APPLICATION OF THE HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) SYSTEM IN THE FOOD PROCESSING AND MANUFACTURING INDUSTRIES

I. INTRODUCTION

1.1 Promotion of exports from developing countries to the European Union (EU) and other industrialized countries - an overview

Supplying safe and high quality foods is more important than ever, as importers of food products demand safe food in compliance with strict hygiene rules. Quality improvement, however, is a continuous process. The present concerns in quality with respect to insects, extraneous matter, moisture, ash, micro-organisms, insects, mites, mycotoxin, pesticide residues, heavy metals, non permitted colors, animal excreta, etc. will be addressed if appropriate pre- and post-harvest operations, storage and packaging are adopted.

Though this is not an easy task, a fair degree of acceptability of produce will be attained, if normal care and attention are given at various stages of handling the produce, from growing to packaging.

Anyone who owns, manages or works in a food business in the EU - apart from those working in primary food production - is affected directly (and indirectly if supplying to the EU) by the common food hygiene rules across the European Union, as set out in the Food Hygiene Directive (93/43/EEC). Application of the Food Hygiene Directive (93/43/EEC) will force exporters to a higher and safer quality of produce supplied and to improve production circumstances and methods in the country of origin.

Every process which deals with preparing or selling food can be classed as a food business activity, including: preparation, processing, manufacturing, transportation, distribution, handling, packaging, storage, selling and supplying.

1.2 Hazard Analysis Critical Control Points (HACCP) system

The Food Hygiene Directive (93/43/EEC) obliges food businesses in the European Union to implement systems that are based on the principles of Hazard Analysis and Critical Control Point (HACCP). Though non-EU suppliers of food products do not legally have to comply directly with the EU directive on Food Hygiene, they are affected by the EU Hygienic rules. It was clearly confirmed that food businesses in Europe, implementing systems to ensure that hazards are identified and controls are in place, have become increasingly selective in dealing with their (foreign) suppliers and requested a strict application of HACCP in the countries of origin of imported products. In some cases, they have even set out additional hygienic requirements for their suppliers regarding specific product(s).

Food businesses in Europe and in other industrialized countries applying systems to assure food safety will not buy any raw material if they think that, even after sorting and processing, it could make food unfit for human consumption. Any raw material or processed food product which is only suspected or known to be infected or contaminated with parasites or foreign substances will not be accepted.

Therefore there is a growing need to promote appreciation for and understanding of HACCP by governments and food industry, particularly in developing countries.

So, from a market point of view, manufacturers and non-EU exporters of food products to the EU should take into account the introduction of systems based on HACCP in food businesses in the EU, consider food safety procedures and apply HACCP. Even more, manufacturers and exporters of food stuff should also
contact their importers or brand organizations, in the countries to which they export, to find out if there are any hygiene codes which contain specific recommendations of (foreign) supply for a specific product.

The HACCP system is a relatively new approach to the prevention and control of food borne diseases. The Hazard Analysis Critical Control Point (HACCP) system identifies specific hazards and preventative measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on preventative measures rather than relying mainly on end-products testing. Any HACCP system is capable of accommodating change, such as advances in equipment, design, processing procedures or technological developments related to the product.

II PREREQUISITE PROGRAMMES

Prerequisite programmes are defined as the universal procedures used to control the conditions in the food plant environment which contribute to the overall safety of the products; documented prerequisite programmes as the foundation of food safety management. HACCP is not a stand alone programme but is part of a larger control programme; implementation of HACCP relies on adherence to prerequisite programmes. Prerequisite programmes MUST be developed, implemented and documented. Prerequisite programmes include Good Manufacturing Practices (GMP) and other programmes.

III. HACCP APPLICATION TO FOOD MANUFACTURING AND PROCESSING

HACCP can be applied throughout the food chain from the primary producer to final consumer. As well as enhanced food safety, benefits include better use of resources and more timely response to problems. In addition, the application of HACCP system can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety. The successful application of HACCP requires the full commitment and involvement of management and the workforce. It also requires a team approach; this team should include appropriate experts; examples might be agronomists, veterinarians, production personnel, microbiologists, food technologists, chemists and engineers, according to the particular study.

The application of HACCP is compatible with the implementation of quality management systems, such as ISO 9004 series, and is the system of choice in the management of food safety within such systems. Many food manufacturers and processors have already applied the HACCP system to their operations. The level of safety assurance offered by the HACCP system is fast becoming the standard for the food industry in industrialized countries.

Food safety authorities in the United States, Canada and European Union (EU) promote the use of HACCP. HACCP is also being incorporated into the Codex Codes of Practice for a number of food commodities. Consequently, there is a growing need to promote appreciation for and understanding of HACCP by governments and the food industry, particularly in developing countries.

The application of HACCP is not limited to food manufactured and processed by medium to large-scale operations but may also be applicable to smaller operations where safety of foods is of critical importance.

Benefits

There are numerous benefits for the food industry while applying HACCP system as a management tool for food safety control. Some key benefits are as follows:

* The HACCP approach is a systematic approach which can be applied to all aspects of food safety, including biological, chemical and physical hazards, to all stages of the food chain, including raw materials, growth, harvesting, purchase, production, distribution, and storage to final product use.
HACCP system provides scientifically sound bases for demonstrating that all reasonable protections have been taken to prevent a hazard from reaching the consumer.

The HACCP approach shifts emphasis from statistically unreliable end-product testing which is often retrospective to a prevention-oriented approach for the production of safe food products.

Application of the HACCP concept is a cost-effective method of assuring food safety and preventing food borne disease and injuries.

HACCP system focus resources on those parts of the process critical for assuring safe products.

HACCP system can reduce product losses due to spoilage.

HACCP system encourage confidence in the safety of food products and thus promotes confidence in food trade and stability of food businesses.

HACCP system can facilitate the design and construction of new food processing facilities and equipment by predicting potential hazards and suggesting control measures.

**Principles**

HACCP is a system which identifies specific hazard(s) and preventative measures for their control. The system consists of following seven principles:

**Principle 1**

Identify the potential hazard(s) associated with food production at all stages, from growth, processing manufacture and distribution, until the point of consumption Assess the likelihood of occurrence of the hazard(s) and identify preventative measures for their control.

A hazard is an unacceptable contamination of a biological, chemical or physical nature and/or survival or multiplication of microorganisms of concern for food safety, and/or unacceptable production or persistence in foods of toxins or other undesirable products of microbiological metabolism.

Biological hazards include pathogenic microbes (parasites, bacteria and viruses) and toxigenic plants and animals.

Chemical hazards include, among others, pesticides, cleaning compounds, antibiotics, heavy metals, and additives such as sulfites.

Physical hazards include objects - such as metal fragments, glass and stones, that may cut the mouth, break teeth, cause choking or perforate the alimentary tract.

Control measures are those actions and activities that can be used to eliminate hazards or reduce their impact or occurrence to acceptable levels. More than one measure may be required to control a specific hazard and more than one hazard may be controlled by a specified measure. No attempt is made at this step to establish CCP.

**Principle 2**

Determine the points/ procedures/operational steps that can be controlled to eliminate the hazard(s) or minimize its likelihood of occurrence - Critical Control Point (CCP). A step means any stage of food
production and/or manufacture including raw materials their receipt and/or production, harvesting, transport, formulation processing, storage, etc.

After hazards have been identified, a CCP decision tree may be used to determine whether a step is a CCP for the identified hazard. A model HACCP decision tree for establishing CCP is given in Annex III. Application of the model decision tree may differ slightly, depending on whether the operation is for production, slaughter, processing and manufacturing, storage, distribution or other sectors. All hazards which may be reasonably expected to occur, or to be introduced at each step, should be considered. If a hazard has been identified for which no control measure exists, the product or process should be modified so that the hazard is eliminated or reduced to acceptable or minimal levels.

Principle 3

Establish critical limit(s) which must be met to ensure the CCP is under control.

Critical limits must be specified for each control measure at each CCP. In some cases, more than one critical limit will be specified at a particular CCP. Criteria often used include temperature, time, moisture level, pH, water activity, available chlorine, and sensory parameters such as visual appearance and texture. Critical limits may be derived from a variety of sources such as regulatory standards or guidelines, literature surveys, experimental studies and/or expert advice.

Principle 4

Establish a system to monitor control of the CCP by scheduled testing or observations.

Monitoring is the periodic measurement or observation at a CCP to determine whether a critical limit or target level has been met. The monitoring procedure must be able to detect loss of control at the CCP.

Principle 5

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

Corrective actions are those actions to be taken either when monitoring results show that a CCP has deviated from its specified critical limit or target level, or, preferably, when monitoring results indicate a trend towards loss of control. In the latter case, action may be taken to adjust the process and maintain control before the deviation leads to a loss of control and hence to a safety hazard.

Disposition action need to be taken with food that has been produced during the time period that the CCP was out of control. Both corrective actions and disposition actions should be documented in the HACCP record-keeping. Responsibility for documenting these actions must be clearly assigned.

Principle 6

Establish procedures for verification which include supplementary tests and procedures to confirm that the HACCP system is working effectively.

Procedures for verification must be established to ensure that the HACCP system is working correctly. Monitoring and auditing methods, procedures and tests including random sampling and analysis can be used for this purpose.
Principle 7

Establish documentation concerning all procedures and records appropriate to these principles.

APPLICATION OF THE PRINCIPLES OF HACCP

During the hazard analysis and subsequent operations in designing and applying HACCP system, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, consumer populations at risk and epidemiological evidence relative to food safety.

The intent of the HACCP system is to focus control at CCP. Redesign of the operation should be considered if a hazard is identified but no CCP are found. HACCP should be applied to each specific operation separately. CCP identified in any given example in any Codex code of hygienic practice might not be the only ones identified for a specific application or might be of a different nature.

The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process or any step. It is important when applying HACCP to be flexible given the contest of the application.

The application of HACCP principles requires the following tasks as identified in the LOGIC SEQUENCE for the Application of HACCP- Annex III:

1. Assemble HACCP team

Assemble a multi disciplinary team that has specific knowledge and expertise appropriate to the product. Where such expertise is not available on site, expert advice should be obtained from other sources.

2. Describe product

A full description of the product should be drawn up, including information on composition and method of distribution.

3. Identify intended use

The intended use should be based on the expected uses of the product, by the end user or consumer. In specific cases, vulnerable groups of the population, eg., institutional feeding, may have to be considered.

4. Construct flow diagram

The flow diagram should be constructed by the HACCP team. Each step within the specified area of operation should be analyzed for the particular part of the operation under consideration to produce the flow diagram. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

5. On-site verification of flow-diagram

The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.

6. List all hazards associated with each step and consider any preventative measures to control hazards (Principle 1)
The HACCP team should list all the biological, chemical or physical hazards that may be reasonable expected to occur at each step and describe the preventative measures that can be used to control these hazards. The HACCP team next analyses each hazard.

For inclusion in the list, hazards must be of a nature such that their elimination or reduction to acceptable levels is essential to the production of a safe food. The team must then consider what preventative measures, if any, exist which can be applied for each hazard.

Preventative measures are those actions and activities that are required to eliminate hazards or reduce their impact or occurrence to acceptable levels. More than one preventative measure may be required to control a specific hazard) and more than one hazard may be controlled by a specified preventative measure.

7.  Apply HACCP Decision Tree to Each Step (Principle 2)

The identification of a CCP in the HACCP system is facilitated by the application of a decision tree (Annex III). All hazards that may be reasonably expected to occur, or be introduced at each step, should be considered. Training in the application of the decision tree may be required.

If a hazard has been identified at a step where control is necessary for safety, and no preventative measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a preventative measure.

Application of the decision tree determine whether the step is a CCP for the identified hazard. Application of the decision should be flexible, given whether the operation is for production, slaughter, storage, distribution or other.

8.  Establish critical limits for each CCP (Principle 3)

Critical limits must be specified for each preventative measure. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, Aw, and available chlorine, and sensory parameters such as visual appearance and texture.

9.  Establish a Monitoring System for Each CCP (Principle 4)

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. Further, monitoring should ideally provide this information in time for corrective action to be taken to regain control of the process before there is a need to reject the product.

Data derived from monitoring must be evaluated by a designated person with authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCP will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing.

Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring CCP must be signed by the persons) doing the monitoring and by a responsible reviewing official of the company.
10. **Establish Corrective Actions (Principle 5)**

Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

Corrective action should also occur when monitoring results indicate a trend towards loss of control at a CCP. Action should be taken to bring the process back into control before the deviation leads to a safety hazard.

11. **Establish Verification Procedures (Principle 6)**

Establish procedures for verification that the HACCP system is working correctly. Monitoring and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to provide assurance that the HACCP plan and its implementation will prevent food safety problems. Examples of verification activities include:

* Review of the HACCP system and its records;
* Review of deviations and product dispositions;
* Operations to determine if CCP are under control;
* Validation of established critical limits.

12. **Establish Record Keeping and Documentation (Principle 7)**

Efficient, adequate, accurate record-keeping and documentation are essential to the application of the HACCP system. Documentation of HACCP procedures at all steps should be included and assembled in a manual.

Examples are records associated with:

* Ingredients;
* Product safety;
* Processing;
* Packaging;
* Storage and distribution;
* Deviation file;
* Modification to the HACCP system.

An example of a HACCP worksheet is attached in Annex B.

13. **Implementation of the HACCP plan**

Once the HACCP plan has been developed for the process, it has to be applied and implemented. The following points will need to be considered in order to facilitate this:

a  Allocation of responsibility for the management and supervision of the plan, monitoring of CCP and record-keeping and documentation;

b  Development of simple, but clear, work instructions for the monitoring of CCP;

c  Development of recording sheets and other documentation;
d. Training and education of staff based on the HACCP plan and on work instructions indicating what, how, when and who should do what;

e. Allocation of responsibility for decisions on corrective actions and disposition actions.

14. Review of the HACCP plan

In addition to the verification procedures outlined above it is necessary to have a system in place that will automatically initiate a review of the HACCP plan prior to any changes which may affect the safety of the product, including the following:

a) change in raw material or product formulation;
b) change in processing system;
c) change in factory layout or environment;
d) change in packaging, storage or distribution system;
e) change in cleaning and disinfection programme;
f) change in staff and/or responsibilities;
g) anticipated change in consumer use and receipt of information indicating a health risk associated with the product.

Data arising from HACCP reviews must be documented and form part of the HACCP record-keeping system. Any changes arising from a HACCP review must be fully incorporated into the HACCP plan. This is because these changes may mean that certain CCPs control measures or specified critical limits or target levels may have to be changed and/or additional CCP or control measures may have to be put in place.

It is essential for a user to be sure that accurate up-to-date information is available from the records. Additionally, senior management will quite properly expect that resources used to establish HACCP are not wasted and that record-keeping and documentation reflect the actual operation of the process. A system of management for the maintenance of the HACCP record-keeping system is, therefore, required and its proper operation is essential.
Annex I  GLOSSARY OF HACCP TERMS

Control: To manage the condition of an operation to establish the state wherein correct procedures are being followed and critical limits or target levels are being met.

Control Measure: Those actions and activities that can be used to eliminate hazards or reduce their impact or occurrence to acceptable levels.

Corrective Action: The action taken when monitoring at a CCP indicates a potential loss of control or when a critical limit is not met.

Critical Control Point (CCP): A point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels.

Critical Limit: A value which separates acceptability from unacceptableness.

HACCP Plan: The written document which is based upon the principal activities of HACCP and which indicates the procedures to be followed to assure the control of a specific process or procedure.

Hazard: A biological, chemical or physical agent or condition with the potential to cause harm.

Hazard Analysis: The process of collecting and interpreting information to assess the risk and severity of potential hazards.

Monitor: To conduct a planned sequence of observations or measurements of a control parameter to assess whether a CCP is under control.

Risk: An estimate of the likely occurrence of a hazard.

Severity: The seriousness of a hazard.

Step: Any location or stage in food production and/or manufacture (including raw materials), their receipt and/or production, harvesting, transport, formulation, processing/manufacture, storage, etc. as identified in the flow diagram.

Target Levels: Values which are used to assure that critical limits are met.

Verification: The use of methods, procedures, or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan, and/or whether the HACCP plan needs modification and revalidation.
Annex II  HACCP WORKSHEET

1. Describe Product

2. Diagram process Flow

3. List:

<table>
<thead>
<tr>
<th>Process step</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazards)</td>
<td></td>
</tr>
<tr>
<td>Preventative Measures)</td>
<td></td>
</tr>
<tr>
<td>Critical Limits)</td>
<td></td>
</tr>
<tr>
<td>Monitoring Procedures)</td>
<td></td>
</tr>
<tr>
<td>Corrective Actions)</td>
<td></td>
</tr>
<tr>
<td>Responsibility for Monitoring and Corrective Actions</td>
<td></td>
</tr>
<tr>
<td>Records &amp; Location</td>
<td></td>
</tr>
<tr>
<td>Minimum CCP Verification Activities:</td>
<td></td>
</tr>
<tr>
<td>a. Activity (What?)</td>
<td></td>
</tr>
<tr>
<td>b. Frequency (How often?)</td>
<td></td>
</tr>
<tr>
<td>c. Responsibility (Who?)</td>
<td></td>
</tr>
</tbody>
</table>
Annex III  LOGIC SEQUENCE FOR APPLICATION OF HACCP

1. Assemble the HACCP Team
   ▼
2. Describe Product
   ▼
3. Identify Intended Use
   ▼
4. Construct Flow Diagram
   ▼
5. On-site Verification of Flow Diagram
   ▼
6. List all identified hazards associated with each step and consider preventative measures to control hazards

<table>
<thead>
<tr>
<th>Step:</th>
<th>Identified Hazard(s):</th>
<th>Preventative Measure(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Biological</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Chemical</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Physical</td>
<td></td>
</tr>
</tbody>
</table>
7. Apply HACCP Decision Tree to Each Step with Identified Hazards) (Answer Questions in Sequence)

Q1:  
Do Preventative Measures Exist?  
no  Modify step, process or product  
Is control at this step for safety  
no  Not a CCP  STOP (*)

Q2:  
Is the Step Specifically Designed to Eliminate or Reduce the Likely Occurrence of a Hazard to an Acceptable Level?  
no  
Q3:  
Could Contamination with Identified Hazard(s) Occur in Excess of Acceptable Level(s) or Could These Increase to Unacceptable Level(s)?  
no  Not a CCP  STOP (*)

Q4:  
Will a Subsequent Step Eliminate Identified Hazards) or Reduce Likely Occurrence to an Acceptable Level?  
no  Critical Control Point

Not a CCP  STOP (*)

(*) Proceed to the next identified hazard in the described process

8. Establish Critical Limits for Each CCP 1
9. Establish a Monitoring System for Each CCP
10. Establish Corrective Action for Deviations that May Occur
11. Establish Verification Procedures
12. Establish Record Keeping and Documentation
Bibliography

a) UNIDO 1999 - Backstopping Officer: Dr. A. Ouauich; Expert: L.H. Ababouch - Project: XA/BKF/98/609 - Formation: les technologies alimentaires et les HACCP.


