

Chapter 5: Principle 1: Hazard Analysis*Overhead 1***Objective:**

In this module you will learn:

- What hazard analysis is.
- How to conduct a hazard analysis.
- How to identify significant hazards.
- What control measures are.
- How to identify control measures.

The hazard-analysis step is fundamental to the HACCP system. To establish a plan that effectively prevents food-safety hazards, it is crucial that all significant safety hazards and the measures to control them be identified.

*Overhead 2***Principle 1:**

Conduct a hazard analysis.

- Likelihood of occurrence
- Severity

As previously stated, a hazard is a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. The term hazard, when used in the context of HACCP, is limited to safety.

• ***Considerations for the HACCP Team***

During the hazard analysis, the potential significance of each hazard should be assessed by considering the likelihood of occurrence and severity. This is usually based upon a combination of experience, epidemiological data and information in the technical literature. Severity is the seriousness of a hazard.

During the hazard analysis, factors that may be beyond the immediate control of the processor must be considered. For example, product distribution may be beyond the direct control of your firm, but information on how the food will be distributed could influence how the food will be processed and/or packaged.

For some processors, the expertise necessary to properly assess the likelihood of occurrence and severity of the various hazards is available within the company. However, others may need to seek outside assistance to address this issue correctly.

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Explanatory Note:

HACCP traditionally deals only with food-safety hazards. Participants may realize that issues associated with GMPs — sanitation, economic fraud and wholesomeness — are important and must be properly handled by the processor. However, unless these issues specifically affect food safety, they should not be part of a company's HACCP program.

Explanatory Note:

Smoked fish offers an example of considering factors beyond the immediate control of the processor. Due to the possibility of temperature abuse during distribution and/or retail sales of smoked fish, the potential exists for germination, growth and toxin production of *Clostridium botulinum* type E. The hazard is controlled by brining fish to achieve salt concentrations at some specified level (e.g., 3.5 percent water-phase salt in the finished product).

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Notes:

Explanatory Note:

The list of hazards and FDA's Fish and Fishery Products Hazards and Controls Guide can be very useful, especially for firms that do not have strong technical expertise. These firms may also need to seek technical assistance in developing their HACCP programs.

The HACCP team has the initial responsibility to decide which hazards are significant and must be addressed by the HACCP plan. Keep in mind that there may be differences of opinion, even among experts, as to the significance of a hazard. The HACCP team may rely on available guidance materials and the opinions of experts who assist in the development of HACCP plans. During the hazard analysis, safety concerns must be differentiated from quality concerns.

Overhead 3

Safety concerns must be differentiated from quality concerns

Hazard Analysis

One approach to hazard analysis divides it into two activities—hazard identification and hazard evaluation. Hazard identification should result in a list of potential hazards at each operational step (use flow diagram) in the process from the receipt of raw materials to the release of the finished product. During hazard identification, the team need not be confined by the hazard's likelihood of occurrence or its potential for causing disease.

All potentially significant hazards must be considered. To assist in this, the following list of hazards will be valuable.

Overhead 4

Hazards List

Biological Hazards:

- Pathogenic microorganisms (e.g., bacteria, viruses)
- Parasites

Chemical Hazards:

- Natural toxins
- Chemicals
- Pesticides
- Drug residues
- Unapproved food and color additives
- Decomposition (safety only, e.g., histamine)

Physical Hazards:

- Metal, glass, etc.

After hazard identification, the team conducts a hazard evaluation: a three-step process in which the list of potential hazards developed during the hazard identification is narrowed to those hazards that are significant to the product and process in question. The steps in hazard evaluation are:

1. Assess severity of health consequences if potential hazard is not properly controlled;

2. Determine the likelihood of occurrence of potential hazard if not properly controlled; and
3. Determine, using information from steps 1 and 2, if the potential hazard is to be addressed in the HACCP plan.

HACCP focuses solely on hazards that are **reasonably likely to occur and likely to result in an unacceptable health risk to consumers if not controlled**. Without this focus, it would be tempting to try to control too much and thus lose sight of the truly relevant hazards.

Overhead 5

Hazard Analysis

A hazard must be controlled if it is

- reasonably likely to occur, and
- likely to result in an unacceptable risk to consumers.

• Hazard-Analysis Worksheet

A hazard-analysis worksheet can be used to organize and document the considerations in identifying food-safety hazards. Although there is no specific or required form, the worksheet should document specific information (see HACCP Worksheets, Appendix II). In the cooked-shrimp example, each step in the process flow diagram should be first listed in Column 1. The results of the hazards identification are recorded in Column 2. The results of the hazard evaluation should be recorded in Column 3, with the justification for accepting or rejecting the listed potential hazards stated in Column 4.

Control Measures

Control measures are actions and activities that can be used to prevent or eliminate a food-safety hazard or reduce it to an acceptable level. In practice, control measures encompass a wide array of activities.

On the hazard-analysis worksheet, please note the hazards that are identified for IQF cooked shrimp. At the receiving step, bacterial pathogens and chemicals have been identified as significant hazards for the two raw material forms (fresh and frozen) used by this company. Bacterial pathogens (e.g., Vibrios) are known to be associated with raw (fresh and frozen) shrimp, hence they must be identified as significant hazards. Additionally, sulfiting agents used to inhibit the development of blackspot are considered significant hazards.

As ABC Shrimp Co. analyzed its process, it did not identify any control measures that are taken at the receiving step for bacterial pathogens on incoming product. However, it did determine control measures for chemicals. Previously sulfited product will be labeled. For raw product received from boats, the company will test for sulfiting agents. For frozen

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Explanatory Note:

First-time HACCP writers often identify **too many** hazards! This is a problem because the potential exists to dilute a processor's ability to focus efforts and control the truly significant hazards. The dilemma is deciding what is significant. A hazard must be controlled if it is: **1) reasonably likely to occur AND 2) if not properly controlled, it is likely to result as an unacceptable health risk to consumers**. In the case of hazards for which regulatory action levels, tolerances or other limits have been established for safety concerns (e.g., pesticides, animal drugs), an unacceptable health risk is the risk that the limit has been exceeded, not the mere presence of the substance at a detectable level. Therefore, if violation of an action level in that type of food is reasonably likely to occur, then the processor's hazard analysis should identify that hazard as one to be controlled through its HACCP system.

Explanatory Note:

Verification procedures will be discussed later, but ABC Shrimp Co. may verify the results of the supplier testing by randomly conducting its own tests.

Notes:

shrimp received from other suppliers, ABC Shrimp Co. will rely on supplier declarations. ABC Shrimp Co. also has identified sulfites as a significant hazard at the weigh/pack/label stage because of the need to identify the presence of any sulfite residual. ABC Shrimp Co. resolved this hazard by training weigh/pack/label personnel to identify and use the correct label.

Cold storage is identified in the hazard analysis as potentially important in terms of food safety. Unless temperatures are properly maintained, bacterial pathogens can increase. Therefore, maintaining refrigerated storage conditions is a control measure.

ABC Shrimp Co. also noted a significant hazard at the cooking step. At this step, where it is most concerned about the survival of pathogens that may contaminate the finished product, ABC Shrimp Co. has determined three measures that are important in controlling this hazard. First, an adequate cook time and temperature will be established that ensures the destruction of bacterial pathogens. Second, cook time and temperature are monitored to ensure that they meet the requirements of the established process. Third, cooker personnel will be trained to operate all cooking equipment, including monitoring devices (timers and temperature recorders).

Examples of Control Measures

The following are examples of control measures that could be used to control the three types of hazards.

A. Biological Hazards

Bacteria

1. Time/temperature control (e.g., proper control of refrigeration and storage time minimizes the growth of pathogens).
2. Heating and cooking processes (e.g., thermal processing).
3. Cooling and freezing (e.g., cooling and freezing retard the growth of pathogenic bacteria).
4. Fermentation and/or pH control (e.g., lactic acid-producing bacteria in yogurt inhibit the growth of some pathogenic bacteria that do not grow well in acidic conditions).
5. Addition of salt or other preservatives (e.g., salt and other preservatives inhibit growth of some pathogenic bacteria).
6. Drying (e.g., the drying process may use enough heat to kill pathogenic bacteria, but even when drying is conducted at lower temperatures, it may remove enough water from the food to prevent some pathogens from growing).
7. Source control (e.g., the presence or amount of pathogens in raw materials may be controlled by obtaining them from non-contaminated sources).

Notes:

Viruses

1. Cooking methods (e.g., adequate cooking will destroy viruses).

Parasites

1. Dietary control (e.g., preventing the parasite from having access to the food. For example, infection from *Trichinella spiralis* in pork has decreased due to better control of pigs' diets and environments. However, this control method is not always practical for all species of animals used for food. The diet and environment of wild fish cannot be controlled, for instance).
2. Inactivation/removal (e.g., some parasites are resistant to chemical disinfection but can be inactivated by heating, drying or freezing. In some foods, visual examination may detect parasites. A procedure called "candling" enables processors to examine fish on a brightly lit table. Over the light, worms, if present, are easy to see and remove. This procedure cannot ensure 100 percent detection. Therefore, it should be combined with other means of control, such as freezing.)

B. Chemical Hazards

1. Source control (e.g., vendor certification and raw-material testing).
2. Production control (e.g., proper use and application of food additives).
3. Labeling control (e.g., finished product properly labeled with ingredients and known allergens).

C. Physical Hazards

1. Source control (e.g., vendor certification and raw-material testing).
2. Production control (e.g., use of magnets, metal detectors, sifter screens, destoners, clarifiers, air tumblers, x-ray equipment, and visual inspection).

NOTE: Control measures for each significant hazard should be recorded in column 5 of the hazard-analysis worksheet.

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Hazard-Analysis Worksheet

ABC Shrimp Co.

IQF Cooked Shrimp Production

*Example: For Illustrative Purposes Only**

Note: The ABC Shrimp Co. will serve as our model seafood processing firm. Following the discussion of each HACCP principle, that principle will be applied to the ABC Shrimp Co. Please become familiar with the process flow diagram and process narrative associated with the model.

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What control measure(s) can be applied to prevent significant hazards?	(6) Is this step a critical control point? (Yes/No)
Receiving Fresh Shrimp	BIOLOGICAL Bacterial pathogens	Yes	Raw seafoods can be natural reservoirs for marine vibrios and, depending on the quality of the harvest, can harbor terrestrial pathogens such as <i>Salmonella</i> .	A cook step follows that assumes a high bacterial load.	
<i>Note: If this product were marketed raw, the answer in column 3 would be no because the product is highly unlikely to be used by a consumer without adequate cooking. In this case, this would not be a significant hazard.</i>					
	CHEMICAL Sulfiting agent	Yes	Sulfiting agents may cause an allergic-type reaction.	Labeling control based on product screening.	
<i>Note: If shrimp were aquacultured, hazards could include chemicals such as pesticides, herbicides and heavy metals. Additionally, drugs used to prevent disease, control parasites, and affect growth should be considered.</i>					
	PHYSICAL None				
Cold Storage	BIOLOGICAL Bacterial pathogen growth CHEMICAL None PHYSICAL None	Yes	Without controlled temperature, bacterial pathogens may increase in numbers.	A cook step follows that assumes a high bacterial load.	
Firm Name: _____ Product Description: _____ Firm Address: _____ _____ Method of Storage and Distribution: _____ _____ Signature: _____ Intended Use and Consumer: _____ Date: _____					

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled, or enhanced at this step?	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What control measure(s) can be applied to prevent the significant hazard?	(6) Is this step a critical control point? (Yes/No)
Receiving Frozen Shrimp	<p>BIOLOGICAL Bacterial pathogens</p> <p>CHEMICAL Sulfiting agent</p> <p>PHYSICAL None</p>	<p>Yes</p> <p>Yes</p>	<p>Frozen seafoods can be natural reservoirs for marine vibrios and, depending on the quality of the harvest, can harbor terrestrial pathogens such as <i>Salmonella</i>.</p> <p>Sulfiting agents may cause an allergic-type reaction.</p>	<p>A cook step follows that assumes a high bacterial load.</p> <p>Labeling control based on supplier declaration.</p>	
Frozen Storage	<p>BIOLOGICAL None</p> <p>CHEMICAL None</p> <p>PHYSICAL None</p>				
Receiving Packaging Material	<p>BIOLOGICAL Bacterial pathogen contamination</p> <p>CHEMICAL Chemical contaminants</p> <p>PHYSICAL None</p>	<p>No</p> <p>No</p>	<p>Not likely to occur</p> <ul style="list-style-type: none"> • Not likely to occur • No history of occurrence 		
Dry Storage	<p>BIOLOGICAL None</p> <p>CHEMICAL None</p> <p>PHYSICAL None</p>				
Thawing	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogen growth • Bacterial pathogen contamination <p>CHEMICAL None</p> <p>PHYSICAL None</p>	<p>Yes</p> <p>No</p>	<p>If not properly controlled, bacterial pathogens can grow during thawing.</p> <p>Controlled by SSOP</p>	<p>A cook step follows that assumes a high bacterial load.</p>	

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IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled, or enhanced at this step?	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What control measure(s) can be applied to prevent the significant hazard?	(6) Is this step a critical control point? (Yes/No)
Size Grading	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogen growth • Bacterial pathogen contamination <p>CHEMICAL</p> <p>Sanitizer residues</p> <p>PHYSICAL</p> <p>None</p>	No No No	<p>Not likely to occur because of the continuous process.</p> <p>Controlled by SSOP</p> <p>Controlled by SSOP</p>		
Peeling	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogen growth • Bacterial pathogen contamination <p>CHEMICAL</p> <p>Sanitizer residues</p> <p>PHYSICAL</p> <p>None</p>	No No No	<p>Not likely to occur (See size grading)</p> <p>(See size grading)</p> <p>Controlled by SSOP</p>		
Razor Slide	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogen growth • Bacterial pathogen contamination <p>CHEMICAL</p> <p>Sanitizer residues</p> <p>PHYSICAL</p> <p>Metal fragments</p>	No No No No	<p>Not likely to occur (See size grading)</p> <p>(See size grading)</p> <p>Controlled by SSOP</p> <p>Subsequent processing removes any fragments. No historical problem.</p>		
Tumbler/Deveiner	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogen growth • Bacterial pathogen contamination <p>CHEMICAL</p> <p>Sanitizer residues</p> <p>PHYSICAL</p> <p>None</p>	No No No	<p>Not likely to occur (See size grading)</p> <p>(See size grading)</p> <p>Controlled by SSOP</p>		
Cull Table	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogen growth • Bacterial pathogen contamination <p>CHEMICAL</p> <p>Sanitizer residues</p> <p>PHYSICAL</p> <p>None</p>	No No No	<p>Not likely to occur (See size grading)</p> <p>(See size grading)</p> <p>Controlled by SSOP</p>		

IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled, or enhanced at this step.	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision in column 3.	(5) What control measure(s) can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Cold Storage	BIOLOGICAL Bacterial pathogen growth	Yes	Without controlled temperatures, bacterial pathogens may increase in numbers.	A cook step follows that assumes a high bacterial load.	
	CHEMICAL Sanitizer residues PHYSICAL None	No	Controlled by SSOP		
Cooker	BIOLOGICAL Bacterial pathogen survival	Yes	Without proper processing time and temperature, bacterial pathogens such as <i>Listeria monocytogenes</i> , <i>Salmonella</i> spp. and <i>Vibrio</i> spp. may survive.	Adequate cooking time and temperature	
	CHEMICAL Sanitizer residues PHYSICAL None	No	Controlled by SSOP		
Shuffler	BIOLOGICAL • Recontamination with bacterial pathogens	No	Controlled by SSOP		
<i>Note: Companies that DO NOT have SSOPs in place would need to control post-processing contamination with appropriate HACCP sanitation CCPs.</i>					
	• Bacterial pathogen growth	No	Not likely to occur because of the continuous process		
<i>Note: Under different conditions where time and temperature abuse may occur, controls must be sufficient to minimize the growth of bacterial pathogens in the product. Remember, this product does not have to be heated by the consumer.</i>					
	CHEMICAL Sanitizer residues PHYSICAL None	No	Controlled by SSOP		
Cull	BIOLOGICAL • Recontamination with bacterial pathogens	No	Controlled by SSOP		
	• Bacterial pathogen growth	No	(See remarks for shuffler)		
	CHEMICAL Sanitizer residues PHYSICAL None identified	No	Controlled by SSOP		
Spiral Freezer	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur due to rapid freezing rate		
	CHEMICAL Sanitizer residues PHYSICAL None identified	No	Controlled by SSOP		

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IQF Cooked Shrimp

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step?	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3.	(5) What control measure(s) can be applied to prevent the significant hazard?	(6) Is this step a critical control point? (Yes/No)
Glaze Station	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Recontamination with bacterial pathogens • Bacterial pathogen growth <p>CHEMICAL</p> <p>Sanitizer residues</p> <p>PHYSICAL</p> <p>None</p>	No No No	<p>Use potable water and equipment cleaned per SSOP.</p> <p>(See shuffler)</p> <p>Controlled by SSOP</p>		
Weigh/Pack/Label	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Recontamination with bacterial pathogens • Bacterial pathogen growth <p>CHEMICAL</p> <p>Sulfiting agent</p> <p>Sanitizer residues</p> <p>PHYSICAL</p> <p>None identified</p>	No No Yes No	<p>(See shuffler)</p> <p>(See shuffler)</p> <p>Potential allergic-type reaction (accurate label declaration)</p> <p>Controlled by SSOP</p>	Accurate label declaration	
Mastercase/Palletize	<p>BIOLOGICAL</p> <p>Bacterial pathogen growth</p> <p>CHEMICAL</p> <p>None</p> <p>PHYSICAL</p> <p>None</p>	No	Not likely to occur because frozen		
Freezer Storage	<p>BIOLOGICAL</p> <p>Bacterial pathogen growth</p> <p>CHEMICAL</p> <p>None</p> <p>PHYSICAL</p> <p>None</p>	No	Not likely to occur because frozen		