

REVISITING THE HAZARD ANALYSIS

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Principle #1 of HACCP

Conduct a Hazard Analysis

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Which has meant:

“The process of collecting and evaluating information on hazards and the conditions leading to their presence in order to decide which are significant for food safety and should be addressed in the HACCP plan”

In the Hazard Analysis, Codex Alimentarius Charges Us to :

- List all potential hazards associated with each step.
- Conduct a hazard analysis.
 - Decide if the hazard is significant.
 - Evaluate the likelihood of occurrence.
- Consider any measures that can be used to control identified hazards.
- Choose from the control measures and decide if they will be applied at this step.

For Those of Us in the USA, We Have Further Guidance:

- You must conduct a hazard analysis to identify and evaluate, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control
 - Based on experience, illness data, scientific reports, and other information,
 - “You” means the owner, operator, or agent in charge

In Addition:

- The hazard analysis must be written regardless of its outcome.

Known or reasonably foreseeable hazards include:

- Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
- Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
- Physical hazards (such as stones, glass, and metal fragments); and

Known or reasonably foreseeable hazards may be present in the food for any of the following reasons:

- The hazard occurs naturally;
- The hazard may be unintentionally introduced; or
- The hazard may be intentionally introduced for purposes of economic gain.

Hazard evaluation

- The hazard analysis must include an evaluation of the hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.
- The hazard evaluation must include an evaluation of environmental pathogens
 - Whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen

Significantly Minimize...

- Let's leave this concept for later.
- Instead let's deal with the definition of a hazard

According to the Regulation, a Hazard is Defined as...

- Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Does this square with...?

- "...include an evaluation of the hazards to assess the severity of the illness or injury if the hazard were to occur...
- I wish to argue that a hazard, by definition, must have a preventive control

The Evaluation of a Potential Hazard

- The probability that the hazard will occur in the absence of preventive controls is usually referred to as “likelihood of occurrence”
- Since we have already defined a hazard as a condition that has a potential to cause illness or injury, if it is determined to be “likely to occur,” we must provide a preventive control

In Order to Inform our Hazard Analysis and Give it Structure...

- Codex Alimentarius provides for Preliminary Steps for the HACCP Team to follow
 1. Product description, including ingredients, their potential degradation, or toxic effects, and conditions of use.
 2. Identification of sensitive populations and how the product is to be prepared and consumed.
 3. Process flow diagram annotated with inputs and rework such as air, water and gasses, and process conditions including temperature and time.
 4. The verified flow diagram provides structure to the hazard analysis.

Structuring the Hazard Analysis

- It is common to conduct a hazard analysis on ingredients separately in a table
- The traditional way of organizing the hazard analysis on the process is to use the steps in the flow diagram
- I recommend that each step in the process be described and the conditions noted on the Hazard Analysis Worksheet

Getting Started

- Identify potential hazards at each step in the flow diagram.
 - This is a directed brainstorming session informed by appropriate guidance resources.
- Avoid the urge to evaluate the hazards in the initial steps.
- Identify the hazard and its occurrence.
- Identify hazards, not conditions.

Documenting the Occurrence...

Process Step	Potential hazard with occurrence	Preventive control
Receiving broccoli heads	Presence of pathogens from the field	-Destroy by cooking
Washing and trimming broccoli	Contamination from -Water -Personnel	-Water program and re-chlorination -Personal hygiene
Cooking and cooling broccoli	Recontamination from equipment	-Sanitation program

Resources for Conducting the Hazard Analysis

- Experience with the product or similar products, or processes.
- Scientific reports, illness data, predictive models.
- Expert advice from third parties, including established regulatory controls.
- Trade organizations.
- Hazard guides and textbooks.

Who Conducts the Hazard Analysis?

- The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.

In Conducting the Hazard Analysis, Consider the Following on the Safety of the Finished Food

- The formulation of the food;
- The condition, function, and design of the facility and equipment;
- Raw materials and other ingredients;
- Transportation practices;
- Manufacturing/processing procedures;
- Packaging activities and labeling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use;
- Sanitation, including employee hygiene; and
- Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).

Identifying Potential Hazards

- Remember the definitions for hazards.
- Concentrate on safety, and not quality nor regulatory items.
- Identify hazards not conditions.
- Temperature is a condition, while growth of a pathogen is a potential hazard.
- Be specific to the occurrence of the hazard.
- Presence on incoming materials.
- Contamination or cross contact
- Growth or concentration in the process.
- Toxin production.

Evaluating Potential Hazards

- By classifying potential hazards according to their occurrence, the method of management or control may become obvious.
- Some potential hazards are “not likely to occur” as a result of properly implemented preventive controls

Occurrence	Management
Presence on incoming raw material	Thermal process (Process control)
Contaminated from process	Sanitation control
Growth or toxin production	Temperature control (Process control)
Allergen cross contact	Allergen swab (Sanitation – Allergen control)

Hazards Requiring a Preventive Control

- A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis...
 - Establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system

Documenting the Hazard Analysis

- Maintain the minutes of HACCP team meetings and decisions.
- Sources of technical information used to make decisions and determine control measures should be logged.
- Hazard analysis is summarized on the Hazard Analysis Worksheet.

Hazard Analysis Worksheet

<p>(1) Ingredient/ Processing Step</p>	<p>(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step.</p>	<p>(3) Are any <u>potential</u> food-safety hazards reasonably likely to occur?</p>	<p>(4) Justify your decision for any “no” in column 3</p>	<p>(5) What control measure(s) can be applied to prevent, reduce, or eliminate the food safety hazards?</p>	<p>(6) Is this step a critical Control point? (Yes/No)</p>
<p>Pumping <i>Milk is conveyed to the filler under pressure using sterile air</i></p>	<p>Biological, B7-Recontamination of sterilized milk with pathogens or spoilage microorganisms which might cause gas formation or loss of package integrity</p>	<p><input checked="" type="checkbox"/></p>		<p>Air sterilization protocol</p>	<p>YES CCP# 6 Air sterilization protocol</p>
<p>Packaging material preparation <i>Roll stock packaging material is conveyed into the hydrogen peroxide bath then the H₂O₂ is evaporated by heat. This is part of the protocol of the packaging machinery</i></p>	<p>Biological, B8 Recontamination of the sterile milk by non-sterile packaging Chemical, C2 H₂O₂ residues on packaging material</p>	<p>B8, <input checked="" type="checkbox"/> C2, no</p>	<p>C2 Though residues of more than 5 ppm H₂O₂ is not allowed by regulation, this is a regulatory limit and not directly related to safety in this product</p>	<p>B8 Sterilization of aseptic filler Maintenance of H₂O₂ concentration of 35% and heat of 130C to evaporate the residues</p>	<p>NO CCP is monitored at the aseptic filler</p>
<p>Filling and closing <i>Milk is packaged in an aseptic form fill seal machine in a properly designed and maintained aseptic zone</i></p>	<p>Biological, B9 Recontamination of sterilized milk with pathogens or spoilage microorganisms which might cause gas formation, loss of package integrity</p>	<p><input checked="" type="checkbox"/></p>		<p>Aseptic filler sterilization protocol</p>	<p>YES CCP# 7 Aseptic filler sterilization protocol <input type="checkbox"/></p>