SECTION IV.

HACCP APPLIED TO PRIMARY PRODUCTION
Systematic and preventive approach that addresses biological, chemical and physical hazards through **anticipation and prevention**, rather than through end-product inspection and testing.
Advantages

• can be applied throughout the food chain “from farm to plate”
• more effective use of resources, savings to the food industry and more timely response to food safety problems.
• enhances the responsibility and degree of control throughout the food chain
• Consumer protection, guarantee of food safety products.
• Compatible with the quality control systems.
• Flexibility according to technological changes, procedures, etc.
Why is HACCP internationally recognized?

The work of the Codex Alimentarius Commission, including the Guidelines for the application of the Hazard Analysis Critical Control Point (HACCP) system, has become the reference for international food safety requirements.
What has to be done before applying HACCP?

- Establishing pre-requisite programmes (GAP, GMP, SOS, training programmes, etc.)
- Compromise and responsibility of people involved.
- Multidisciplinary approach.
- Applied to every operation.
- Controls applied only on critical points.
- Flexibility in its application.
What has to be done before applying HACCP?

HACCP is as a table, needs solid legs.
HACCP PLAN:
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.
Some definitions

HACCP SYSTEM:

Results of implementing the HACCP plan.
Some definitions

Control:

A) To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

B) To state wherein correct procedures are being followed and criteria are being met.
Some definitions

Monitoring

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

Control Point (CP):

Any step or procedure at which biological, physical or chemical hazards can be controlled.
Some definitions

Critical Control Point (PCC):

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.
Guideliness for application

A logical sequence of consisting 12 steps:

• Plan design
• Plan elaboration
• Plan implementation
Assemble the HACCP team

Product description

Identify product intended used

Construct flow diagram

On-site confirmation of flow diagram

List all potential hazards, conduct a hazard analysis and consider any measures to control identified hazards.
Determine CCP

Establish critical limits for each critical control point

Establish a monitoring system for each CCP

Establish corrective actions

Establish verification procedures

Establish documentation and record keeping
HACCP Team

- Group of people responsible for elaborating and implementing the HACCP Plan.
Team work's responsibilities

- define the objectives and scope of the HACCP Plan.
- product (s) to be considered.
- procedures-stages to be considered.
- kind of hazards to be included.
- evaluate human and financial resources.
Multidisciplinary team members, with knowledge in:
- the identification of hazards associated to produce production and post-harvest stages.
- production and post-harvest produce operations
- the principles and practices of HACCP and GAP, GMP, GHP, SOP, etc.
- product market requirements.

And experienced in:
- training methodologies and transferring technology projects.
- implementing Integrated Crop Management systems (ICM) and Integrated Pest Management systems (IPC).
Considerations

- Small teams.
- Team leader.
- Initial training to the team members.
Product (s) to be included.

- Convenient to carry out HACCP plans by product, and then to integrate them into a unique safety assurance programme for the company.
Define the specific process

- Farm activities.
- Packaging activities.
- During transport.

Keep in mind...the food chain approach..
Define the type(s) of hazards to be included

**Physical Hazards?**
Higher risk in raw consumed products.

**Chemical Hazards?**
Raw products, exposed surfaces, etc.

**Biological Hazards?**
Highly perishable, with exposed surfaces, washed, etc.
Financial Resources

- 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.
Description of: product composition, packing, transport and distribution conditions and requirements, proper handling, post-harvest life and use instructions.
Objective

• to assist in the identification of all possible hazards associated with the product use (raw or processed, peeled or unpeeled, etc.)

• Identification of critical stages of the process. (post-harvest operations i.e., washing, packaging materials, etc.).

• Product’s sensitivity according type of consumers (children, adults, pregnant women, etc.).
Objective:

- to easily identify routes of potential contamination.
- to suggest methods of control and to discuss these among the HACCP team.
- to support the identification of Critical Points in the process.

It should include: sequence of all process steps, if possible records of the time required to properly perform the operations, time/temperature history of all raw materials and intermediate and final products, equipment design features, packaging design and location, etc.
Once the process flow diagram and packaging layout have been drafted, they must be confirmed by an on-site inspection for accuracy and completeness.
What is a hazard analysis?

- The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.
Sources of information:

• Reference texts.

• Product rejections texts.

• Scientific publications and bibliographic revision.

• FAO/WHO.

• Internet (Global Network of Outbreak Reports).

• Experience of the HACCP team and other food chain actors.
1. List of potential hazards (physical, chemical, biological) that may be reasonably expected, at each process stage.

2. Evaluate the importance of the hazard: the potential risk of each hazard.....probability of occurrence and its severity.
Combining experience, epidemiological data and technical information.

Severity .... the degree of consequences that can result when a hazard exists.
Hazards addressed under the HACCP system must be of such a nature that their prevention, elimination or reduction to acceptable levels is essential to the production of safe foods.

Hazards of a low probability of occurrence and a low severity should be addressed through GAP and GMP.
How to carry out the hazard analysis?

- Review inputs (at production-post-harvest operations).
- Evaluate processing operations for hazards.
- Observe actual operating practices.
- Take measurements.
- Analyze the measurements.
In the primary production some inputs are:

- Soil.
- Water.
- Seeds.
- Agrochemicals: pesticides, fertilizers, etc.
- Organic fertilizers.
- Labor.

“Same approach when applying GAP, GMP”
Step 6  

Review the inputs

In post-harvest some inputs are:

- The product itself.
- Water for product washing.
- Water for personal use and cleaning programmes (locations, equipments, etc.)
- Agrochemicals: waxes, fungicides, disinfectants.
- Labor (personal)
- Packing materials
Step 6  Evaluate operations for hazards

• Assign a number to each processing step on the process flow diagram. Separate clean area or dirty areas.

• Examine each step on the process flow diagram and determine if a hazard (biological, chemical or physical) exists for that operation.

• Review the plant layout and employee traffic pattern.
Evaluate operations for hazards

- Observe the employees
- Observe hygienic practices and note the hazards.
- Analyze if there is a “kill step” (process which destroys all microorganisms), if so, attention should be focused on potential cross-contamination after this processing operation.
Sometimes it is important to take measurements of key operational parameters to confirm actual operating conditions:

Such as: temperature in cooling rooms, product temperature, Relative Humidity, Drying temperature, pH of water, analysis of contact surfaces, water analysis, etc.
any actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

• one measure may be required to control a specific hazard
• more than one hazard may be controlled by a specified measure.
Chemical and physical hazards:

- Source control, i.e., control of raw materials.
- Processing control, i.e. the proper use and control of fungicides.
- Control of incidental contamination from chemicals.
- Labeling and packing control, i.e. assuring that the finished product is accurately packed and labeled with ingredients and known allergens.
CONTROL MEASURES
microbiological contamination of
product washing water

Prevention:
• Water use for product washing must be drinkable. In order to demonstrate its quality, periodical analysis are required.
• Recycled water should be treated and maintained in conditions that do not constitute a risk to the safety of fresh fruits and vegetables. The treatment process should be effectively monitored and controlled (use of filters).

Reduction and elimination:
• in order to reduce and/or eliminate the microorganisms from the water, the sanitation process should include the following methods……
Determine 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”.
Control Point:

“Process stage at which a loss of control will unlikely result in an unacceptable risk for consumers, but action is required. GAP, GMP and GHA focus CP.
How does this concept apply to the primary production?

Normally, there is not a unique control measure, that once applied to a process step, it can reduce or control a hazard; instead of that, several measures are required to control or prevent an identified hazard.
What could be considered an acceptable level in fresh fruit and vegetables?

Difficult to define, because.....for microbiological hazards for example...

• Once the product is contaminated, if the conditions are appropriate, the pathogenic growth rate is quite high.

• The ability of a pathogen to cause adverse damage depends on the age and host condition.
An acceptable level in terms of the primary production could be defined as:

An accepted value or range of values and “practices”, required by the market, a code of practice, a law or regulation, in order to assure product safety and its aptitude for use.
It is important to verify if any of the identified hazards are fully controlled by the application of GAPs, GMPs, GHPs.

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 GMP/GHP measures.

Hazards that are not fully controlled by prerequisites programmes, should be analyzed to determine whether they are CCPs or not.
If a hazard has been identified at a step where control is necessary for safety and if no control measure exists at that step or at any other, then the product or process should be modified at that step, or at an earlier or later stage, to include a control measure.
GAP, GMP, GHP are essentials to prevent and control hazards at primary production…but when they don’t completely do so...

What control points in the process are critical to reduce or eliminate hazards, once they occur?
Control of inputs.
Water: possible source of product contamination, **Control Points** during process stages, those implying direct product contact with water, such as:

- Irrigation by aspersion.
- Water used for aspersion of agrochemical.
- Washing water (water in post-harvest)
- Water used in pre-cooling treatments (ice, dipping, etc).
Determine CCP

Are those really Critical Control Points?
Water:
Hazards associated to water contamination can be prevented or controlled through application of GAP, GMP, GHP. However, procedures such as sanitation of washing water are specially designed to reduce and eventually eliminate the microbiological contamination, so this stage will be considered a CCP.
Manure (organic fertilizers): high source of potential contamination.

Associated Control Points are for example:

- quality of fertilizers used (certified they have been properly treated: drying, anaerobic digestion, alkaline stabilization, etc.).

- Proper production, application and storage conditions.

There is not a “unique” stage, where a control measure can completely control or prevent the hazard...several control measures should be applied.
Determine CCP

Control points for hazards introduced by persons are those process stages related with direct product handling, for example:

Manual harvesting, selection, manual grading, packing, etc. Hazards associated to people contamination can generally be prevented and controlled through GHP.
The process stages that reduce or eliminate the hazards to acceptable levels are **Critical control points**

- Water sanitation.
- Irradiation.
- Temperature treatments (for quality aspects rather than safety ones).
- Drying temperature.
- Metal control.
Chemical contaminants: potential control points:

- Agrochemical sprays.
- Selection process during packaging - eliminate mycotoxins (i.e., patuline).
- Quality of the water used in post-harvest (washing, post-harvest sprays, etc.)

Chemical contamination can be prevented by GAP, GMP, and implementation of Integrated Crop Systems and Integrated Pest management systems.
Physical contaminants: they can normally be prevented and controlled by application of GAP, GMP and GHP. So they are not CCP.

**Exception**: Metal detector used in minimal processed food.
At primary production:

**Control Points**: process steps where control measures should be applied in order to prevent and control food safety hazards (GAP, GMP, GHP).

Several control measures associated to a hazard, it is important to define the **control points** and the **control measures** that could have a big impact in the prevention and control of the hazard.

**A Control point is Critical**: when there are process stages where it is possible to apply a control measure in order to **reduce** to an acceptable limit or **eliminate** the identified hazard.
Determine CL for each CCP.

Step 8

Criteria which separates **acceptability** from **unacceptability**.
Step 8  Determine CL for each CCP.

Principle 3.

But, an acceptable level at primary production is:
Step 8. Determine CL for each CCP.

Principle 3.

Accepted levels referred to for example:

- Presence of total and fecal coliforms in water and soil.
- Optimal refrigeration temperature.
- Minimal concentration of Chlorine and time of contact with the product.
- pH and temperature of product washing water.
Chemical hazards:

- Maximum levels of pesticides allowed in the product.
- Pre-harvest interval for pesticides applications
- Limits referring to process conditions: recommended doses, threshold for pest control, etc.
The accepted values should come from:

- Results of research
- Requirements and regulations
- Opinions of specialist in the topic.
- Experimental studies
Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits.

What, how, who, when to monitor?
What will be monitored?

• Measurement of the time and temperature of a thermal process.

• Measurement of cold-storage temperatures.

• Visual revision of the control measures implemented (i.e., visual revision of the packed product).

• Verification of quality certificates of raw materials.
How will critical limits and preventive measures be monitored?

Thermometer, clock, Scales, pH-meters, water activity meter, chemical analytical equipment, etc.

Microbiological analysis are not cost effective,,,take Time, need quick results reviewing the operational conditions.
Monitoring frequency
Where possible, continuous monitoring is preferred to non-continuous one.

Frequency depends on historical knowledge of the product and process.
Who will monitor?

- 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
• "any action to be taken when the results of monitoring at the CCP indicate a loss of control".

• Loss of control is considered as a deviation from a critical limit for a CCP.

  Deviation : "failure to meet a critical limit".
Corrective Actions

Principle 5.

- Identification of the cause of deviation.
- Corrective action is taken following any deviation to ensure the safety of the product and to prevent recurrence of the deviation.
- Follow up with monitoring and reassessment to ensure that the action taken is effective.
- Information should be recorded in the deviation and corrective action records.
Examples of corrective actions:

• Calibration and equipment maintenance programmes.
• Repeat the treatment.
• Adjustment of records and documents.
• Buying new equipment.
• Training of personnel.
Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the **HACCP system is working correctly.**
• Review of the hazard analysis ·
• CCP determination
• Justification for critical limits, based for example on current good science and regulatory requirements
• Determination of whether monitoring activities, corrective actions, record keeping procedures and verification activities are appropriate and adequate
• Review of HACCP audit reports
• Review of changes to the HACCP plan and the reasons for those changes
• Review of past validation reports
• Review of deviation reports
• Assessment of corrective action effectiveness
• Review of information on consumer complaints
• Review of linkages between the HACCP plan and GMP programmes.
• Support documentation for developing the HACCP plan
• Records generated by the HACCP system
• Documentation of methods and procedures used.
• Records of employee training programmes
Data used to establish: the control measures to prevent microbiological growth, the shelf-life of the product (if age of the product can affect safety), the adequacy of critical limits in ensuring the safety of the product.

Product description and intended use, flow diagram, hazard analysis, identification of CCP, 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 preventive measures for each hazard.
Documents generated by the HACCP plan:

- Documented deviation and corrective action plans.
- Planned verification activities and procedures.
- Identification of the preventive measures for each hazard.
Documentation of methods and procedures used:

• Description of the monitoring system for the critical limit of each CCP, including: the methods and equipment used for monitoring, the frequency of monitoring and the person performing the monitoring.

• 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.
Limitations:
Difficult to establish CCP and CL (as strictly defined by HACCP).

However,,,, what is most useful is the systematic HACCP approach for analyzing food hazards.

The GAP guidelines are based on this approach to analyze the risk of each hazard- classifying the control measures as : major, minor and recommended control measures according to the risk each hazard represents. The control measures are seen as a way to PREVENT hazards instead or to reduce or eliminate them once they have occurred.
GAP guidelines follow the HACCP principles

- List all potential hazards associated with each step, conduct a hazard analysis and consider any measures to control identified hazards.
- Establish control points and define priorities in terms of the control measures to be applied. Control seen as a Preventive measures.
- Defined what is acceptable and unacceptable level of acceptability for each control point.
- Establish corrective actions.
- Establish monitoring procedures.
- Establish verification systems.
- Documents and record keeping.
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