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Fostering Academia Industry Collaboration
In Food Safety & Quality

attachment I:

FOOD SAFETY MANAGEMENT SYSTEMS

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HACCP – HAZARD ANALYSIS AND CRITICAL CONTROL POINTS

1. Introduction

The HACCP System is designed to control the production process and is based on principles and preventive concepts. It is intended to apply measures that guarantee an efficient control, through the identification of points or stages where the hazards can be controlled, which can be of biological, chemical or physical nature.

1. Introduction

This system is scientifically based and is based on a systematic approach that not only ensures food safety but also reduces operational costs by reducing the need for microbiological analysis and destruction or reprocessing for safety, of the final product.

1. Introduction

The implementation of the HACCP System reduces the need for inspection and analysis of the final product, thus increasing consumer confidence and safety. The implementation of a HACCP System facilitates compliance with legal requirements, and allows the most efficient use of resources in the immediate response to food safety issues.

2. The concept of the HACCP system

The Hazard Analysis and Critical Control Points (HACCP) system is a systematic approach to biological, chemical and physical hazards, rather than inspection and testing of final products, and is therefore a preventive system through which, by identifying Of potential risks, preventive measures are taken to reduce the likelihood of occurrences that could jeopardize the safety of products and consequently of consumers.

2. The concept of the HACCP system

HACCP is based on an engineering system known as Failure Mode and Effect Analysis (FMEA), which identifies, at each step of the process, the errors that can occur, Their probable causes and their effects, to establish the most adequate control mechanisms.

2. The concept of the HACCP system

The result led to the collaboration of the Pillsbury Company with the US Army and NASA to develop a program for the production of safe food for the American space program. Thus, the Pillsbury Company developed and adopted the HACCP System to ensure more safety while simultaneously reducing the number of inspections to the final product.

2. The concept of the HACCP system

The HACCP System was first introduced by the Pillsbury Company in 1971 at a food safety conference and published the first document detailing the HACCP technique in 1973.

2. The concept of the HACCP system

The Codex Alimentarius Commission has incorporated the "Guidelines for the Implementation of the HACCP System" in 1993, in the Recommended International Practices - General Principles of Food Hygiene [CAC / RCP 1-1969, Rev. 3, Amd.1 (1999a)], that was last amended in 1999.

2. The concept of the HACCP system

The European Union has harmonized the general rules for foodstuffs, incorporating the principles of the HACCP system, by adopting the Directive no. 93/43/EEC of 14 June 1993.

3. The principles of HACCP

The HACCP System is based on a set of 7 fundamental principles:

Principle 1 - Hazard analysis;

Principle 2 - Determination of critical control points (CCPs);

Principle 3 - Establishment of critical limits;

3. The principles of HACCP

Principle 4 - Establishment of a monitoring system;

Principle 5 - Establishment of corrective actions;

Principle 6 - Establishment of verification procedures;

Principle 7 - Establishment of documentation and registration.

3. The principles of HACCP

Principle 1 - Hazard analysis

Conducting a hazard analysis requires the identification of the potential hazards associated with all phases of the process, from raw materials to the final consumer. Inherent in this analysis of hazards is the assessment of the probability of occurrence and the severity of the hazard identified, as well as the analysis of possible preventive measures established for its control, in order to determine their significance.

3. The principles of HACCP

Principle 2 - Determination of critical control points

It is based on the determination of critical control points (CCPs) that can be controlled to eliminate the hazard or minimize the likelihood of its occurrence. A critical control point shall be a point, procedure, operation or stage at which control shall be applied and shall be essential to prevent, reduce to acceptable levels or eliminate a hazard related to food safety.

3. The principles of HACCP

Principle 3 - Establishment of critical limits

It consists in establishing the critical limits that must be ensured in order to ensure that each CCP is controlled. Critical limit means the value or criterion that differentiates acceptance from non-acceptance of the process.

3. The principles of HACCP

Principle 4 - Establishment of the monitoring system

It consists in the establishment of a monitoring system to ensure systematic monitoring of CCPs. As a monitoring system is meant the observation or measurement of control parameters to assess whether a critical control point is within acceptable values.

3. The principles of HACCP

Principle 5 - Establishment of corrective actions

It presupposes the establishment of corrective actions to be taken when monitoring indicates that a particular CCP is not under control. Loss of control means a deviation from the critical control limit of a CCP.

3. The principles of HACCP

Principle 6 - Establishment of verification procedures

It is based on the establishment of verification procedures to confirm the effectiveness of the HACCP System. Verification means the application of methods, procedures, tests and other assessments to confirm compliance with the HACCP Plan and the effectiveness of the HACCP System.

3. The principles of HACCP

Principle 7 – Documents and registers

It is based on the establishment of documentation on all procedures and records appropriate to these principles and their application. The records constitute the evidence of the performance of activities associated with the operation of the HACCP System.

4. The HACCP methodology

The practical implementation of a HACCP System normally follows a methodology consisting of 12 sequential steps, which is based on the 7 stated principles. To these are added 5 preliminary steps that correspond to the structuring of the team that will develop the study and planning of HACCP and the compilation of information of support relevant for conducting the analysis of hazards-

4. The HACCP methodology

Step 1 - Establishment of the HACCP Team;

Step 2 - Description of the product;

Step 3 - Identification of the intended use;

Step 4 - Construction of the flowchart;

Step 5 - Confirmation of the flowchart in the field;

4. The HACCP methodology

Step 6 - Hazard identification and analysis, analysis and identification of preventive measures to control identified hazards (principle 1);

Step 7 - Determination of critical control points (principle 2);

Step 8 - Establishment of critical control limits for each CCP (principle 3);

4. The HACCP methodology

Step 9 - Establishment of the monitoring system for each CCP (principle 4);

Step 10 - Establishment of corrective actions (principle 5);

Step 11 - Establishment of verification procedures (principle 6);

Step 12 - Establishment of control of documents and data (principle 7).

4. The HACCP methodology

Figure – HACCP methodology

4. The HACCP methodology

4.1. The HACCP Team

The HACCP study and planning should be performed by a multidisciplinary team - the HACCP Team - which should include people from various areas (e.g. quality, production, packaging).

4.1. The HACCP Team

HACCP Team selected on the basis of criteria such as:

- Responsibilities;

- Knowledge and experience in the company;

- Knowledge and experience regarding relevant products, processes and hazards within the scope of the HACCP study.

4.1. The HACCP Team

The HACCP Team should, where necessary in certain phases of the study, be extended with elements from other areas whose knowledge and experience is relevant in those phases.

The HACCP Team may, if necessary, include outside consultants who possess know-how and information, which do not exist in the company, which are indispensable for the conduct of the HACCP study.

4.1. The HACCP Team

HACCP team coordinator

The HACCP Team should have a coordinator. The HACCP Team should not be organized conditioned by the hierarchical structure of the company.

4.1. The HACCP Team

HACCP team coordinator

The HACCP Team Coordinator will be responsible for:

- Ensure that the composition of the HACCP Team is adequate for the needs of the HACCP study to be carried out;

- Suggest modifications in the HACCP Team whenever necessary;

4.1. The HACCP Team

HACCP team coordinator

- Coordinate the work of the HACCP Team;

- Ensure that the pre-established plan is followed;

- Distribute work and responsibilities to HACCP team members;

- Ensure the use of a systematic approach in conducting the HACCP study;

4.1. The HACCP Team

HACCP team coordinator

- Ensure that the scope of the HACCP study is fully considered;

- Coordinate the meetings of the HACCP Team, ensuring the conditions for unrestricted participation of all its elements;

4.1. The HACCP Team

HACCP team coordinator

- Ensure that deviations and / or conflicts between elements of the HACCP Team or their departments are avoided;

- Establish mechanisms for the decisions of the HACCP Team to be communicated to the organization;

4.1. The HACCP Team

HACCP team coordinator

- Represent the HACCP Team before the Directorate / Administration.

- Be thoroughly familiar with the HACCP study and have a thorough knowledge of the company's activities.

4.1. The HACCP Team

Initial training

The HACCP Team should receive initial training regarding the HACCP Principles, the implementation and application of the HACCP System.

4.1. The HACCP Team

Initial training

Initial training shall ensure that:

- The HACCP Team work in groups with shared goals and using the same language;

- That the objectives of the HACCP study are adequately understood by all.

4.1. The HACCP Team

Exercise – HACCP Team composition

4.2. Product description

In the implementation of a HACCP System, the HACCP Team should begin by describing the food, which description should take into account both the raw materials used and the final product.

4.2. Product description

4.2.1. Raw material

At the level of the description of the raw materials the HACCP Team should characterize:

- Type of raw materials, packaging materials, method of transportation and packaging, ...

- Percentage in the final product;

- Source;

4.2.1. Raw material

- Physical-chemical characteristics (pH, water activity - wa, viscosity, temperature, concentration in aqueous solution, ...);

- Microbiological characteristics;

- Conservation conditions;

- Preparation / processing conditions before use.

4.2.2. Final product

For the final product, the description should take into account the following elements:

- General characteristics (composition, volume, structure, ...);

- Physical-chemical characteristics (pH, water activity, type and concentration of additives, modified atmosphere, storage temperature, ...);

4.2.2. Final product

- Microbiological characteristics;

- Information at labeling level (product life, conservation instructions / preparation mode, ...);

- Storage and distribution conditions.

4.2.2. Final product

Exercise – Product Specification

4.3. Intended use for the product

The HACCP Team should take into account the identification of the normal customer / consumer groups and the assessment of the existence of potentially sensitive consumer groups among them, in terms of ingredients (e.g. gluten, lactose), and in terms of level of microbiological contamination (e.g. infants, elderly, sick).

4.3. Intended use for the product

The communication to the consumer of the presence of ingredients to which certain groups are intolerant and the conditions of preparation / processing of the product by the consumer are essential in order to avoid their misuse. This communication is made through the labeling, meeting the legal requirements at the level of food labeling established in Regulation no. 1169/2011.

4.3. Intended use for the product

This evaluation of the intended use by the consumer, which is important in assessing the danger associated with improper use of the same, may even determine the recasting of the product and / or process to adapt it to the actual conditions of use of the consumer without such conditions There are more significant hazards.

4.3. Intended use for the product

Exercise – Intended use

4.4. Construction of the flowchart

As important as an adequate description of the product and its intended use is the knowledge of all stages of the process, from the raw materials to the final product, given that it is this set of information that will support the realization of the HACCP study.

The description of processes and their interactions can be described in a systematic way with the use of flowcharts.

4.4. Construction of the flowchart

The construction of flowcharts should take into account:

- The sequence of all steps of the manufacturing process;

- The phases in which inputs of raw materials and intermediate products (including subcontracted products) occur;

4.4. Construction of the flowchart

- The phases where re-work or recycling of raw materials / products occurs;

- The phases where intermediate products, by-products or waste are removed;

- The time / temperature conditions throughout the process.

4.4. Construction of the flowchart

In addition to the flow charts, the plant layout should be taken into account with the layout.

This information is relevant because it is the best way of facilitating the subsequent cross-contamination hazard analysis.

4.4. Construction of the flowchart

Thus, on plant facilities and equipment/plant layout should be marked:

Personnel circuits;

The circuits of raw materials, intermediate products and final products;

Potential pathways of cross-contamination;

Areas of segregation.

4.4. Construction of flowchart

Exercise – Flowchart

4.4. Intended use for the product

Exercise – Layout and flows

4.5. Verification of the flowchart

Since sometimes the construction of the flowchart is totally or partially carried out in the room, it is essential to ensure that the flowchart elaborated corresponds to the present situation. This step is very important because, in many cases, organizations already have process flowcharts, plant plans and equipment layouts, developed at a given moment, but do not have routines for updating these documents.

4.5. Verification of the flowchart

In this situation, or in the absence of full flowcharts, it is recommended that the HACCP Team begin by collecting or initial confirmation of the information at the facility. At the end, after the construction of the flowchart, the HACCP Team must confirm it by following the process. This should be done several times throughout production, covering all operations, to ensure that processes are always conducted in the same way.

4.6. Hazard analysis

Hazard analysis is the key element in the development of the HACCP Plan.

The hazard analysis consists of a process of collecting and evaluating the information on the hazards and the circumstances that result in their presence, in order to decide what are the significant ones for the safety of the food and which should therefore be addressed in the HACCP Plan.

4.6. Hazard analysis

Conducting hazard analysis requires identifying the potential hazards associated with all stages of the process, from raw materials to final consumers.

Inherent in this analysis of hazards is the risk assessment according to the probability of occurrence and the severity of the hazard identified, in order to determine their significance.

4.6. Hazard analysis

Only the dangers considered significant are taken to the "decision tree" to identify critical control points. The analysis of hazards also presupposes the analysis of possible preventive measures established for the control of significant hazards.

Hazard analysis must be performed for each product or process type and for each new product.

4.6. Hazard analysis

In addition, the hazard analysis of a product associated with any type of process should be reviewed whenever there is any change in the raw material, product formulation, processing or expected use of the product by the consumer. Hazard analysis must take into account biological, chemical and physical hazards.

4.6. Hazard analysis

Hazard analysis shall be performed in a systematic and sequential manner in order to minimize the likelihood of not identifying all significant hazards.

Particular attention in this analysis should be given to the raw materials and the process, which are, directly or indirectly, the origin of most occurrences of dangerous situations that were not properly controlled and reflected to the consumer.

4.6. Hazard analysis

At the level of the analysis of hazards related to raw materials it is important to consider, when selecting and / or receiving various issues, such as:

- Are there pathogenic micro-organisms, toxins, chemicals or physical objects that may be present?

- Do the raw materials used incorporate preservatives or other additives in their formulation?

4.6. Hazard analysis

- Is any ingredient (e.g. additive) dangerous if used in excess or, if used in less than recommended amount, can result in a danger of allowing the growth of microorganisms or germination of sporulated cells?

- How can the pH and water activity of raw materials affect growth of micro-organisms in final product?

- At what temperature should the raw materials be maintained during storage and transport?

4.6. Hazard analysis

When analyzing processing-related hazards, including aspects related to the flow of raw materials and product and the movement of operators, it is also possible to list some of the issues that may facilitate the identification of hazards:

- Contaminants can come in contact with the product during this process operation, through operators, equipment or utensils?

4.6. Hazard analysis

- Can any pathogenic microorganism multiply or survive during this stage of the process to the point of danger?

-The operations are performed by operators, respecting good manufacturing practices and good hygiene practices?

- Are there later steps that eliminate or can reduce the identified hazards to acceptable levels ?

4.6. Hazard analysis

Examples – Hazard analysis

4.7. Determination of critical control points

In order to determine the points in the process where controls should be applied in order to prevent, eliminate or reduce hazards to acceptable levels - Critical Control Points - the so-called "decision tree" is used.

4.7. Determination of critical control points

The "decision tree" is a protocol consisting of a sequence of structured questions, applied at each step of the process, to determine if a given control point at this stage of the process constitutes a Critical Control Point. The four questions used in the decision tree and their interpretation are presented here.

4.7. Determination of critical control points

Figure - Decision Tree

4.7. Determination of critical control points

Q1. Are there preventive measures for the hazard identified?

Question Q1 should be interpreted as asking whether the operator could use a preventative measure for this operation to control the identified hazard (e.g. temperature control, visual inspection, metal detector).

4.7. Determination of critical control points

If the answer to Q1 is "yes" then the control measures that the operator could use and follow for Q2 of the decision tree should be described.

4.7. Determination of critical control points

If the answer is "no", i.e. no preventive measure, the manner in which the hazard identified will be controlled before or after the manufacturing process shall be indicated. If it is necessary to ensure food safety, the operation, process or product must be modified in such a way as to provide for a preventive measure. This means that, for all significant hazards implemented, preventive measures must be in place.

4.7. Determination of critical control points

Q2. Has this step been specifically designed to eliminate the possible occurrence of the hazard or to reduce it to an acceptable level?

If the process or operation is designed for the specific purpose of eliminating the possible occurrence of the hazard or reducing it to an acceptable level the response shall be "yes" and it is a CCP.

4.7. Determination of critical control points

If the stage is not specifically designed, answer "no" and proceed to the next question (Q3).

4.7. Determination of critical control points

Q3. Can contamination of identified hazard occur above acceptable levels, or may it increase to unacceptable levels?

Question Q3 is intended to verify that the hazard has an impact on the safety of the product, taking into account the likelihood and severity associated with it.

4.7. Determination of critical control points

Regardless of whether the answer is "yes" or "no", it should justify a response, for future reference. This is especially useful in dealing with certain dangers which may be controversial and where it is necessary to review the risk analysis, in particular as a result of changes in the process or the characteristics of the raw materials and the intended end product.

4.7. Determination of critical control points

If the company's history or if the scientific literature suggests that the contamination with the identified hazard may increase to an unacceptable level and result in a health hazard, the answer should be "yes" and then move on to the next "tree" question Of decision ": question Q4.

4.7. Determination of critical control points

If the contamination does not pose a significant threat to health or there is no possibility of occurrence, the answer should be "no", implying that this hazard is not a significant hazard. In this situation one should move to the application of the decision tree to the next significant danger identified in the process.

4.7. Determination of critical control points

Q4. Will a subsequent step eliminate the identified hazard or reduce the possible occurrence to an acceptable level?

The purpose of this question is to identify hazards which pose a threat to human health or which may increase to an unacceptable level and to assess whether these hazards will be controlled by a subsequent operation in the process.

4.7. Determination of critical control points

If there is no subsequent step in the process to control the hazard, the response should be "no" and in this case the step under review becomes a CCP and should be identified as such. If there is any subsequent operation in the process that will eliminate the identified hazard or reduce it to an acceptable level, the response should be "yes", in which case the step does not constitute a CCP. However, the subsequent steps that control the hazard must be identified before proceeding to the next identified hazard.

4.7. Determination of critical control points

The determination of CCPs concludes the HACCP study phase. The following steps, encompassing principles 3 to 7 of the HACCP System, lead to the development of the HACCP Plan. The HACCP Plan includes the establishment of: (i) critical limits, (ii) the monitoring system, (iii) corrective actions. The HACCP System is completed with the establishment of verification procedures and maintenance of HACCP.

4.8. Establishment of critical limits

For the critical control points identified in the previous step it is necessary to establish the respective critical limits, understood as the value or the criterion that differentiates the acceptability from the non-acceptability.

Critical limits must be established for each parameter associated with a CCP.

4.8. Establishment of critical limits

The parameters associated with each CCP must clearly demonstrate that it is controlled (e.g., temperature, time, flow rate, relative humidity, water activity, pH).

The critical limits must comply with legally established requirements and be in conformity with existing scientific and technical knowledge. Whenever possible, critical limits should be supported by evidence.

4.8. Establishment of critical limits

Critical limits based on subjective data (e.g. visual inspection) must be supported by clear specifications of what is considered acceptable or unacceptable.

4.8. Establishment of critical limits

The establishment of critical limits should be done within the scope of the HACCP Team. In establishing these limits, the HACCP Team may use various sources of information, including:

- Data from scientific publications or research;

- Legal requirements;

4.8. Establishment of critical limits

- Specialists (e.g. consultants, food engineers, microbiologists, equipment manufacturers, university professors and researchers);

- Experimental studies (e.g. internal, sub-contracted or performed by third parties).

4.8. Establishment of critical limits

If the information necessary to establish the critical limits is not available, a conservative value should be established, while relying on technical-scientific knowledge, in particular that associated with other products.

The bibliographic references used in the reasoning of the decisions taken constitute the documentation supporting the HACCP System and should therefore be registered.

4.8. Establishment of critical limits

Potential hazards	Product temperature	Maximum accumulated time of exposition
Clostridium botulinum Tipo A, and proteolyptic B e F	10-21ºC Above 21ºC	11 hours* 2 hours*
Escherichia coli	7-10ºC 11-21ºC Above 21ºC	14 days 6 hours 3 hours
Listeria monocytogenes	-0.4-5C 6- 10º C 11-21ºC Above 21ºC	7days 2 days 12 hours 3 hours
Salmonella spp.	5.2-10ºC 11-21ºC Above 21ºC	14 days 6 hours 3 hours
...		

4.8. Establishment of critical limits

Operational limits

In practice, in any processing, it is desirable that steps can be taken when monitoring processes indicate a tendency for loss of control, even before the critical threshold is reached.

It is therefore appropriate to establish more restrictive limits, known as operational limits, which, once achieved, will give rise to the initiation of corrective actions without any violation of the critical limits.

4.8. Establishment of critical limits

This approach reduces the number of situations where critical limits are reached, with costs substantially lower than those that would inevitably be associated if critical limits were reached (e.g. acidification process: critical limit = 4.6 and operational limit = 4.4).

4.9. Establishment of monitoring system

4.9.1. Monitoring system

The monitoring consists of carrying out a planned sequence of measurements of the control parameters to evaluate if their respective critical limits are respected.

The monitoring should provide timely information to enable corrective action to be taken to keep the process under control before segregation and/or product rejection (e.g. t/T measurements, salt concentration, pH, …) are need.

4.9.1. Monitoring methodology

The monitoring of a critical control point may be carried out continuously or batch by batch. Continuous monitoring is preferable since it allows, more reliably, to identify deviations from established values more quickly.

4.9. Establishment of monitoring system

4.9.2. Monitoring methodology

However, this type of monitoring is not always possible, often because of the very nature of the measurement (e.g. it is not possible to do it in real time as it takes some time to perform the measurement / analysis) or associated costs.

4.9.2. Monitoring methodology

In such situations, sampling size and frequency should be defined taking account of the process variability itself, the distance between the critical limit and the operational limit, and the ability to correctly identify the potentially affected product and to trigger corrective actions when deviations occur.

4.9.2. Monitoring methodology

When problems are detected, the monitoring frequency should be increased until the root cause of the problem has been identified and effective corrective actions have been implemented.

Measurements of a physical-chemical nature (e.g. time, temperature, pH, moisture content) or visual observations are preferably used for the rapidity of their realization.

4.9.2. Monitoring methodology

The monitoring plan for critical control points is what is commonly called the HACCP Plan. This should indicate which:

- Critical control points;

- The control parameters associated with each critical point (e.g. time, temperature, pH, wa);

- Critical limits of control for each CCP;

- The method as parameters will be monitored (e.g. temperature probe, stopwatch, pH meters);

4.9.2. Monitoring methodology

- The frequency of monitoring;

- Who is responsible for monitoring;

- Actions to be taken in case of deviation from the established critical limits;

- The location where the monitoring data is recorded.

4.9.2. Monitoring methodology

Monitoring should be performed by trained personnel with defined knowledge and authority to specify and implement corrective actions where necessary.

Monitoring procedures and associated records shall provide operators with sufficient information to enable them to take decisions on the acceptance or rejection of a product and to support the initiation of appropriate corrective actions or the immediate communication of deviations to those having the authority to trigger such actions .

4.9.2. Monitoring methodology

Persons with responsibility for monitoring critical points should:

- Know the process they are monitoring;

- Know the monitoring process and carry out the monitoring activities with the established frequency;

- Record monitoring results;

4.9.2. Monitoring methodology

- Interpret the results of monitoring and trigger, where necessary, corrective actions in accordance with the authority assigned to it in the HACCP Plan;

- Immediately report deviations within critical limits.

4.9. Establishment of monitoring system

Exercises – CCP Monitoring

4.10. Establishment of corrective actions

Corrective action may be defined within a HACCP system as an action to be implemented when the results of CCP monitoring indicate a loss of control, i.e.: a deviation from the critical limit of a CCP.

4.10. Establishment of corrective actions

The corrective action procedure should detail:

- The actions to be taken to ensure that the CCP is brought back into control limits;

- The authority for the definition / implementation of corrective action;

- What actions to take to deal with the defective product.

4.10. Establishment of corrective actions

In case of deviations from the critical limits the company must:

- Have a system to identify deviations when they occur;

- Have effective procedures for isolating, clearly identifying and controlling all product produced during the deviation period;

4.10. Establishment of corrective actions

Evaluate the product using a qualified person to ensure that:

(i) the sampling is appropriate to identify the extent of the problem, as well as appropriate testing;

(ii) the assessment is based on a logical and systematic analysis;

(iii) the product is not released until the assessment determines that there is no potential hazard.

4.10. Establishment of corrective actions

Depending on the nature and extent of the diversion, the product may have diverse destinations ranging from its reprocessing or use in another type of process or product to disposal.

4.10. Establishment of corrective actions

With the implementation of corrective actions it is intended:

- Determine the cause of the problem;

- Take action to avoid recurrence;

- Follow up through monitoring and reassessment to ensure the effectiveness of the implemented action.

4.10. Establishment of corrective actions

Following the implementation of the corrective action, consideration should be given to the need to revise the HACCP system in order to prevent any recurrence.

4.10. Establishment of corrective actions

Exercises – Corrective actions

4.11. Establishment of verification procedures

The purpose of the verification is to determine:

- If the HACCP System is implemented according to the HACCP Plan (correct determination of the PCC, correct definition of the parameters and respective critical limits of control, adequate monitoring) and that the necessary corrective measures have been implemented;

4.11. Establishment of verification procedures

- If the current HACCP Plan is properly developed and implemented taking into account the current products and processes, that is, it proves to be effective.

4.11. Establishment of verification procedures

Verification procedures shall clearly state the responsibility, frequency and methods used.

Verification should be carried out by qualified personnel with knowledge of the HACCP Plan / System (e.g. elements of the HACCP Team) capable of detecting deficiencies in the plan or its implementation.

4.11. Establishment of verification procedures

This activity must be carried out:

- Upon completion of the HACCP study, for validation;

- Whenever there is a change that may affect hazard analysis (e.g. change of raw materials, product or process);

- When a deviation occurs;

4.11. Establishment of verification procedures

- When scientific knowledge of new potential hazards or control measures;

- Due to unsatisfactory results in the scope of auditing;

- Faced with customer or consumer complaints;

- At regular intervals, according to a predetermined program.

4.11. Establishment of verification procedures

The verification of the HACCP System involves the analysis of HACCP document documents and their records, the scientific evaluation of all the hazards considered, to ensure that all those that could be considered significant and the analysis of critical threshold deviations and corrective actions taken for each deviation.

4.11. Establishment of verification procedures

Periodic verification should help to improve the HACCP Plan by exposing and strengthening weaknesses in the system and eliminating unnecessary or ineffective control measures. Key verification activities include:

- Validation of the HACCP plan;
- Audits to the HACCP System;
- Collection and analysis of samples.

Validation of the HACCP plan

The validation of the HACCP Plan corresponds to the activity of assessing whether the HACCP Plan adequately identifies and controls all significant hazards to food safety or reduces them to an acceptable level.

The evaluation should be supported in a review of the literature to ensure an adequate scientific and technical basis for decisions.

Validation of the HACCP plan

Validation of the HACCP Plan should include:

- Review of hazard analysis;

- Determination of CCPs;

- Justification for critical limits (e.g. legal requirements or available scientific data);

- Evaluation of monitoring results / records of the HACCP Plan;

Validation of the HACCP plan

- Analysis of corrective actions implemented and their effectiveness;

- Review of HACCP audit reports;

- Review of changes to the HACCP Plan;

- Review of previous validation reports;

Validation of the HACCP plan

- Evaluation of the effectiveness of corrective actions implemented;

- Review of information on customer and consumer complaints;

- Review of the links between the HACCP Plan and the good manufacturing and hygiene practice.

Audits of the HACCP system

Audits, as part of the verification, are performed to compare the actual practices and procedures of the HACCP System with those written in the HACCP Plan.

Audits of the HACCP System are intended to carry out independent and systematic assessments through on-site observations, interviews and document and record analyzes to determine whether the procedures and activities set out in the HACCP Plan are effectively implemented and are complied with.

Audits of the HACCP system

The on-site observation can be used to verify several elements of a HACCP Plan, of which the following stand out:

- Proper description of products and flowcharts;

-Compliance with CCP monitoring in accordance with the HACCP Plan;

Audits of the HACCP system

- The execution of the processes within the established critical limits;

- Records of HACCP activities (e.g. monitoring records as established in the HACCP Plan, corrective action records triggered against deviations from established critical limits, calibration records of inspection and measurement equipment).

Audits of the HACCP system

Audits should be carried out at an frequency to ensure the maintenance of the effectiveness of the HACCP system, taking into account the risk specificities of the products and the variability of processes.

At the very least, a full audit of the HACCP System should be carried out once a year.

Following failure situations of the HACCP System, the need to carry out extraordinary audits that were not initially planned should also be considered.

Sample collection and analysis

The sampling and analysis plan consists of the collection and analysis of product and raw materials samples to ensure that critical limits are adequate for product safety.

Sampling of raw materials may be carried out to verify the supplier, in particular where the reception of the raw material constitutes a critical control point.

Sample collection and analysis

In general, sampling and microbiological analyzes are not sufficient to ensure the safety of the food.

Microbiological analyzes are rarely effective in monitoring CCP and cannot be used as a means of controlling the process due to delayed analytical procedures and the inability to deliver results in real time.

Sample collection and analysis

However, microbiological analyzes are useful in checking the HACCP System when critical limits are established to eliminate or reduce pathogens to an acceptable level to verify the efficiency of the HACCP Plan and to ensure that the identified microbiological limits are not exceeded.

The performance of microbiological analyzes is very useful in process validation.

Sample collection and analysis

Samples of products may also be collected at points of sale and analyzed for any problems not considered in the hazard analysis but which may arise along the food chain due to inadequate storage or handling of the product of customers.

Microbiological analyzes shall be carried out in accordance with a pre-established program which shall take into account the nature of the processes and the level of risk associated with the raw materials and products.

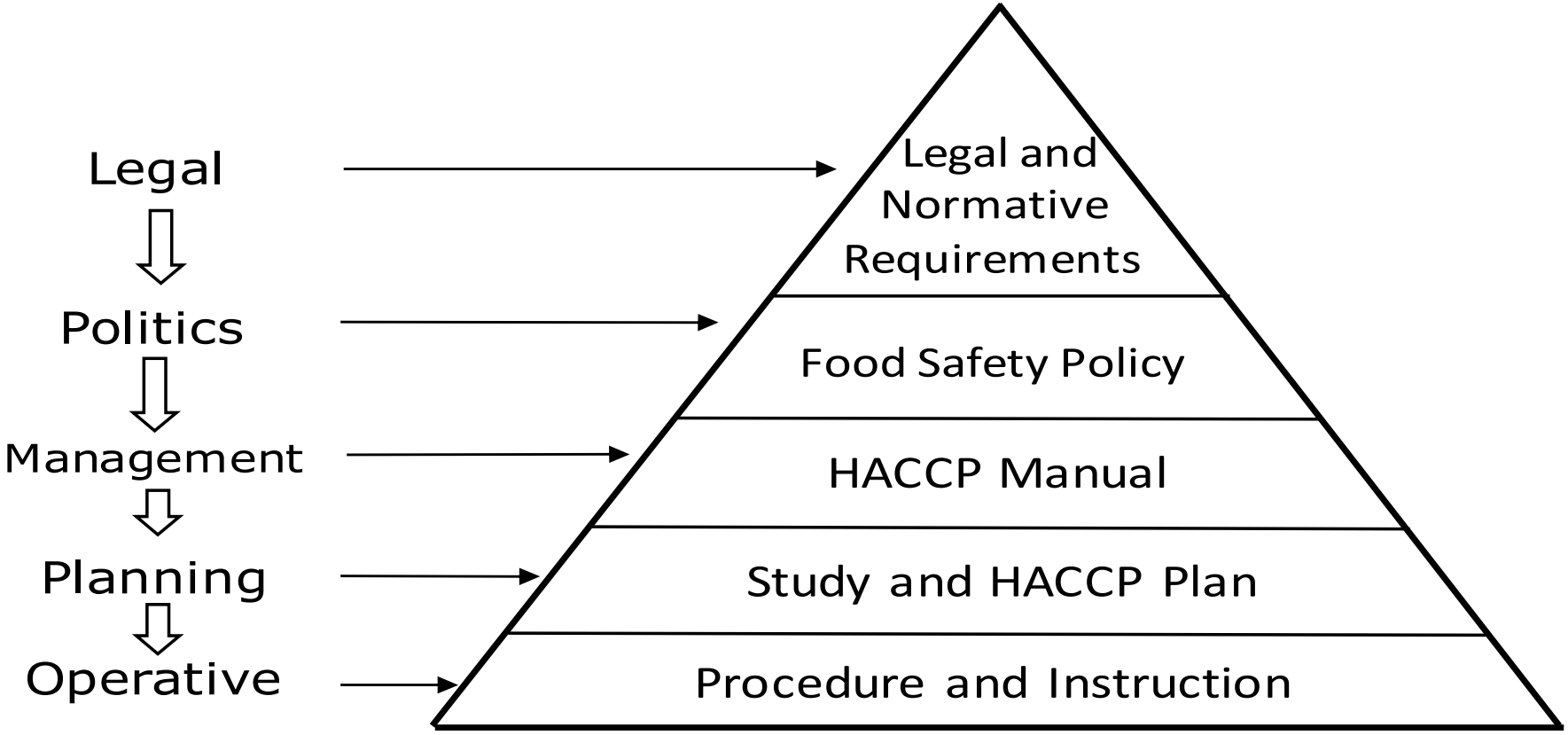
4.12. Documents and registers

The HACCP System is a documented system.

An adequate establishment of documentation is essential for an effective implementation of the HACCP System.

Documentation normally found in a HACCP management system has hierarchy levels.

4.12. Documents and registers



4.12. Documents and registers

Types of documents and records

Among the documents and records to be considered in a HACCP System are the following:

- The procedures describing the HACCP System;

- Descriptions of the products and their expected use;

Flowcharts of production processes;

Types of documents and records

- Documents and data used in hazard analysis and establishment of the HACCP Plan (e.g. data used to define control measures and establishment of critical control limits; data obtained in process validation and product shelf-life);

Hazard analysis and the determination of critical points;

Types of documents and records

- The HACCP Plan, including the description of critical limits for each CCP and its monitoring;

- Records associated with CCP monitoring;

- The reports / minutes / minutes produced at HACCP Team meetings;

- Deviations and associated corrective / preventive actions;

Types of documents and records

- HACCP audit reports;

- Product Technical Data Sheets;

- Technical Data Sheets of Raw Materials;

- Identification cards of the state of inspection and testing;

- Sanitation plan;

Types of documents and records

- Pest control plan;

- Training plan;

- Training records (e.g. program content, summaries, attendance list);

- Calibration Plan;

- Calibration records (e.g. calibration certificates);

Types of documents and records

- Maintenance plan;

- Maintenance records (e.g., equipment registration forms);

- Internal Audit Plan;

- Internal Audit Reports;

- HACCP Team Meeting Minutes;

Types of documents and records

Registration Control Table;

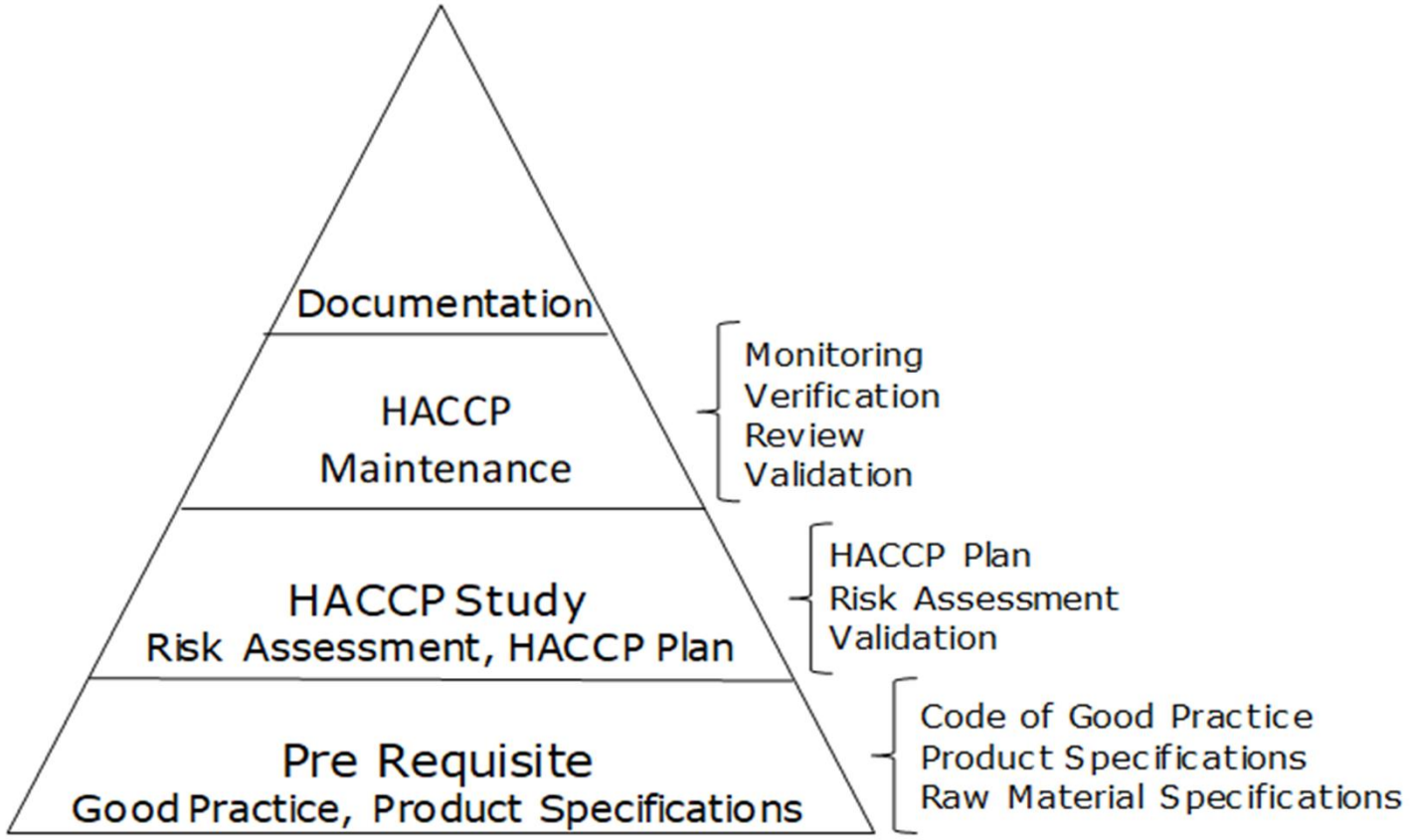
- Document Control Table;

- Various procedures (e.g. Management review, Control of Documents and Records, Control of Inspection, Measurement and Monitoring Equipment, Treatment of Non-conformities, Corrective and Preventive Actions, Control of HACCP Records, Internal HACCP Audits, Training).

4.12. Documents and registers

Exercises – Examples of documents

4.12. Documents and registers



4.12. Documents and registers

Management of documents and records

Documents and records shall be managed in accordance with a specific procedure. Documents must:

- Find themselves indexed;

- Be available for consultation where needed for the activity;

Management of documents and records

- May be modified / updated (procedures and forms);

- Be maintained during pre-defined periods, established based on the life time of the product and other criteria, namely of a legal nature;

- Indicate the update status.

Management of documents and records

An adequate archive of records makes it possible to prove, under any circumstances, that the HACCP Plan procedures are being complied with in accordance with the requirements of the HACCP System.

Thus, these records are used to demonstrate compliance with the specific critical limits established for each CCP in food processing.

Records review can also be an instrument for identifying trends and making adjustments to operational limits.