IPD guides for success in export

Topic 2: HACCP
How to use the “IPD Guide on HACCP”

+ This guide is a resource to help you and your company better understand the topic of “HACCP”. It is not a comprehensive guide to all HACCP concerns in any industry, but instead a “key issues” guide to messages every international operating company should know about.

In this guide, you will learn:

✓ What is HACCP and important definitions
✓ Origin of HACCP
✓ What are some global food safety concerns
✓ What are the categories of food safety hazards
✓ Why should I apply HACCP
✓ The responsibilities for HACCP
✓ What are prerequisites for HACCP
✓ The principles of HACCP
✓ Steps to implementation of HACCP
Explanation
What is HACCP?

Definition of HACCP:

HACCP is an acronym for Hazard Analysis and Critical Control Points. It is a system which identifies, evaluates and controls hazards which are significant for food safety.

Hazard is any biological, chemical or physical agent in food with the potential to cause and adverse health effect.

Food safety is the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Origin of HACCP

+ HACCP originated in the 1960’s, when the National Aeronautics and Space Administration (NASA), the Pillsbury Company, and the U.S. Army Laboratories collaborated together to provide safe food for upcoming space expeditions. It was decided that NASA’s engineering management requirements, Critical Control Points, would be used as a guideline for this food safety initiative.

+ Critical Control Points (CCP) was used to test weapon and engineering system reliability and by using CCP, NASA and Pillsbury were able to identify and eliminate the “critical failure areas” in the food processing procedures.

+ By this means, NASA and Pillsbury were able to successfully provide safe food for their space expeditions.

+ The HACCP concept was adopted by the European Union in the Regulation (EC) No 852/2004.
Some global food safety concerns

+ People have the right to expect that the food they eat is safe and suitable for human consumption.

+ Some past events related to food borne illnesses, outbreaks and even death have proved that controls may be weak at various levels of control.

+ Foodborne illness and foodborne injury are unpleasant, and can be fatal.

+ Spread of foodborne disease is easier due to international trade, more people eating out and international travels.

+ Visit the Rapid Alert System for Food and Feed (RASFF) portal to see product rejections and causes. RASSF enables urgent notifications to be shared efficiently between European countries: https://webgate.ec.europa.eu/rasff-window/portal/
Why should I apply HACCP?

+ There are some strong reasons why producers and companies should take on the implementation of a food safety system:

- Facilitates international trade due to **increased confidence** in supply chain!
- Provides focused approach to addressing hazards based on risk, hence it is **cost effective**!
- It is **systematic** in its application covering all aspects from raw material to final product!
- **Increased profit** from reduced spoilage which is wasteful and costly!
- Focused on **prevention** rather than end product inspection and correction!
- Assures **control of hazards** if implemented correctly!
- Is a **mandatory** requirement for some markets!
Categories of food safety hazards

Three main categories of hazards recognized are:

1. **Chemical hazards e.g.**
   + naturally occurring e.g.
     - food allergens, mycotoxins, decomposition by-products
   + used in formulation e.g.
     - food additives, color additives, preservatives
   + unintentionally or incidentally present e.g.
     - cleaning and sanitizing chemicals, pesticides, industrial chemicals, heavy metals, drug residues, radiological hazards

2. **Biological hazards e.g.**
   + bacteria, viruses, protozoa, yeasts, molds, prions etc.

3. **Physical hazards e.g.**
   + foreign objects such as glass and brittle plastic, metal wood and stones, etc.

→ Some of the above mentioned hazards may result in diseases, cuts, broken teeth, inner injuries or even death.
Who can apply HACCP?

Every one in the food chain from primary production to final consumption can apply it. The application should be guided by scientific evidence of risks to human health.

+ **Farmers and growers**: responsible for Good Agricultural Practices (GAP) including correct use of approved chemicals, antibiotics and pesticides

+ **Manufactures and processors**: responsible for Good Manufacturing Practices (GMP) including correct application of additives and preservatives, ensuring clean hygienic environment, correct application of process controls, use of qualified personnel, provision of correct information and advise to consumers, using only raw materials from known sources with known specifications

+ **Food handlers**: observation of hygiene practices and correct application of all operating procedures

+ **Consumers**: responsible for correct storage and use of product as advised by manufacturer/processor
Before HACCP consider the environment for operations

+ Clean and hygienic work environment form a firm foundation for application of HACCP. The **basic principles of hygiene should be applied across all operations.**

+ Procedures, including Good Manufacturing Practices (GMPs), that provide the basic environmental and operating conditions necessary to support the food safety are known as **Prerequisite Programs (PRPs).**

+ **Training** is required for staff to understand and effectively implement GMP and hygienic practices.

+ **Different codes** of hygiene practice or guidelines for microbiological criteria may be required for different industries.
Hygiene principles should be considered for the following*

- **Primary production**: consider sources of raw material, handling, storage and transportation, and personnel hygiene
- **Establishment (design and facilities)**: consider location, layout of rooms, equipment and facilities
- **Establishment (maintenance and sanitation)**: consider the cleanliness and maintenance programs, pest control, waste management and how to monitor effectiveness, both inside and outside.
- **Personnel Hygiene**: consider health status, illness, injury of personnel, personnel cleanliness, behavior, as well of incoming visitors
- **Transportation and consumer information**: consider use and maintenance, lot identification, labelling and traceability

*For details refer to [Codex general principles for food hygiene or country regulations](#)
7 HACCP Principles

The application of HACCP principles is the responsibility of each individual business:

+ **Principle 1**: Conduct Hazard analysis  
+ **Principle 2**: Determine Critical Control Points (CCPs)  
+ **Principle 3**: Establish critical limit(s)  
+ **Principle 4**: Establish a system to monitor control of the CCPs  
+ **Principle 5**: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control  
+ **Principle 6**: Establish procedures for verification to confirm that the HACCP system is working effectively  
+ **Principle 7**: Establish documentation concerning all procedures and records appropriate to these principles and their application.
12 stages of the Codex Alimentarius

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP

1. Assemble the HACCP team
2. Describe the product
3. Identify the intended use and customers
4. Construct flow diagram to describe the process
5. Perform on-site confirmation of flow diagram
6. Conduct a hazard analysis
7. Determine Critical Control Points (CCPs)
8. Establish critical limit(s) for each CCP
9. Establish a monitoring system for each CCP
10. Establish corrective actions
11. Establish verification procedures
12. Establish documentation and record keeping

*Notice that steps 6 to 12 are the application of the 7 HACCP principles discussed previously.
Step 1: Assemble the HACCP team

+ Form a team with multidisciplinary knowledge on the specific product(s) e.g. individuals from different departments, such as: engineering, production, sanitation, quality assurance, sales and marketing (recommended: 4 – 7 people)
+ You may include external experts as consultants, trade associations and regulatory authorities.
+ Appoint the team leader (authorized by management)

What is the role of the HACCP team?
- Define the scope of the HACCP plan (the segment of the food chain)
- Develop documents necessary to support operations
- Oversee the implementation and review HACCP plan when necessary
- Prepare a HACCP annual plan including meetings and reviews
- Identify staff training needs and provide training as needed
Step 2: Describe the product and its distribution

The **product description** should include:

- The product names(s)
- Important food safety composition of the product, if any (e.g. pH, aw, preservatives)
- Processing method (e.g. thermal treatment, freezing, brining, smoking)
- Products of similar characteristics/processing can be grouped together

<table>
<thead>
<tr>
<th>Product description example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product name</strong></td>
</tr>
<tr>
<td><strong>Product description</strong></td>
</tr>
<tr>
<td><strong>Ingredients</strong></td>
</tr>
<tr>
<td><strong>Packaging used</strong></td>
</tr>
<tr>
<td><strong>Shelf life</strong></td>
</tr>
<tr>
<td><strong>Labelling instructions</strong></td>
</tr>
<tr>
<td><strong>Storage and transport conditions</strong></td>
</tr>
<tr>
<td><strong>Additional claims</strong></td>
</tr>
</tbody>
</table>
Step 3: Describe the intended use and consumers

Describe:

+ **The expected use** of the product by end consumer: Intended use and reasonably foreseeable unintended use need to be considered

+ Intended **consumers**: Consider...
  
  + ...whether the product is intended for supply to the industry or direct to the final consumer.
  
  + ...whether target consumers fall into one of the following vulnerable groups (referred to as “YOP!“): Young, Old, Pregnant, Immunosuppressed.

+ ...that it is your responsibility to understand your target group. Ask yourself “Do the consumers of my product have a particular food safety requirement?”

+ **Labeling instructions** relevant to food safety e.g. (instructions for storage, expiry date, preparation and use, groups of consumers, list of ingredients, caution on allergens)
Step 4: Construct a flow diagram and describe the process

A flow diagram is an important tool to describe the processes in a company. It should be constructed by the HACCP team.

- Include all the steps within the facility’s control for a specific product or product categories.
- It is possible to have one flow diagram for a number of products that are manufactured using similar processing steps.
- Include reworked product, by-product and diverted product, if applicable.
- Develop a written description for each step in the flow diagram.
- Flow charts must be dated and regularly updated.
Step 5: On-site confirmation of flow diagram

+ The HACCP team performs an on-site review of the operation to verify the accuracy and completeness of the flow diagram.
+ The review must be carried out for all steps.
+ Make changes, if necessary!
+ The review must be documented in a protocol or on the flow chart.
Step 6 / Principle 1: Conduct a hazard analysis

“Hazard analysis is the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which ones are significant for food safety and therefore must be addressed in the HACCP Plan.”

Source Codex CAC/RCP1:1969 2003

1. List all process steps and ingredients for the flow diagram
2. Identify known or reasonably foreseeable (i.e. potential) food safety hazards for each step
3. Determine if the hazard is significant and requires control (the risk)
   - Is it likely that the hazard can be present (hazard likelihood)?
   - How severe would the consequences be (hazard severity)?
4. Justify the decision
5. Identify preventive controls for significant hazards
**Example: Hazard analysis work sheet**

<table>
<thead>
<tr>
<th>Raw material, Ingredient or process step</th>
<th>List all potential hazards which could be present, may be introduced, may increase or should be controlled at each step</th>
<th>Evaluate if the Potential hazard is significant. Can it cause adverse health effect? (Yes/No)</th>
<th>Justify your answer for the decision on column 3</th>
<th>List what measures can be applied to control the significant hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ingredients / raw material</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Receiving of dried red pepper</em></td>
<td>Presence of aflatoxin, yes</td>
<td>Aflatoxin are know to occur in red pepper, and can cause adverse health effect. Previously red pepper has been intercepted and rejected at border control see RASFF (2003) due to aflatoxin content</td>
<td>Supply chain control: Approved supplier</td>
<td></td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Steps from the flow chart</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Metal detection</em></td>
<td>Inclusion of metal, Yes</td>
<td>Metal to metal contact may introduce metal fragments</td>
<td>Magnet to remove metal and Metal detector</td>
<td></td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Example: Potential hazard control measures**

**Biological hazards**
- Process controls that kill pathogens  
  e.g. cooking, sterilization, pH adjustment
- Process controls that inhibit growth  
  e.g. time/temperature controls,  
  checking formulation
- Supply-chain programs for sensitive ingredients used without a kill step
- Sanitation controls that prevent recontamination

**Chemical hazards**
- Supply-chain programs
- Allergen control
- Sanitation controls to prevent allergen cross-contact

**Physical hazards**
- Controls such as  
  + Filtering  
  + metal detection  
  + X-ray devices
Step 7 / Principle 2: Determine Critical Control Points (CCPs)

- CCP is 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.

- Examples for CCPs:
  - Metal detection
  - Heat Treatment (core temperature 70°C for 2 minutes)
  - Pasteurisation (milk: 72°C for 15 seconds)

- Use the decision tree to decide whether a CCP is existing

Q1. Is there a hazard at this process step? What is it?

Q2. Do control measure(s) exist for the identified hazard?

Q3. Is the step specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level?

Q4. Could contamination occur at or increase to unacceptable level(s)?

Q5. Will a subsequent step or action eliminate or reduce the hazard to an acceptable level?

* STOP and proceed with the next hazard at the current step or the next step in the described process

Step 8 / Principle 3: Establish a critical limit for each CCP

Critical limit:
“A criterion which separates acceptability from unacceptability.”

Source Codex CAC/RCP1:1969 2003

+ Define a critical limit for each CCP. Values above the limit indicate that the process is not under control any more.
+ The effectiveness of a control measure at each CCP has to be validated.
+ Criteria typically include measurements of temperature, time, moisture level, pH, Aw, available chlorine, and also visual such as appearance and texture.
Step 9 / Principle 4: Establish a monitoring system for each CCP

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

Source: Codex CAC/RCP1:1969 2003

- Establish an effective monitoring system for each CCP in order to recognize if the process is out of control.
- The effective monitoring of each system is to be verified by recordings. Must be able to provide information in good time for process adjustments to be made.
- The recordings must be evaluated by a designated person with knowledge and authority to carry out corrective action.
- The frequency should be able to guarantee that the CCP is in control. All records must be signed by responsible person in the company.
- Monitoring records typically include
  - Time of recording
  - Responsible staff
  - Outcome
Step 10 / Principle 5: Establish corrective actions

Corrective action:
“Corrective action is any action to be taken when results of monitoring at CCP indicate a loss of control.”

Source Codex CAC/RCP1:1969 2003

+ Define corrective actions for each CCP in order to regain control over the process.
+ These actions have to be immediately conducted if a staff member recognizes the lack of control at a certain CCP.
+ Corrective action may be taken on the product or the process.
+ All corrective actions taken have to be documented!

Examples of correction on the process
✓ Immediate adjustment of process
✓ Employees stop line when deviation occurs
✓ Apply alternate process
✓ Repair equipment
✓ Retrain employees
✓ Evaluate operation

Examples of correction on the product
✓ Hold product
✓ Evaluate product
✓ Determine product disposition
✓ release, rework or destroy product
Step 11 / Principle 6: Establish verification procedures

Verification:
“Verification is the application of methods and procedures, tests and other evaluation in addition to monitoring to determine compliance with HACCP plan.”

Source Codex CAC/RCP1:1969 2003

- The verification of a HACCP-plan needs to be carried out at least once a year and every time the production system undergoes a change. This may be subject to country specific regulations
- Some examples of verification activities include
  - Checking equipment calibration
  - Targeted product sampling and testing
  - Visual inspection of equipment
  - Environmental monitoring for pathogens
  - Internal audits or third party audits
- Verification activities should be performed by somebody having technical expertise but NOT responsible for performing the monitoring
- Another important aspect of verification is the initial validation of the HACCP plan. By validating the plan, evidence is obtained that the control measures will be capable of effectively controlling the hazards that are identified. Questions to ask include: Are the limits still correct? Are the methods used to monitor them suitable?
Step 12 / Principle 7: Establish documentation and record keeping

+ Precise documentation is necessary for the HACCP-process.
+ Efficient and accurate record keeping is essential to the application of HACCP system.
+ Documentation of the application of all steps 1 to 12 needs to be kept.

Examples of documentation include:
+ HACCP team members
+ Product description
+ Hazard analysis results
+ CCP determination
+ Established critical limits

Records include:
+ CCP monitoring activities
+ Deviation and associated corrective actions
+ Results of verification activities
+ Any modifications of the HACCP plan
+ Training records
Critical to success of HACCP

Team approach in implementation of the system by use of multidisciplinary approach (inclusion of different departments and potentially external expertise).

Ongoing training and awareness of all staff involved and continued updating of the system.

Management commitment through provision of resources and support to the HACCP team is the single most important factors of success.

Well-established internal business processes.
If you would like to get more information on HACCP, we recommend the following websites and links:

- [https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm](https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm)
- [https://ec.europa.eu/food/safety/general_food_law_en](https://ec.europa.eu/food/safety/general_food_law_en)