure</th>
<th>CCP</th>
<th>Critical Limit Monitoring procedure</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase</td>
<td>Presence of metal in potatoes</td>
<td>Safe, approved supplier</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sieving</td>
<td>Persistence of metal in flavoring</td>
<td>Correct sieving</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal detection</td>
<td>Persistence of metal contamination</td>
<td>100% metal detection</td>
<td>Yes</td>
<td>X mm (ferrous) Y mm (non ferrous) metal</td>
<td>If metal detector is activated when there is no test piece, production must be stopped, the last batch of product must be removed, sent through detector again until metal found and removed. This source of the metal should be investigated and the problem recorded.</td>
</tr>
</tbody>
</table>

2.12.3 DOCUMENTATION OF FOOD SAFETY PROCEDURES

An essential step in managing food safety is the formalization of food safety procedures and this is a major part of any food safety management system, including pre-requisites. This is achieved through the development of clear, easy to follow instructions for all procedures that affect food safety. These are often referred to as Standard Operating Procedures (SOPs) and should relate to the specific business.

SOP examples include:
- Description of the monitoring system for the critical limit of each CCP
- Plans for corrective actions for critical limit violations or situations resulting in potential hazards
- Description of record keeping procedures, including copies of all record forms
- Description of verification and validation procedures

SOPs are only of value if they are written with sufficient detail so that employees can understand the follow them. As a guide, SOPs should be:
- Easy to understand (e.g. pictures or diagrams)
- Easy to read (e.g. large, clear lettering)
- Not too long (e.g. no unnecessary details)
- Cover all the steps required (e.g. nothing important missed out)
- Written with employee involvement (e.g. who have practical experience of the procedures)
- Tested by employees (to ensure they can be followed)
- Validated (to make sure they are safe)
- Easily accessible (e.g. in the place where they are used)

2.12.4 HACCP RECORD KEEPING

HACCP record keeping systems record what actually takes place on a daily basis and forms a history of actual events. The records are kept to demonstrate adherence of the HACCP system with the HACCP plan. These records are used to demonstrate, for example, control at CCPs in the food process by tracking records generated by the HACCP system, an operator or manager can become aware that a process is approaching its critical limit. Review of records can be instrumental in identifying trends and in making operational adjustments. Timely corrective action can be taken if a critical limit is violated.

The records generated by the HACCP system include all activities and documentation required by the plan, as follows:
- Monitoring records for all CCPs
- Corrective action records
- Verification records
- In-house on-site inspection
- Equipment testing and evaluation
- Accuracy and calibration of monitoring equipment
- Training of employees

3. HACCP SYSTEM MAINTENANCE

The HACCP system, if developed and applied according to the previous 12 steps, will be have the potential to control specific food safety hazards and, in combination with pre-requisites, to produce safe food products. However, HACCP requires, like any other management system, actively maintained and reviewed regularly to ensure 'continuous improvement'.

REFERENCES
APPENDICES

APPENDIX 1 - DECISION TREE: EXAMPLE 1


APPENDIX 2 - DECISION TREE: EXAMPLE 2

APPENDIX 3 - PRODUCT DESCRIPTION: EXAMPLE

Product: Canned mushrooms

1. Product name(s)  Canned mushroom
2. Important product characteristics of end product (i.e., pH, Aw, etc.)  pH 4.8 to 6.5 (low acid)
   Aw > 0.85 (high moisture)
3. How the product is to be used  Normally heated before serving (casseroles, garnishes, etc.) or served unheated (salads, appetizers, etc.)
4. Packaging  Hermetically sealed metal container
5. Shelf-life  Two years plus, at normal retail shelf temperatures
6. Where the product will be sold  Retail, institutions and food service. Could be consumed by high-risk groups (infirn, immune compromised, elderly)
7. Labeling instructions  None required to ensure product safety
8. Special distribution control  No physical damage, excess humidity or temperature extremes

DATE: ___________________  APPROVED BY: ____________________


APPENDIX 4 - INGREDIENT AND RAW MATERIAL APPROVAL FORM: EXAMPLE

Product: Canned Mushroom

<table>
<thead>
<tr>
<th>RAW MATERIAL</th>
<th>PACKAGING MATERIAL</th>
<th>DRY INGREDIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mushrooms</td>
<td>Cans</td>
<td>Salt</td>
</tr>
<tr>
<td>(domestic, white)</td>
<td>Ends</td>
<td>Ascorbic acid</td>
</tr>
<tr>
<td>Water</td>
<td></td>
<td>Citric acid</td>
</tr>
<tr>
<td>(municipal)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DATE: ___________________  APPROVED BY: ____________________

APPENDIX 5- PROCESS ANALYSIS DOCUMENT: EXAMPLE

Product: Canned Mushroom

<table>
<thead>
<tr>
<th>MUSHROOM (Raw)</th>
<th>EMPTY CANS/ENDS</th>
<th>DRY INGREDIENTS</th>
<th>WATER (municipal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>Receiving</td>
<td>Receiving</td>
<td>Intaking</td>
</tr>
<tr>
<td>Storing</td>
<td>Storing</td>
<td>Storing</td>
<td></td>
</tr>
<tr>
<td>Dumping/Washing</td>
<td>Inspecting/Depalletizing</td>
<td>Dumping</td>
<td></td>
</tr>
<tr>
<td>Blanching</td>
<td>Conveying</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conveying/Inspecting</td>
<td>Washing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slicing/Dicing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign object removing</td>
<td>Filling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weighing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water filling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Head-spacing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End feeding/Closing/Inspecting</td>
<td>Chlorinating</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermal processing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conveying/Drying</td>
<td>Labelling/Storing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shipping</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DATE: _______________ APPROVED BY: ___________________


APPENDIX 6- HACCP CHART: EXAMPLE 1

This is a simplified HACCP Control Chart used to identify any critical controls for pesticides in the chickpeas purchased for the production of humus. The complete chart would have a lot of extra detail (e.g. SOPs, justification, record sheets) to support it. It would also be necessary to cross-reference the process steps against the flow diagram and control measures, monitoring procedures and corrective actions would be required to be documented as SOPs.

The specific pesticide(s) of concern would also be identified.

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Hazard</th>
<th>Control Measure</th>
<th>CCP</th>
<th>Critical Limit</th>
<th>Monitoring procedure</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase of chickpeas</td>
<td>Pesticide residues above approved levels in product</td>
<td>Purchase only from safe, approved supplier with verifiable GAP (ref: supplier specification in relation to pesticides)</td>
<td>Yes</td>
<td>Every batch from approved supplier only, with supporting documents.</td>
<td>Operative to check every batch, and only allow through if on approved list and with supporting documents</td>
<td>If batch is not from approved supplier, put on hold. Investigate to ensure safety. If documentation is not in place/not in accordance with specification put on hold and contact supplier to request further details (if needed immediately request faxed copy). Record all problems in corrective action log, and review supplier appraisal.</td>
</tr>
</tbody>
</table>

DATE: _______________ APPROVED BY: ___________________
APPENDIX 7: HACCP CHART: EXAMPLE 2
This is an extract from a generic HACCP Chart that identifies the analysis of the chilled storage process step.

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Step</td>
<td>Hazards Identified</td>
<td>CCP? Critical Control Limits</td>
<td>Monitoring</td>
<td>Corrective Actions</td>
<td>Verification</td>
<td>Documentation &amp; Recording</td>
</tr>
<tr>
<td>Chilled Storage</td>
<td>Uncontrolled temperature may result in multiplication of pathogenic microorganisms to unacceptable levels</td>
<td>CCP?</td>
<td>4ºC for Chilled</td>
<td>Temp. Digital</td>
<td>Stores</td>
<td>Every 3 hours</td>
</tr>
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</tr>
</tbody>
</table>

APPENDIX 8: HACCP PLAN: EXAMPLE (BOTTLED WATER)

8.1 IN-LINE MONITORING OF CCP

8.2 HACCP CHART: EXAMPLE 1

Extract from HACCP PLAN: Verification and Record Keeping
Product: Bottled Drinking Water

<table>
<thead>
<tr>
<th>Process Step/CCP</th>
<th>Verification (What/Who/When)</th>
<th>Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reverse Osmosis (RO) Bromate analysis</td>
<td>Laboratory/QC supervisor verify the Finished Product Bromate analysis report on daily</td>
<td>Finished Product Release/Hold Report (Bromate Analysis)</td>
</tr>
<tr>
<td>Post Ozonation</td>
<td>QA Supervisor verify the Daily post ozone monitoring report on daily</td>
<td>Daily Production Line Monitoring Report</td>
</tr>
</tbody>
</table>
### Extract from HACCP PLAN: Critical Limits, Monitoring and Corrective Actions

**Product:** Bottled Drinking Water

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reverse Osmosis (RO) Hazard: Chemical Hazard High Bromate in the Finished Product</td>
<td>≤0.02 ppm</td>
<td>Who: Lab Technician / HSEQ&lt;br&gt;What: Bromate level less than 0.02 ppm&lt;br&gt;When: Before releasing the FP to the market&lt;br&gt;How: Analyze the finished product with Iron Chromatograph&lt;br&gt;Where: Laboratory</td>
<td>Immediate: Isolate product, reject lot or hold until documentation provided. By: Lab technician/ Production supervisor/ Warehouse Supervisor Preventive: Monitoring of RO performance By: Water Treatment Operator</td>
</tr>
<tr>
<td>Post Ozonation Hazard: Microbiological Hazard Ozone presence after filling</td>
<td>0.02 ppm to 0.05ppm</td>
<td>Who: Water Treatment Operator&lt;br&gt;What: Presence of Ozone Level&lt;br&gt;When: Every 2 hours&lt;br&gt;How: With HACH portable instrument / DPD Tablet Method&lt;br&gt;Where: Near Post Ozone Unit &amp; in the Laboratory</td>
<td>Immediate: Stop the production line &amp; Hold the Finished Product from the last inspection time. Re-set the Ozone Unit By: QA Supervisor/ Production Supervisor Preventive: Proper maintenance &amp; calibration of Ozone unit By: Maintenance Team &amp; Lab Technician</td>
</tr>
</tbody>
</table>

### APPENDIX 9: HACCP PLAN AUDITOR CHECKLIST: EXAMPLE

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Describe the Product</strong>&lt;br&gt;a. does the HACCP plan include:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. The procedure / establishment and the product name?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ii. The ingredient and raw materials used along with the product receipt or formation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>iii. The temperature at which the product will be prepared for consumption?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. <strong>Conduct a Hazard Analysis</strong>&lt;br&gt;a. Have all steps in the process been identified and listed where hazards of potential significance occur?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Have all hazards associated with each identical step been listed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Have safety concerns been differentiated from quality concerns?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Have preventive measures to control the identified hazard been identified, if they exist and listed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. <strong>Identify Critical Control Points</strong>&lt;br&gt;a. Has the CCP decision tree been used to help determine if a particular step is a CCP for a previous identified hazard?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Have the CCPs been entered on the forms?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Have all significant hazards identified during analysis been addressed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. <strong>Establish Critical Limits</strong>&lt;br&gt;a. Have critical limits been established for each preventive measure at each CCP?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Has the validity of the critical limits to control the identified hazard been established?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Have critical limits obtained from the regulation, processing authority, etc?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Is documentation attesting to the adequacy of the critical limits maintained on file at the establishment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. <strong>Establish Monitoring Procedure</strong>&lt;br&gt;a. Have the monitoring procedure been developed to assure that preventive measures necessary for controls at each CCP are maintained within the established limits?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Are the monitoring procedures continuous or, when continuous Monitoring is not possible, is the frequency of monitoring sufficiently reliable to indicate that the hazard is under control?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Have procedure been developed for systematically recording the monitoring data?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Have employees responsible for reviewing monitoring records been identified and trained?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Have procedures been developed for using the results of monitoring to adjust the process and maintain control?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. <strong>Establish Corrective Actions</strong>&lt;br&gt;a. Have specific corrective actions been developed for each CCP?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Do the corrective actions addressed:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. Re-establishment of process control?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ii. Disposition of affected product?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>iii. Procedure to correct the cause of non-compliance and to prevent the deviation from recurring?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Have procedure been established to record the corrective actions?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Have procedure been established for reviewing the corrective actions records?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. <strong>Establish Record keeping procedures</strong>&lt;br&gt;a. Have the procedure been established to maintain the HACCP plan on file at the establishment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Do the HACCP records include:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. Description of the product and its intended use?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ii. Flow diagram for the process, indicating the CCPs?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>iii. Critical limits?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>iv. Monitoring systems</td>
<td></td>
<td></td>
</tr>
<tr>
<td>v. Corrective action plan for deviation from critical limits?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vi. Record keeping procedure for monitoring?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vii. Procedures for verification of HACCP system?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. <strong>Establish verification Procedures</strong>&lt;br&gt;a. Have procedure been included to verify that all significant hazards were identified in the HACCP?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Plan when it was developed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Have procedures been included to verify that the critical limits are adequate to control the identified hazard?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Are procedures in place to verify that the HACCP system is functioning properly?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Are procedures in place to reassess the HACCP plan and system on a regular basis whether significant, process or packaging changes occur?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 10- VALIDATION PROCEDURES: EXAMPLES

This document contains examples of several approaches to validating control measures or combinations of control measures. All of the examples described below are for purposes of illustration only, do not represent actual validation scenarios in a global sense and should not be replicated as presented. Also, the examples below are presented in a specific format only for consistency and this format is not intended to be a general model for validation.

In the examples below, it is assumed that the control measures have not been previously validated, that they have a decisive impact on the control of the specific hazard, and that they have been prioritized for validation.

EXAMPLE ONE: CONTROL OF METAL FRAGMENTS

1. Pre-validation Tasks:
   a. Hazard: Metal fragments
   b. Food Safety Outcome: Less than 1 metal fragment over 2 mm in 100,000 kg of product.
   c. Control Measure: Introduction of a sieve into a production line


3. Parameters and Decision Criteria:
   Control measure will be considered validated if a metal detector indicates that production with the sieve will allow < 1 metal fragment ≥ 2 mm in 100,000 kg of final product. Operational data will be collected for one month and reviewed to determine the size of any metal pieces in products rejected by the metal detector.

4. Assemble relevant validation information:
   a. Determine the size of metal fragments in products rejected by the metal detector.
   b. Ensure that the metal detector is sensitive enough and calibrated to detect metal pieces of 2 mm or more in the specific product.
   c. Ensure that the sieve remains intact during normal operations.

5. Analyze the results:
   Determine the size of metal fragments in products rejected by the metal detector.

6. Document and review the validation:
   a. Document all findings from the metal detector.
   b. Document the integrity of the sieve and the sensitivity and calibration of the metal detector.
   c. Document the survey results

7. Conclusion:
   The control measure can be implemented because data indicated that because of the label instructions more than 25% of the population plan to change their current practice and begin refrigerating eggs at 5°C (41°F) and, when appropriate, cooking eggs until the yolk is firm.

EXAMPLE TWO: VALIDATION OF A SAFE-HANDLING LABEL FOR TABLE EGGS

1. Pre-validation Tasks:
   a. Hazard: Salmonella enteritidis (SE) in table eggs (shell eggs).
   b. Food Safety Outcome: Reduced frequency of consumption of eggs contaminated with SE.
   c. Control Measure: Labeling (one control measure among several beginning at primary production (on-farm practices) through consumer use (cooking, storage temperatures)). The label will state: “To avoid illness, refrigerate eggs at 5°C (41°F) and cook eggs until the yolk is firm.”

2. Approach: A representative survey of consumers

3. Parameters and Decision Criteria:
   a. A risk assessment has shown that, in concert with control measures elsewhere in the food chain, the number of servings of eggs contaminated with SE will be significantly reduced if there is a 25% increase in the number of consumers that store table eggs at 5°C (41°F) and cook eggs until the yolks are firm.
   b. The control measure (label) will be considered validated if a specified percentage of the population understands the label (i.e., having read it, they can state what they would do if following the label instructions) and indicates that they plan to follow the instructions.

4. Assemble relevant validation information:
   a. Identify target demographic for survey
   b. Design a statistically-valid survey to determine
      • Current consumer practices
      • Whether the label is understandable
      • Whether consumers plan to change their current practices, if necessary, based on the label instructions.

5. Analyze the results:
   a. Determine the percentage of the population that is currently following the practices described on the label.
   b. Determine the percentage of the population that understands the label instructions.
   c. Determine the percentage of the population that indicates that they plan to change their current practice and follow the label instructions.

6. Document and review the validation:
   a. Document the development of the survey
   b. Document the identification of the target demographics for the survey
   c. Document the survey results

7. Conclusion:
   The control measure will be considered to be validated if, after implementation of cleaning and disinfection protocols, food contact surfaces meet microbiological criteria established for aerobic plate counts or other indicator microorganisms as appropriate.
