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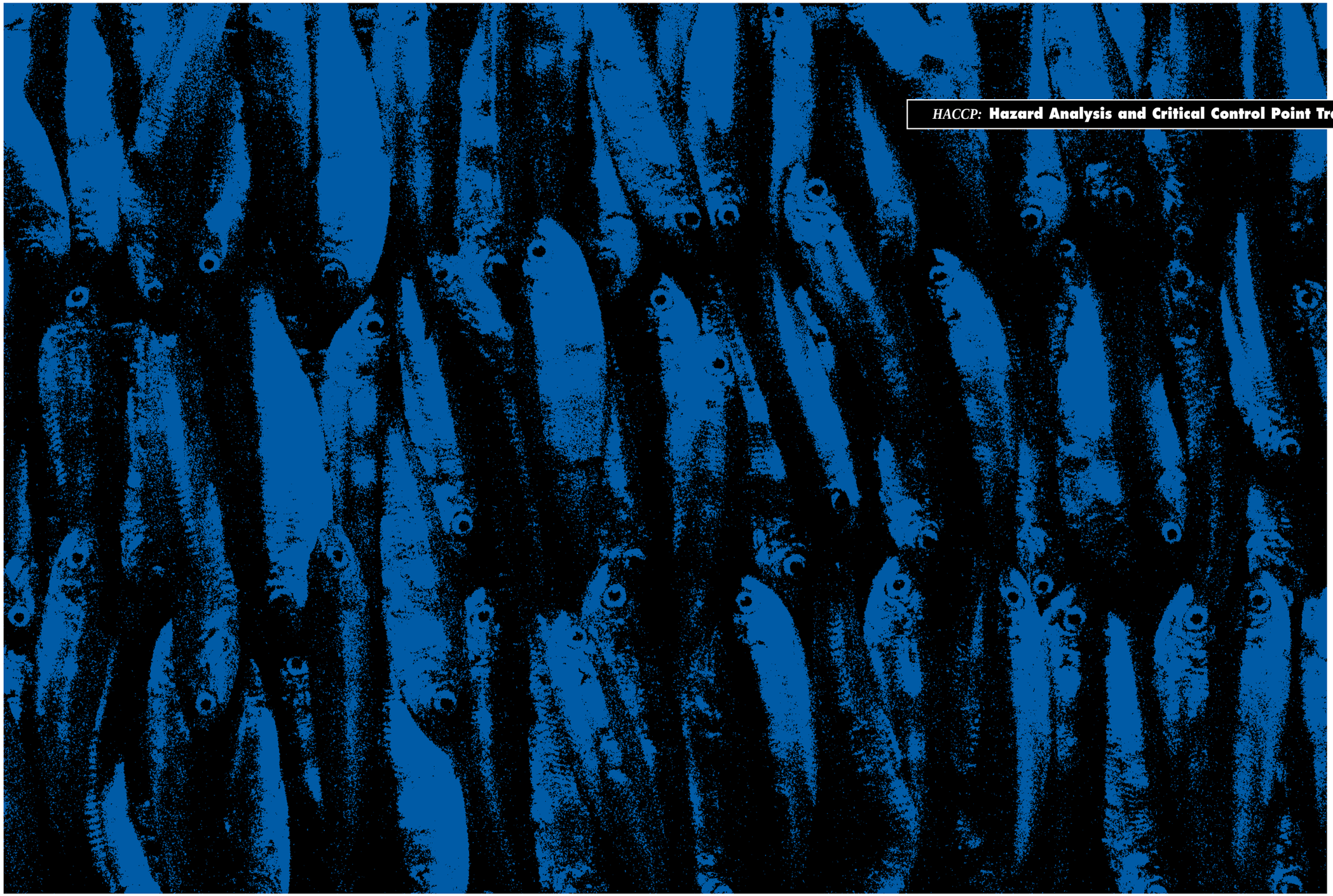

HACCP: Hazard Analysis and Critical Control Point Training Curriculum

Developed by the
National Seafood
HACCP Alliance
for Training
and Education

Fourth Edition
November 2001

National Seafood HACCP Alliance

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HACCP: **Hazard Analysis and Critical Control Point Training Curriculum**

Developed by the
Seafood HACCP Alliance
for Education and Training

Fourth Edition,
November 2001
based on revisions of
the original edition
issued in July 1996

Forward: National Seafood HACCP Alliance

The National Seafood HACCP Alliance for education and training began as an idea during the April 1993 National Sea Grant Forum on Seafood Safety and Quality. In conjunction with the Association of Food and Drug Officials of the Southern States (AFDOSS), the Board of Directors passed a resolution to advance a seafood HACCP training program. The Council of Sea Grant Directors supported a joint meeting between a selection of industry, regulatory and academic experts to explore financial support for a partnership in HACCP education. The National Sea Grant College Program approved two years of support and the first meeting of the National Seafood HACCP Alliance was held in December 1993. The Alliance Steering Committee decided to:

- organize an Alliance for HACCP training based on existing programs and established educational networks;
- produce a standard core HACCP training manual to be complemented with the U.S. Food and Drug Administration's Fish and Fishery Products Hazard and Control Guide;
- adopt a protocol to assure a uniform education program that would be recognized by state and federal regulatory agencies;
- train a national cadre of qualified instructors recognized by the Association of Food and Drug Officials (AFDO) that reflect regional needs; and
- assist with HACCP education and implementation by developing a compendium of methods, maintaining a list of research needs and enhancing public awareness.

Alliance activity has continued with additional support through the Association of Food and Drug officials and the U.S. Food and Drug Administration. The original HACCP training program has been complemented with a training program for required Sanitation Control Procedures (SCP) and a Compendium of Fish and Fishery Product Processes, Hazards, and Controls. Likewise, the Alliance's HACCP course has been made available through Internet delivery. Further Alliance activities will maintain the training programs with revised editions of the training materials and other training programs to advance implementation of HACCP and SCP, and practices for seafood safety in domestic and international commerce.

The Alliance approach recognizes the essential role of state regulatory authorities, the educational networks of Sea Grant and the Cooperative Extension Service, and the need for regional programs due to seafood diversity. The Alliance does not plan to set or recommend policy. They will strive to provide uniform education for the seafood and aquaculture industry and federal, state, and local food inspectors. The plan is not intended to be a single private, institutional, and/or government-based program. Those completing this program will be recognized by "Certificates of HACCP and SCP Course Completion" to be issued and recorded by AFDO.

Table of Contents: HACCP Training Curriculum

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About the Course Manual

This course manual and accompanying HACCP models and overheads were developed by the National Seafood HACCP Alliance — a group comprised of federal and state food-inspection officials, university food-science educators and seafood-industry representatives. The course was designed to meet the HACCP training requirements established under 21 CFR Part 123.10 of the U.S. Food and Drug Administration's mandatory seafood HACCP inspection program.

Part 123.10 requires that certain HACCP activities must be completed by a "HACCP-trained individual." A HACCP-trained individual is one who has successfully completed FDA-recognized training in the application of HACCP to fishery products (at least equivalent to that received under a "standardized curriculum" recognized by FDA) or has acquired the knowledge through job experience. **The National Seafood HACCP Alliance course is the standardized curriculum by which FDA will evaluate other training courses**.

Maintaining Course Integrity

Because this course will be used to evaluate HACCP-training equivalency, it is imperative that course instructors adhere to the course format and material to the extent possible. The course is divided into three segments. The first teaches the student the seven principles of HACCP. The second segment explains the seafood HACCP regulations and guidance materials available to help develop a HACCP plan. The last segment is a class exercise where students are divided into small groups and asked to conduct a hazard analysis and develop a HACCP plan for one or more of the eight seafood processing models found in Appendix IV. Each of these segments is necessary to give students an adequate foundation to establish their firm's HACCP mandate. Instructors are urged not to delete the material in the course because this defeats the course objective of standardizing the training experience. But instructors may wish to augment the course with examples pertinent to their region.

It is noteworthy that segment one, dealing with the seven principles, was designed to address the HACCP training needs for any FDA-regulated food product. In some instances, nonfishery product examples are used to demonstrate the application of HACCP principles. Additionally, discussion on seafood-specific hazards is provided later in Appendix III.

In 2001, the Alliance introduced an internet, self-taught version of this HACCP course (http://seafoodhaccp.cornell.edu) which can be coupled with one day of classroom instruction if the participants want to receive a certificate of course completion issued by the Association of Food and Drug Officials.

Continued

Tools for Developing HACCP Plans

The course material incorporates teaching tools to assist students in conducting a hazard analysis and developing a HACCP plan. A fictional seafood processing firm (the ABC Shrimp Co.) that produces IQF cooked shrimp is used to illustrate how a HACCP plan may be developed. It is important that instructors understand (and that they help students understand) that the model developed for ABC Shrimp Co. as well as other models are illustrative. The National Seafood HACCP Alliance does not suggest that the models represent the only way or necessarily the best way to develop HACCP plans for the products in question

A hazard-analysis worksheet is introduced in Chapter 5. In Chapter 6, a decision tree is used to help determine which steps in the production of IQF cooked shrimp are critical control points (CCPs). It must be remembered that tools such as the decision tree are not perfect since not all products and processes fit neatly into the tree. In some circumstances, the decision tree may not lead to an appropriate answer. Students must be taught to factor in all pertinent data and information about the plant operation and the characteristics of the product to determine if and where a CCP exists.

The development of ABC Shrimp Co.'s HACCP plan continues in Chapters 7 to 11. A HACCP plan form is used to identify critical limits, monitoring activity, corrective actions, verification procedures and records associated with the CCPs.

The forms and worksheets are completed step-by-step as the instructor covers each chapter. The manual provides the forms and worksheets along with responses. Instructors are urged to have students use the blank worksheets and forms found in Appendix II to fill in their own answers before turning to the completed forms in the manual. Students may then be instructed to check their answers against those found at the end of each chapter.

Convening the Course

Instructors may wish to begin the program by introducing themselves and asking each student to give his/her name, title, affiliation or the nature of the company or organization. Students may be from the private sector or from government agencies. If the student is from industry, the types of products each processes and handles might be discussed briefly.

After the introduction, the instructors should cover meeting logistics: directions to bathrooms, phones, food establishments, smoking areas, etc. Students should be informed that the course is designed to provide a morning and afternoon break each day. Instruction should proceed with the introduction provided in Chapter 1.

Course Agenda: National Seafood HACCP Alliance

Day One

30 minutes	Welcome and Course Objectives	Chapter 1
90 minutes	Hazards (Biological, Chemical and Physical)	Chapter 2
45 minutes	Prerequisite Programs and HACCP Preliminary Steps	Chapter 3
	Commercial Processing Example: IQF Cooked Shrimp	Chapter 4
120 minutes	Hazard Analysis and Preventive Measures	Chapter 5
60 minutes	Identification of Critical Control Points	Chapter 6
60 minutes	Establish Critical Limits	Chapter 7
60 minutes	Critical Control Point Monitoring	Chapter 8

Day Two

60 minutes	Corrective Actions	Chapter 9
60 minutes	Record-Keeping Procedures	Chapter 10
60 minutes	Verification Procedures	Chapter 11
165 minutes	The Seafood HACCP Regulation	Chapter 12
60 minutes	Sources of Information on Preparing HACCP Plans	Chapter 13
60 minutes	Review and Preparation for Developing HACCP Plans Work Session	Appendix IV

Day Three

240 minutes	Work Sessions on Developing HACCP Plans (break into groups)
240 minutes	Work Session Reports (discussions, questions and answers)

Instructor's Note:

The course agenda is a suggested outline of how the course may be structured. All material must be covered. However, instructors are free to alter both the time allocation and chapter sequence (e.g., some may choose to teach the HACCP regulation on day one prior to HACCP principles). Also, instructors may elect to supplement information in Chapter 2 (Hazards) with seafood-specific hazards material in Appendix III.

Instructor's Note:

Schedule lunch and breaks as appropriate.

Notes:

Chapter 1: Introduction to Course and HACCP

Overhead 1

Objective:
In this module, you will learn the:
- Objective of the course,
- Format of the course,
- Expectations of the participant and
- Meaning and importance of HACCP.

Course Objective

Food and Drug Administration Seafood regulations based on the principles of **H**azard **A**nalysis and **C**ritical **C**ontrol **P**oint (HACCP) became effective in the United States in December, 1997. The Food and Drug Administration (FDA) issued these regulations to ensure safe processing and importing of fish and fishery products. These regulations specify that certain critical jobs in seafood processing be performed by someone trained in HACCP. This person is responsible for developing and modifying the HACCP plan and reviewing records. This course contains the information necessary for you or a team to meet the HACCP-training requirements. It is also designed to provide inspectors with the knowledge they need to evaluate HACCP plans and practices.

Course Format

This seafood HACCP course is divided into three distinct segments:
- HACCP fundamentals,
- Relationship of HACCP and FDA's regulation to the seafood industry, and
- Work session to develop a seafood HACCP plan.

The first segment defines the seven principles of HACCP. Learning these principles will give a clear understanding of the fundamentals on which HACCP is based. As each principle is discussed, the class will develop a HACCP plan for cooked shrimp using the fictional ABC Shrimp Co. as a model. This will help you understand HACCP principles and how they interrelate.

The second segment explains the seafood HACCP regulations and guidance materials that are available to help you develop a HACCP plan. The manual also presents information about seafood-specific hazards.

The third segment demonstrates how to develop a seafood HACCP plan. During this part of the course, the class will be divided into teams to write a HACCP plan based on a narrative and flow chart.

Continued

Notes:

Notes:

What is Expected of the Participant

HACCP is a common sense technique used to control food-safety hazards. It is an important safety-management system and can be integrated into any operation. However, HACCP can seem complicated and demanding until its concepts are understood. Therefore, you are encouraged to ask questions and to contribute first-hand experiences to discussions. This manual includes exercises that require class participation throughout the training. Keep in mind that the more you contribute to these exercises, the less complicated the HACCP system will seem and the easier it will be to implement a HACCP plan later.

How to Use This Manual

This manual is yours. Become familiar with it. Learn where the definitions are, where the forms are that will help you develop a HACCP plan, and where to find other basic information. Make as many notes and marks in the text as needed to assist in creating and understanding a HACCP plan. Use the manual as a reference. This manual does not have a copyright. Make as many copies of its forms as necessary or copy the whole manual to share with others in your company.

Meaning and Importance of HACCP

Many people may not have heard the term "HACCP" until recently. However, it is neither a new term nor a new concept.

Overhead 2

HACCP stands for:
Hazard **A**nalysis and **C**ritical **C**ontrol **P**oint

HACCP is merely an acronym that stands for **H**azard **A**nalysis and **C**ritical **C**ontrol **P**oint. But the concept behind this term is important.

Overhead 3

HACCP is:
- Preventive, not reactive.
- A management tool used to protect the food supply against biological, chemical and physical hazards.

HACCP is a preventive system of hazard control rather than a reactive one. Food processors can use it to ensure safer food products for consumers. To ensure safer food, the HACCP system is designed to identify hazards, establish controls and monitor these controls. Hazards can be harmful microorganisms or chemical and/or physical contaminants.

Overhead 4

Origins of HACCP:
- Pioneered in the 1960s.
- First used when foods were developed for the space program.
- Adopted by many food processors and the U.S. government.

The Pillsbury Co. pioneered the application of the HACCP concept to food production during its efforts to supply food for the U.S. space program in the early 1960s. Pillsbury decided that their existing quality-control techniques did not provide adequate assurance against contamination during food production. The company found that end-product testing necessary to provide such assurance would be so extensive that little food would be available for space flights.

Overhead 5

HACCP is not a zero-risk system.
It is designed to minimize the risk of food-safety hazards.

The only way to ensure safety, Pillsbury concluded, would be to develop a preventive system that kept hazards from occurring during production. Since then, Pillsbury's system has been recognized worldwide as the state-of-the-art measure for food-safety control. It is not a zero-risk system, but it is designed to minimize the risk of food-safety hazards. The FDA first required HACCP controls for food processing in 1973 for canned foods to protect against *Clostridium botulinum*, which causes botulism.

Overhead 6

Recommendation:
"The HACCP approach be adopted by all regulatory agencies and that it be mandatory for food processors."
1985 National Academy of Sciences

Continued

Notes:

Notes:

In an assessment of the effectiveness of food regulation in the United States, the National Academy of Sciences (NAS) recommended in 1985 that the HACCP approach be adopted by all regulatory agencies and that it be mandatory for food processors.

Overhead 7

National Academy of Sciences recommendation led to formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

This recommendation led to the formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). This committee standardized the HACCP principles used by industry and regulatory authorities. The committee's work is the basis of this core curriculum.

Instructor's Note:

NACMCF is continuing to refine the HACCP principles in an effort to make them more user friendly and effective. In August 1997, NACMCF adopted revised HACCP guidelines. To the extent possible, many of the changes have been incorporated into this manual. Most obviously, Principles 6 and 7 were switched, thereby making recordkeeping Principle 7. Additionally, "preventative measures" was changed to "control measures."

Instructors and students should be aware of the dynamic nature of HACCP and not be surprised or confused as the principles are refined.

Overhead 8

Seven principles of HACCP:
1. Conduct hazard analysis.
2. Determine the critical control points (CCPs) in the process.
3. Establish critical limits.
4 Monitor each CCP.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish record-keeping and documentation procedures.

In 1992, NACMCF adopted the following seven HACCP principles. They are:

In 1997, NACMCF adopted the following seven HACCP principles. They are:

1. Conduct hazard analysis.
2. Determine the critical control points (CCPs) in the process.
3. Establish critical limits.
4. Monitor each CCP.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish record-keeping and documentation procedures.

These principles will be explained in more detail in the following sessions. The seafood HACCP regulation and other domestic and international HACCP control systems are based on these principles.

Overhead 9

International use:

- Codex
- European Union
- Canada
- Australia
- New Zealand
- Japan

HACCP has been endorsed worldwide by organizations such as Codex Alimentarius (a commission of the United Nations) and the European Union and by several countries including Canada, Australia, New Zealand and Japan.

Overhead 10

HACCP is not a stand-alone system.

HACCP is a preventive system for ensuring food safety, but it is not a stand-alone system. HACCP must be built upon current food-safety programs such as Good Manufacturing Practices (GMPs) (e.g., sanitation and personal hygiene programs) to make it work.

Overhead 11

Traditional Inspection Methods for Food-Safety Control
versus
The HACCP Approach

The HACCP concept is used by regulators during inspections of food processors to focus their attention on the parts of the process that are most likely to affect the safety of the product.

The inspection of plants operating under HACCP plans differs from traditional inspection methods of food-safety control. Traditional methods evaluate processing practices on the day or days of inspection. The HACCP approach allows regulators to look at what happens in the plant through time by examining the firm's monitoring and corrective action records.

Continued

Notes:

Notes:

Overhead 12

HACCP inpections complement traditional inspection methods.
HACCP:
- Emphasizes process control.
- Concentrates on the points in the process that are critical to the safety of the product.
- Stresses communication between the regulator and industry.

With HACCP, the emphasis is to understand the process system. This requires the regulator and industry to communicate and to work with one another. The inspector will be verifying the HACCP plan by determining that significant food-safety hazards have been properly identified and that industry is consistently controlling these hazards. The inspector will accomplish this by first surveying the plant and then reviewing the HACCP plan and records. Regulatory inspections will continue to look for compliance in areas such as sanitation, economic fraud, food standards, etc.

In defining the roles of industry and the regulatory agencies in HACCP, the NACMCF document indicates: “It is the responsibility of the food industry to develop and implement HACCP plans and for regulatory agencies to facilitate this process." Or, in other words, the role of the government is to ensure that industry adheres to their role.

Overhead 13

"It is the responsibility of the food industry to develop and implement HACCP plans and for regulatory agencies to facilitate this process."
NACMCF, June 1993

As you learn more about HACCP, there will be many new definitions that you will need to understand. To assist you, the most common HACCP definitions are found in the following two pages. Refer back to these pages as needed and add other terms as appropriate that will help you in developing and implementing your own HACCP plan.

The next sessions will explain the basics of HACCP. We will start by first defining the types of hazards.

Notes:

Notes:

Definitions*

- **Continuous Monitoring:** Uninterrupted collection and recording of data such as temperature on a strip chart.
- **Control:** (a) (verb) To manage the conditions of an operation to maintain compliance with established criteria.
  (b) (noun) The state in which correct procedures are being followed and criteria are being met.
- **Control Measure:** Any action or activity that can be used to prevent, eliminate or reduce a significant hazard (previously known as a preventive measure and is still called a preventive measure in FDA's Hazards and Controls Guide).
- **Control Point:** Any point, step or procedure at which biological, physical or chemical factors can be controlled.
- **Corrective Action:** Procedures followed when a deviation occurs.
- **Critical Control Point (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.
- **CCP Decision Tree:** A sequence of questions asked to determine whether a control point is a CCP.
- **Critical Limit:** A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food-safety hazard.
- **Deviation:** Failure to meet a critical limit.
- **HACCP:** A systematic approach to the identification, evaluation and control of food-safety hazards.
- **HACCP Plan:** The written document that is based upon principles of HACCP and that delineates the procedures to be followed.
- **HACCP System:** The result of the implementation of the HACCP plan.
- **HACCP Team:** The group of people who are responsible for developing, implementing and maintaining the HACCP system.
- **Hazard:** A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

- **Monitor:** To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

- **Operating Limits:** Criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation.

- **Prerequisite Programs:** Procedures, including Good Manufacturing Practices (GMPs), that address operational conditions providing the foundation for the HACCP system.

- **Severity:** The seriousness of a hazard (if not properly controlled).

- **Validation:** The element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

- **Verification:** Those activities that determine the validity of the HACCP plan and that the system is operating according to the plan.

* *National Advisory Committee on Microbiological Criteria for Foods, 1997. Hazard Analysis and Critical Control Point Principles and Application Guidelines.*

Notes:

Notes:

Acronyms

- **CCP:** Critical control point
- **CL:** Critical limit
- **FDA:** Food and Drug Administration
- **GMP:** Good Manufacturing Practice
- **HACCP:** Hazard analysis and critical control point
- **MIG:** Mercury-in-glass thermometer
- **NAS:** National Academy of Science
- **NACMCF:** National Advisory Committee on Microbiological Criteria for Foods
- **PPM:** Parts per million
- **SCP:** Sanitation control procedures
- **SOP:** Standard operating procedure
- **SSOP:** Sanitation standard operating procedure

Chapter 2: Hazards - Biological, Chemical and Physical

Overhead 1

Objective:
- Awareness of:
  - Biological hazards
  - Chemical hazards
  - Physical hazards
- Characteristics of certain microorganisms

To perform a hazard analysis for the development of a HACCP plan, food processors must gain a working knowledge of potential hazards. The HACCP plan is designed to control all reasonably likely food-safety hazards. Such hazards are categorized into three classes: biological, chemical and physical.

Overhead 2

Definition:
Hazard: a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Biological hazards include harmful bacteria, viruses or parasites (e.g., salmonella, hepatitis A and trichinella). Chemical hazards include compounds that can cause illness or injury due to immediate or long-term exposure. Physical hazards include foreign objects in food that can cause harm when eaten, such as glass or metal fragments.

It is important to understand that, for the purposes of HACCP, hazards only refer to the conditions or contaminants in food that can cause illness or injury to people. Many conditions are highly undesirable in food, such as the presence of insects, hair, filth or spoilage. Economic fraud and violations of regulatory food standards are equally undesirable. All of these defects must be controlled in food processing. However, they often are not directly related to the safety of the product. Unless these conditions directly affect food safety, they are not included in a HACCP plan.

Continued

Explanatory Note:

Whether a particular hazard listed in this chapter will need to be addressed in a HACCP plan will depend on an evaluation of the actual risk and severity of the hazard in the food. This evaluation is explained in the next chapter.

This chapter is intended as a general discussion on hazards. For information on seafood-specific hazards, refer to Appendix III.

Additional information on potential hazards for specific types of seafood and processing methods is found in the FDA "Fish and Fisheries Products Hazards Control Guidance" referenced in Chapter 13.

Notes:

Overhead 3

In HACCP, "hazards" refer to conditions or contaminants in foods that can cause illness or injury. It does not refer to undesirable conditions or contaminants such as:

- Insects,
- Hair,
- Filth,
- Spoilage,
- Economic fraud and
- Violations of regulatory food standards not directly related to safety.

It is not within the scope of this course to go into detail on foodborne hazards. That topic is too large and would be covered better in separate microbiology, toxicology and food-processing courses. However, this chapter will increase awareness of the kinds of hazards that may occur in foods. This awareness will prepare participants for recognizing what is and is not appropriate to control with HACCP. Food processors may find it necessary to work with technical experts to develop a HACCP plan.

Biological Hazards

Foods can contain biological hazards. These hazards can come from raw materials or from food-processing steps used to make the final product. Table A (at the end of the chapter) provides a list of biological hazards.

• *Microorganisms*

Organisms too small to be seen with the naked eye are called *microorganisms*. Microorganisms live everywhere: air, dirt, fresh and salt water, skin, hair, animal fur and plants.

Microorganisms are classified into various groups. A few groups important in foods include yeasts, molds, bacteria, viruses and protozoa. Since microorganisms are so widespread, it is important to understand when to be concerned about them and how to deal with them.

Although thousands of kinds of microorganisms exist, only a few pose hazards to humans. These hazardous microorganisms, or *pathogens*, will be discussed in more detail later.

Many microorganisms are beneficial. Certain kinds of yeast, molds and bacteria help make cheese, sour cream, yogurt and other fermented dairy products. Particular kinds of yeast are used in making beer, wine and other fermented beverages. We add these microorganisms to our foods intentionally, and they cause no harm. In fact, studies show that some of these microorganisms contribute to good health.

People may come into contact with thousands of kinds of yeasts, molds, bacteria, viruses and protozoa daily without ill effect. Therefore, when foods are processed and preserved, food processors and regulators need only be concerned with some microorganisms, particularly pathogens.

Overhead 4

> Microorganisms can be beneficial, even essential. Some can be pathogenic. It is this class that concerns food processors and public health officials.

Although microorganisms are too small to be seen without a microscope, they are alive and have certain needs to live and grow. Without adequate food, water and temperature, microorganisms stop growing and multiplying. Some die; others stop functioning until they get the elements they need. Some preservation methods, such as drying or smoking, control the water or nutrients in food, making these essential elements unavailable to microorganisms.

Overhead 5

> What do microorganisms (other than viruses) need?
> - Food
> - Water
> - Proper temperature
> - Air, no air, minimal air

Different microorganisms respond differently to air. Like most plants and animals, many microorganisms need air to live and will die or stop growing if deprived. However, many microorganisms can function without air. Some are poisoned by it. Unfortunately, pathogens exist in each of these categories. Although some microorganisms can be controlled by the amount of air they receive, it is not an effective way of controlling all pathogens.

Microorganisms multiply in different ways. The most common method, especially for yeasts, bacteria and protozoa, is to grow large and divide. One microorganism splits into two, two into four, four into eight, eight into sixteen, and so on. By doubling, microorganisms multiply quickly. Under ideal conditions, some bacteria double every 20 minutes. Potentially, one microorganism can multiply to more than 30,000 in five hours and to more than 16 million in eight hours. Fortunately, most microorganisms grow more slowly than this, and we can slow them even more by controlling the food, water and temperature that they need to grow and multiply.

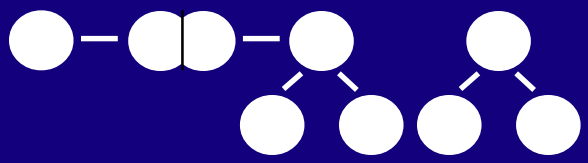
Continued

Notes:

Notes:

Overhead 6

Many pathogenic microorganisms reproduce by dividing in two:



When they grow, microorganisms produce by-products.
- Yeast — bread, beverages, fruit
- Lactic acid bacteria — yogurt, cheese, meats
- *Staphylococcus aureus* — enterotoxin

Most spoiled foods do not present a health risk, and not all food that appears normal is safe to consume.

When microorganisms grow, they often produce by-products. The more they grow, the more by-products they produce. Some of the by-products are desirable in the right foods. For example, when yeasts grow in dough, they produce carbon dioxide, acids and flavors. The dough rises and we make bread. However, when the same yeasts grow and produce the same by-products in another food, such as fruit juice, it may not be desirable. Then we call it spoilage. Such spoilage is undesirable, and processors strive to avoid it in food. In addition, some by-products produced by pathogens are toxic and can cause disease.

Overhead 7

Food spoilage or decomposition that can result in a food-safety problem should be prevented or controlled by a HACCP program.

Spoiled food may not look, smell or taste good, but only food spoiled by pathogens or contaminated by toxic microbial by-products can make a person sick. Food spoilage or decomposition that can result in food-safety problems should be prevented or controlled by a HACCP program.

During the processing of foods, the amounts and types of microorganisms can be increased, held constant, reduced or destroyed. Even though processing can be used to destroy harmful microorganisms, many safe microorganisms can survive the treatment and continue to live.

Example: **Milk is pasteurized, or heat-treated, to destroy pathogens. After pasteurization, milk is safe to drink even though nonpathogenic microorganisms survive.**

Overhead 8

Microbiological hazards include harmful:
- Bacteria,
- Viruses and
- Protozoa

Among the five groups of microorganisms described earlier, only bacteria, viruses and protozoa include the kinds of microorganisms that can make food unsafe. Generally, yeast and molds do not pose a biological hazard in food. Some molds produce hazardous toxins, but these toxins are considered chemical hazards.

Overhead 9

Bacterial Hazards:
- Food infection and food intoxication
- Sporeforming and nonsporeforming bacteria

• *Bacterial Hazards*

Bacterial hazards are defined as those bacteria that, if they occur in food, may cause illness in humans, either by infection or intoxication. Food-borne infections are caused by swallowing live pathogens that grow within the body, usually in the intestinal tract. They differ from food-borne intoxication, which is a condition caused by swallowing preformed toxins (i.e., toxins produced by microorganisms in the food before it is eaten).

Bacterial hazards can also be grouped into sporeformers and non-sporeformers. Certain types of bacteria (e.g., *Clostridium* and *Bacillus* spp.) pass through a dormant stage in their life cycle called a spore. Although the microorganism exists as a spore, it is very resistant to chemicals, heat and other treatments that would normally be lethal to nonsporeforming bacteria. Because they are dormant, spores are not hazardous as long as they stay spores. Unfortunately, if they survive a processing step designed to kill nonsporeforming bacteria, they may become a hazard in the food if they are allowed to grow. When sporeformers are a concern, the process steps used to control them are often much more severe than if only nonsporeformers need to be controlled.

Continued

Explanatory Note:

Students may ask why some hazards are classified as chemical rather than biological. The best answer is tradition. It is important to stress, however, that the significant issue is not the actual classification of a hazard, but accurate identification and control.

Notes:

Overhead 10

Sporeforming Bacteria (Pathogens):
- *Clostridium botulinum*
  - Proteolytic
  - Nonproteolytic
- *Clostridium perfringens*
- *Bacillus cereus*

Overhead 11

Nonsporeforming Bacteria:
- *Brucella abortis, B. suis*
- *Campylobacter* spp.
- Pathogenic *Escherichia coli* (e.g., *E. coli* 0157:H7)
- *Listeria monocytogenes*
- *Salmonella* spp. (e.g., *S. typhimurium, S. enteriditis)*
- *Shigella* spp. (e.g., *S. dysenteriae*)
- Pathogenic *Staphylococcus aureus*
- *Streptococcus pyogenes*
- *Vibrio* spp. (e.g., *V. cholerae, V. parahaemolyticus, V. vulnificus*)
- *Yersinia enterocolitica*

Example:
The following are examples of bacterial hazards found in food and why they are considered hazards:

Microorganism	Why a hazard?
Clostridium botulinum (sporeformer)	Causes an intoxication that affects the central nervous system and causes shortness of breath, blurred vision, loss of motor capabilities and death.
Listeria monocytogenes (nonsporeformer)	Causes an infection with mild flulike symptoms. Severe forms of listeriosis are possible in people with weakened immune systems, causing septicemia, meningitis, encephalitis and stillbirths.
Salmonella spp. (nonsporeformer)	Causes an infection with the following symptoms: nausea, vomiting, abdominal cramps, diarrhea, fever and headache. Death is possible in people with weakened immune systems.

• ***Viral Hazards***

Like other microorganisms, viruses exist everywhere. They are very small particles that cannot be seen with a light microscope and cannot reproduce by themselves. Although they are alive, viruses differ from other microorganisms in what they need to live and how they multiply. Viruses exist in foods without growing, so they need no food, water or air to survive. They do not cause spoilage. Viruses cause illness by infection. They can infect living cells and reproduce inside the host cell using material from it. Viruses only grow once they enter a suitable host. Only some viruses consider humans a suitable host. Viruses can survive in human intestines, contaminated water and frozen foods for months.

Overhead 12

Hazards from viruses in foods
- What are viruses?
- Where do they come from?
- How do they reproduce?
- How can they be controlled?
- What are some examples? (Table A)

Viruses can be found in people who were previously infected but are no longer ill. Viruses can also be present in people who show no outward signs of illness (carriers). Transmission of viruses to foods is usually related to poor hygienic practices. People who have viruses shed the particles when they defecate. Food handlers with viruses can transmit them to food if they forget to wash and sanitize their hands properly. This route can also result in contamination of food with bacterial hazards.

Example:
The following are examples of viral hazards found in food:

Microorganism	Why a hazard?
Hepatitis A virus	Causes fever and abdominal discomfort, followed by jaundice.
Norwalk virus	Causes nausea, vomiting, diarrhea and abdominal pain (gastroenteritis). Headache and low-grade fever may also occur.

Continued

Notes:

Notes:

Overhead 13

Viruses:
- Hepatitis A
- Norwalk Virus Group

• Parasitic Hazards (Worms and Protozoa)

Parasites are organisms that need a host to survive, living on or within it. Thousands of kinds of parasites exist worldwide. Only about 20 percent can be found in food or water, and less than 100 are known to infect people through consumption. There are two types of parasites that can infect people through food or water: parasitic worms and protozoa. Parasitic worms include roundworms (nematodes), tapeworms (cestodes) and flukes (trematodes). These worms vary in size from barely visible to several feet in length. Protozoa are single-cell animals, and most cannot be seen without a microscope.

Table A at the end of the chapter lists the parasitic protozoa and worms most likely to be found in the U.S. food supply. For most foodborne parasites, the food is part of their natural life cycle (e.g., nematode worms in fish and meat). They have the opportunity to infect humans when people eat them along with the food. The two factors most important to parasitic survival are a proper host (i.e., not all organisms can be infected by parasites) and a suitable environment (i.e., temperature, water, salinity, etc.).

Overhead 14

Parasites in Foods
- Parasites are organisms that need a host to survive.
- Thousands of kinds exist worldwide but only about 100 types are known to infect people through food consumption.
- Two types of concern from food or water:
  - Parasitic worms [e.g., roundworms (nematodes), tapeworms (cestodes), flukes (trematodes)]
  - Protozoa
- Role of fecal material in transmission of parasites.

Some parasites may be transmitted through food or water that is contaminated by fecal material shed by infected hosts. Methods of preventing transmission of parasites to foods by fecal contamination include:
- good personal hygiene practices by food handlers,
- proper disposal of human feces,
- elimination of insufficiently treated sewage to fertilize crops, and
- proper sewage treatment.

Consumer exposure to parasites depends on food selection, cultural habits and preparation methods. Most parasites do not harm humans but may be aesthetically unpleasant. Parasitic infections are normally associated with raw or undercooked foods because thorough cooking of foods eliminates all foodborne parasites. In specific instances, freezing can be used to destroy parasites in food.

Example:
The following are examples of parasite hazards found in food:

Organism	Why a hazard?
Giardia lamblia	This protozoa causes diarrhea, abdominal cramps, fatigue, nausea, flatulence (intestinal gas) and weight loss. Illness may last for one to two weeks, but chronic infections can last months to years.
Entamoeba histolytica	This protozoa causes dysentery (severe, bloody diarrhea).
Ascaris lumbricoides	This roundworm causes intestinal and lung infection.
Diphyllobothrium latum	This tapeworm attaches itself to the intestinal wall and can grow to 3 to 7 feet. Symptoms include abdominal pain, cramping, flatulence and diarrhea.

Overhead 15

Parasitic Protozoa and Worms:
- *Cryptosporidium parvum*
- *Diphyllobothrium latum*
- *Entamoeba histolytica*
- *Giardia lamblia*
- *Anasakis simplex*
- *Ascaris lumbricoides*
- *Taenia solium, T. saginata*
- *Trichinella spiralis*
- *Pseudoterranova dicepiens*

Notes:

Continued

Explanatory Note:

Some of these limits (such as for aflatoxin, lead and histamine) can be found in Title 21 of the Code of Federal Regulations and in the FDA Compliance Policy Guides.

Chemical Hazards

Chemical contamination can happen at any stage in food production and processing. Chemicals can be helpful and are purposefully used with some foods, such as pesticides on fruits and vegetables. Chemicals are not hazardous if properly used or controlled. Potential risks to consumers increase when chemicals are not controlled or the recommended treatment rates are exceeded. The presence of a chemical may not always represent a hazard. The amount of the chemical may determine whether it is a hazard or not. Some may require exposure over prolonged periods to have a toxic effect. Regulatory limits are set for some of those contaminants.

Chemical hazards can be separated into three categories:
- Naturally occurring chemicals.
- Intentionally added chemicals.
- Unintenionally or incidentially added chemicals.

The types of chemicals included in these categories are listed in Table B at the end of the chapter.

Explanatory Note:

Allergic reactions are caused by proteins (allergens) that react with the body's natural immune system. This type of chemical hazard is of concern to individuals who are sensitive to the allergen.*

** It is particularly important that foods formulated with components that are known to produce these types of reactions clearly identify these ingredients on the label. HACCP-type controls may be necessary when it may not be obvious that the food contains the allergen.*

• *Naturally Occurring Chemicals (including allergens)*

These chemicals are derived from a variety of plants, animals or microorganisms. In most cases, these naturally occurring chemicals are found prior to or during harvest. Although many naturally occurring toxins are biological in origin, they are traditionally categorized as chemical hazards.

Example:
The following are examples of foods containing naturally occurring chemical hazards:

Source	Why a hazard?
Certain fish species (e.g., tuna, mahi-mahi)	Spoilage of certain species of fish can result in production of toxic levels of histamine and related compounds.
Nuts, Seafood	Certain varieties or species produce an allergic reaction in sensitive people.
Corn	Certain molds that grow on corn can create toxins (e.g., aflatoxin).
Molluscan shellfish	Some of the microscopic organisms and plants upon which they feed can produce a toxin, such as domoic acid, that affect people but not shellfish.

Overhead 16

Types of Naturally Occurring Chemical Hazards:
- Mycotoxins (e.g., aflatoxin)
- Scombrotoxin
- Ciguatoxin
- Shellfish toxins
  - Paralytic shellfish poisoning (PSP)
  - Diarrheic shellfish poisoning (DSP)
  - Neurotoxic shellfish poisoning (NSP)
  - Amnesic shellfish poisoning (ASP)/Domoic Acid

Notes:

• *Intentionally Added Chemicals*

These chemicals are intentionally added to food at some point during the food's growth and distribution. Intentionally added chemicals are safe when used at established safe levels but can be dangerous when those levels are exceeded.

Example:
The following are examples of food additives that may be chemical hazards if used improperly:

Source	Why a hazard?
FD&C Yellow No. 5	Can produce an allergic-type reaction in (food coloring) sensitive people.
Sodium nitrite (preservative)	Can be toxic in high concentrations.
Vitamin A (nutrient supplement)	Can be toxic in high concentrations.
Sulfiting agents (preservative)	Can cause allergic-type reaction in sensitive people.

Explanatory Note:

Certain food additives must have prior approval before they can be used in foods. Before using a new food additive, food processors should review the appropriate regulations for approval status and any limitations on its use.

Chemicals such as lubricants, cleaning compounds, sanitizers and paints must have prior approval.

Notes:

Overhead 17

Intentionally Added Chemicals — Food Additives:
- Direct (allowable limits under GMPs)
  - Preservatives (e.g., nitrite and sulfiting agents)
  - Nutritional additives (e.g., niacin)
  - Color additives

Overhead 18

Unintentionally or Incidentially Added Chemicals:
- Agricultural chemicals (e.g., pesticides, fungicides, herbicides, fertilizers, antibiotics and growth hormones)
- Prohibited substances (Code of Federal Regulations, Chapter 21, Section 189)
- Toxic elements and compounds (e.g., lead, zinc, arsenic, mercury, cyanide)
- Secondary direct and indirect
  - Plant chemicals (e.g., lubricants, cleaning compounds, sanitizers, paint)

• ***Unintentionally or Incidentially Added Chemicals***

Chemicals can become part of a food without being intentionally added. These incidental chemicals might already be in a food ingredient when it is received. For example, certain seafood may contain small but legal residues of approved antibiotics. Packaging materials that are in direct contact with ingredients or the product can be a source of incidental chemicals, such as sanitizers or inks. Most incidental chemicals have no effect on food safety, and others are only a concern if they are present in too high an amount. Incidental chemicals also include accidental additions of prohibited substances such as poisons or insecticides that may not be allowed at any level.

Example:
The following are examples of incidental contaminants that may be chemical hazards:

Source	Why a hazard?
Agricultural chemicals (e.g., pesticides, herbicides)	Can be acutely toxic if present in the food at high levels and may cause health risks with long-term exposure.
Cleaning chemicals (e.g., acids, caustics)	Can cause chemical burns if present in the food at high levels.
Maintenance chemicals (e.g., lubricants, paint)	Chemicals that are not approved for food use and may be toxic.

Explanatory Note:

A partial list of prohibited substances can be found in Title 21, part 189 of the Code of Federal Regulations, "Substances Prohibited from Use in Human Food."

Physical Hazards

Physical hazards include any potentially harmful extraneous matter not normally found in food. When a consumer mistakenly eats the foreign material or object, it is likely to cause choking, injury or other adverse health effects. Physical hazards are the most commonly reported consumer complaints because the injury occurs immediately or soon after eating, and the source of the hazard is often easy to identify. Table C at the end of the chapter lists the types of materials that can be physical hazards in foods.

Example:
The following are examples of materials that may be physical hazards:

Material	Why a hazard?
Glass	Cuts, bleeding; may require surgery to find or remove.
Metal	Cuts, broken teeth; may require surgery to remove.

Explanatory Note:

Exercise caution in listing bone fragments as physical hazards. The presence of bone should be kept as low as possible, which would be product and process dependent. However, in many products (especially seafood), bone fragments are uncontrollable quality defects and not consumer-safety hazards.

Overhead 19

Physical Hazard:
Any potentially harmful extraneous matter
not normally found in food

Notes:

TABLE A

Biological Hazards

I. Bacteria

A. Sporeformers

Clostridium botulinum
Clostridium perfringens
Bacillus cereus

B. Nonsporeformers

Brucella abortis, B. suis
Campylobacter spp.
pathogenic *Escherichia coli* (e.g. *E. coli* O157:H7)
Listeria monocytogenes
Salmonella spp. (e.g., *S. typhimurium, S. enteriditis*)
Shigella spp. (e.g., *S. dysenteriae*)
Staphylococcus aureus
Streptococcus pyogenes
Vibrio spp. *(e.g., V. cholerae, V. parahaemolyticus, V. vulnificus)*
Yersinia enterocolitica

II. Viruses

Hepatitis A and E
Norwalk virus group
Rotavirus

III. Parasitic Protozoa and Worms

Anasakis simplex
Ascaris lumbricoides
Cryptosporidium parvum
Diphyllobothrium latum
Entamoeba histolytica
Giardia lamblia
Pseudoterranova dicepiens
Taenia solium, T. saginata
Trichinella spiralis

TABLE B

Types of Chemical Hazards

I. Naturally Occuring Chemicals

- Mycotoxins (e.g., aflatoxin)
- Scombrotoxin (histamine)
- Ciguatoxin
- Mushroom toxins
- Shellfish toxins
  - Paralytic shellfish poisoning (PSP)
  - Diarrheic shellfish poisoning (DSP)
  - Neurotoxic shellfish poisoning (NSP)
  - Amnesic shellfish poisoning (ASP)/Domoic acid
- Pyrrolizidine alkaloids
- Phytohemagglutinin

II. Intentionally Added Chemicals

- Food additives
  - Direct (allowable limits under GMPs)
    - Preservatives (e.g., nitrite and sulfiting agents)
    - Nutritional additives (e.g., niacin)
    - Color additives

III. Unintentionally or Incidentially Added Chemicals

- Agricultural chemicals
  (e.g., pesticides, fungicides, herbicides, fertilizers, antibiotics and growth hormones)
- Prohibited substances
  (Code of Federal Regulations, chapter 21, section 189)
- Toxic elements and compounds
  (e.g., lead, zinc, arsenic, mercury and cyanide)
- Polychlorinated biphenyls (PCBs)
- Plant chemicals
  (e.g., lubricants, cleaning compounds, sanitizers and paints)

Notes:

Notes:

TABLE C

Physical Hazards and Common Sources

Material	Sources
Glass	Bottles, jars, light fixtures, thermometers, gauge covers
Metal	Machinery, agricultural fields, buckshot, birdshot, wire, staples, buildings, employees

Chapter 3: Prerequisite Programs and Preliminary Steps

Overhead 1

Objective:
In this module, you will learn:
- Prerequisite programs to have in place before starting HACCP, and
- Preliminary steps involved in developing a HACCP plan.

Prerequisite Programs

HACCP is *not* a stand-alone program but is one part of a larger system of control procedures. For HACCP to function effectively, it should be accompanied by the prerequisite programs discussed in this chapter.

Overhead 2

GMP — Good Manufacturing Practice
SCP — Sanitation Control Procedures
SSOP — Sanitation Standard Operating Procedure
HACCP — Hazard Analysis and Critical Control Point

HACCP systems are designed to prevent and control food-safety hazards associated with food from the time a company receives raw material through production to distribution to the consumer. HACCP systems must be built upon a firm foundation of compliance with current Good Manufacturing Practices (GMPs) (Code of Federal Regulations, Title 21, Part 110) and acceptable Sanitation Control Procedures (SCPs). GMPs and sanitation procedures affect the processing environment and should be considered prerequisite programs to HACCP.

Overhead 3

Definition:
Prerequisite Programs: Procedures, including GMPs, that address operational conditions providing the foundation for the HACCP system.

Explanatory Note:

This chapter is not intended to be an exhaustive discussion of all elements of what could be included in prerequisite programs.

Instructor's Note:

See Appendix VI for a copy of the GMPs (21 CFR 110)

Continued

Notes:

Explanatory Note:

Although written SSOPs are not mandated by FDA, eight areas of sanitation are identified in the seafood HACCP rule (discussed in Chapter 12). These areas must be monitored and documented by all processors regardless of whether a firm has a written SSOP or is required to have a HACCP plan.

The Good Manufacturing Practices define measures of general hygiene as well as measures that prevent food from becoming adulterated due to unsanitary conditions. The GMPs are broadly focused and encompass many aspects of plant and personnel operations. The SCPs are usually specified as Sanitation Standard Operating Procedures (SSOPs). SSOPs are procedures used by food processing firms to help accomplish the overall goal of maintaining GMPs in the production of food. Typically, SSOPs describe a particular set of objectives associated with sanitary handling of food and the cleanliness of the plant environment and the activities conducted to meet them.

When SSOPs are well-designed and fully and effectively implemented, they are valuable in controlling hazards. Identification of critical control points may be influenced by the effectiveness of a GMP program, including industry SSOPs. For example, SSOPs can help control bacterial hazards by specifying procedures to: 1) avoid product cross-contamination by proper product flow and limiting employee tasks and movement; 2) locate handwashing and sanitizing stations near the processing area to facilitate proper handwashing; 3) ensure appropriate equipment maintenance and cleaning and sanitizing procedures. SSOPs can likewise be used to help control chemical contamination from sanitizer and other chemicals found in food processing operations.

In some situations, SSOPs may reduce the number of critical control points in HACCP plans. Relegating control of a hazard to SSOPs rather than the HACCP plan does not minimize its importance or indicate lower priority. In fact, hazards are typically controlled effectively by a combination of SSOPs and HACCP critical control points. For instance, plant sanitation, employee hygiene and strict handling procedures are often as important for controlling *Listeria monocytogenes* in cooked food operations as the actual cooking and refrigeration steps that might be identified as critical control points in HACCP plans.

When SSOPs are in place, HACCP can be more effective because it can concentrate on the hazards associated with the food or processing and not on the processing plant environment. If sanitation controls are included as part of a HACCP plan, they must lend themselves to all aspects of a critical control point (CCP) such as establishing critical limits, monitoring, corrective actions, verification and record-keeping procedures.

A Clean-in-Place (CIP) system for equipment is a good example of sanitation controls that could be handled as a CCP within a HACCP plan. A CIP system's effectiveness can be monitored, critical control points can be established, monitoring records can be maintained, and appropriate corrective actions can be established when the critical limits are not met. On the other hand, a processor's pest-control program should be included in its SSOP rather than its HACCP plan.

Even without HACCP, the level of plant sanitation and GMPs must comply with the law. Contrary to popular perception, sanitation control is not limited to cleaning equipment. Although clean equipment and a clean working area are essential for producing safe foods, so are personnel

practices, plant facilities, pest control, warehouse practices, and equipment and operation design. Each should be addressed in a complete written sanitation program designed to comply with existing regulations. An important component in any sanitation program is monitoring. Methods for monitoring sanitation practices will vary according to the type and size of a food-processing operation. Typically, a checklist can be used to record conditions and sanitation procedures. The frequency of checks will vary to assure the SSOPs remain in control. For example, in certain processing plants, the safety of the processing water may be checked annually. However, the location of other plants may require more frequent inspection. Grounds around a plant may require monthly checks to discourage attraction of pests, but cooler-storage areas and floor drains may need daily inspection. Multiple daily checks would be important for work surfaces, hand-wash stations and employee attire. FDA's HACCP regulations require records to cover at least eight key sanitation concerns.

Overhead 4

Eight key sanitation conditions and practices:
- Safety of water
- Condition and cleanliness of food-contact surfaces
- Prevention of cross-contamination
- Maintenance of hand-washing, hand-sanitizing and toilet facilities
- Protection from adulterants
- Labeling, storage and use of toxic compounds
- Employee health conditions
- Exclusion of pests

Most importantly, any correction necessary to maintain control of the SSOPs should also be documented so that it can accompany or be referenced to any noted problem. This corrective action is part of the SSOP records. An example of an SSOP checklist is given in Chapter 4.

- ***Examples of Common Prerequisite Programs***

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This had traditionally been accomplished through the application of GMPs. These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. Common prerequisite programs may include but are not limited to:

Continued

Notes:

Notes:

- **Facilities:** There may be specific state or local code requirements for food handling or processing establishments in your area that specify where your operation should be located, and how it is constructed and maintained. You may also need to obtain specific permits or licenses from state or local authorities.
- **Production Equipment:** All equipment should be constructed and installed according to established sanitary design principles, manufacturer recommendations, and any state or local codes. Preventive maintenance and calibration schedules should be established and documented using manufacturer and other information as appropriate.
- **Standard Operating Procedures:** Procedures that describe how routine operations such as receiving, storage, labeling, shipping, etc. are to be conducted may need to be established to ensure that products and packaging materials are handled and processed appropriately to ensure their safety and wholesomeness.
- **Supplier Controls:** You may need to establish controls to ensure that you suppliers have effective GMP, HACCP, or other food-safety programs in place.
- **Production Specification:** You may need to develop written specifications for all ingredients, products and packaging material and send them to your suppliers. These specifications may include quality requirements, acceptable portion sizes, or other requirements not related to safety.
- **Personnel Policies:** Policies and procedures for employees and other persons who enter the manufacturing plant should be established. These policies may cover a variety of things related to employee behavior and performance and could include training requirements for GMPs, sanitation procedures, personal safety, HACCP, etc.
- **Traceability and Recalls:** Procedures that ensure that raw material and finished products are coded and labeled properly and meet the require ments of all appropriate federal, state, and local food labeling and/or weights and measures regulations. A recall system should also be in place so that rapid and complete traces and recalls can be done when product retrieval is necessary.

Other examples of prerequisite programs might include quality-assurance procedures, standard processing procedures, and product formulations and recipes.

Preliminary Steps in Developing a HACCP Plan

HACCP is often thought of in terms of its seven basic principles. However, it also includes preliminary steps. Failure to properly address the preliminary steps may lead to ineffective design, implementation and management of the HACCP plan.

In preparation for developing a HACCP plan, a firm must have a solid foundation.

Overhead 5

Preliminary Steps
- HACCP team assembly,
- Description, food and distribution
- Identify intended use and consumers of food
- Develop flow diagram
- Verify flow diagram

Notes:

- ***HACCP Team Assembly***

Assembling a HACCP team is an important step in building a HACCP program. The team should consist of individuals with different specialties. The team may include personnel from maintenance, production, sanitation, quality control and laboratory. The HACCP team should include members who are directly involved with the plant's daily operations.

The team develops the HACCP plan, writes SSOPs, and verifies and implements the HACCP system. The team should be knowledgeable about food-safety hazards and HACCP principles. When issues arise that cannot be resolved internally, it may be necessary to enlist outside expertise.

Although one person may be able to analyze hazards and develop a HACCP plan successfully, many industries find it helpful to build a HACCP team. When only one person develops the HACCP plan, some key points can be missed or misunderstood in the process. The team approach minimizes risk that key points will be missed or that aspects of the operation will be misunderstood. It also encourages ownership of the plan, builds company involvement and brings in different areas of expertise.

In small companies, the responsibility for writing the HACCP plan may fall to one person. If it is possible to build a HACCP team in a small company, employees knowledgeable of various divisions, including owners, should be members. Universities, cooperative extension, consulting groups, Sea Grant programs, model plans and published guidance can provide additional assistance.

- ***Description and Intended Use of Product***

Once a HACCP team is established, the members first describe the product, the method of distribution, the intended customer (e.g, general public, infants, elderly) and consumer use of the product (e.g., consumed without further cooking, heat-and-serve, cooked).

Example:
Frozen, cooked, ready-to-eat shrimp, distributed and sold frozen, to be used by the general public.

Notes:

In this example, the presence of certain pathogens is likely to be a significant hazard in cooked, ready-to-eat shrimp because the product may not be heated by the consumer. However, growth of the same pathogens is unlikely to be a significant hazard in raw shrimp because it will be cooked by the consumer before consumption.

- ***Development and Verification of the Product's Flow Diagram***

A flow diagram shows in simple block or symbol form the steps required to manufacture and distribute a food product. This step provides an important visual tool that the HACCP team can use to complete the remaining steps of the HACCP plan development. Only a clear, simple, but complete, description of the process is needed.

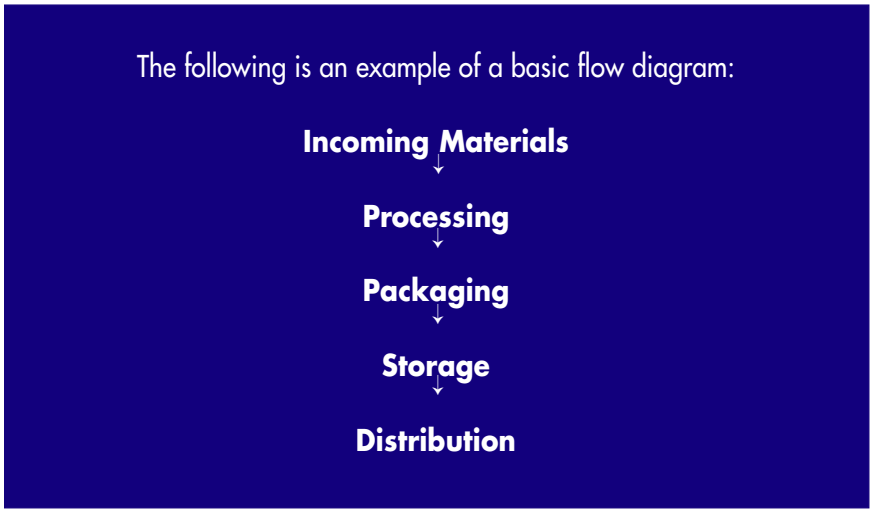
It is important to include all the steps within the facility's control, including receiving and storage steps for all raw materials. The flow diagram should be clear and complete enough so that people unfamiliar with the process can quickly comprehend your processing stages.

Since the accuracy of the flow diagram is critical to conduct a hazard analysis, the steps outlined in the diagram must be verified at the plant. If a step is missed, a significant safety issue may not be addressed.

Overhead 6

Explanatory Note:

This depicts a generic flow diagram. An actual flow diagram needs to be much more detailed.



The HACCP team should walk through the facility and make any changes required in the flow chart. The walk-through allows each team member to gain an overall picture of how the product is made. It may be helpful to invite additional plant personnel to review the diagram during the walk-through.

In addition to the above, experience has shown that the following items need to be addressed in establishing a HACCP system.

Overhead 7

Management Commitment

HACCP Training

- ***Management Commitment***

For a HACCP plan to work, it is extremely important to have the support of top company officials such as the owner, director and chief executive officer. Without it, HACCP will not become a company priority or be effectively implemented.

- ***HACCP Training***

Education and training are important elements in developing and implementing a HACCP program. Employees who will be responsible for the HACCP program must be adequately trained in its principles. This course is designed to meet that need.

Notes:

Notes:

Chapter 4: Commercial Processing Example: IQF Cooked Shrimp

To facilitate our discussion of HACCP, we are introducing the ABC Shrimp Co. With this fictitious company as a base, we will discuss and illustrate the evolution of a HACCP plan for cooked shrimp. Keep in mind that the HACCP plan developed for ABC Shrimp Co. is primarily intended to demonstrate the procedures used in plan development. **Since HACCP plans are very product, process and plant specific, ABC Shrimp Co.'s plan may not be suitable for firms actually processing cooked shrimp.**

Processing Narratives

Processing narratives can help explain the current processing steps needed to produce a product covered by a particular HACCP plan. They offer a historical, working reference for the processor and facilitate communication with the staff and inspectors. For these reasons, a written narrative should accompany a HACCP plan. The narrative should be supported with a basic processing flow diagram (Figure 1).

IQF Cooked Shrimp Processing Narrative

Company: *ABC Shrimp Co.*

Final Product: *IQF cooked, headless, peeled and deveined shrimp*

Intended Use: *Consumption by general public*

Procedures/Steps:

INCOMING MATERIALS

- Frozen, raw shrimp is received in block form from international and domestic sources. The standard block is 5 lbs. (2.27 kg) in a polybag packed with eight to 10 blocks to the master container. Depending on production requirements, product size (count of individual shrimp) can range from less than 15 to more than 500 per pound. The shrimp are received shell-on. Following acceptance, the frozen, raw shrimp are assigned an individual storage lot number and placed in frozen inventory. Buying specifications for all frozen shrimp state that they must not contain any sulfite residual. Furthermore, a supplier certification must accompany each shipment attesting to the absence of sulfites.
- Fresh, raw shrimp are purchased directly from local boats. The shrimp are headed at sea and are often treated with sulfiting agents (i.e., sodium bisulfite and/or sodium metabisulfite dips) to inhibit black spot formation (melanosis). Shrimp/ice mixtures from the boats are emptied into tanks containing potable water. The shrimp are placed in plastic totes for fresh ice and refrigeration. Ice is refreshed daily by topping the totes.
- Packaging materials are delivered in clean, well-maintained and covered vehicles. All materials are checked for integrity and order specifications. Then they are assigned lot numbers and placed into a dry-storage warehouse/room.

Continued

Notes:

Explanatory Note:

Prior use of sulfiting agents to retard melanosis can be determined with rapid test kits that use simple color changes to detect sulfite residual on the edible meat. These tests can be used to monitor for various sulfiting agents.

Notes:

PROCESSING

- The thawing process for the block frozen shrimp uses potable water in a thaw tank maintained at 50 F to 65 F. The tank water is circulated with aeration and through worker stirring. The frozen blocks are removed from the master case, opened and placed in the thaw tank. As blocks rotate through the tank, workers remove any foreign debris. The thawed shrimp are conveyed from the tank directly to a size grader.
- The size grader mechanically sizes the shrimp by passing them over a series of inclined rollers set to segragate individual shrimp by differences in width and/or bulk. As the shrimp cascade through the rollers, the various sizes are diverted by chutes into baskets. The various sizes are placed in separate totes for icing. These totes are rolled to the peeling room.
- The firm's peeling procedure uses a mechanical process. The shrimp are conveyed onto a series of inclined spinning rollers where the shell of the shrimp is cracked/split and peeled. As the shrimp pass down the rollers, they move through a series of cleaning sluices that lead to the deveining process.
- The deveining process occurs on a razor slide set at approximately 45 degrees. The razor edges are set to cut the shrimp, exposing the vein as they slide toward the tumbler/deveiner.
- The tumbler/deveiner is a large cylinder with interior ridges or flanges that tumble the product and pull the exposed vein from the razor-cut shrimp. The deveined shrimp are conveyed to a culling table.
- Workers on either side of the conveyor/cull table will remove defective product (i.e., broken shrimp, pieces, unpeeled or undeveined shrimp, blackspot, crushed material). The properly sized, peeled, deveined, and culled material is iced in totes before being returned to cold storage.
- Before cooking, the cold product is deiced. The raw shrimp will then pass through a steam injection cooker. The cooker is equipped with an auger to tumble the shrimp, ensuring a thorough, uniform cook. The cook time and temperature is based on a pre-established schedule.
- As cooked shrimp exit the cooker, they fall into a shuffler that moves the product toward a final cull table. At the same time, the shuffler exposes the shrimp to a cold-water spray to stabilize and cool the product.

- The final cull table is a conveyer leading to the spiral freezing unit. Workers on either side of the table remove defective product (i.e., clumps, pieces, mutilated material, blackspot, improperly peeled shrimp) before it enters the freezer.
- The spiral freezer is a continuous freezing process based on product exposure to air cooled by standard ammonia refrigeration. As the frozen shrimp exit the freezer, they are conveyed immediately to the glazing station.
- The glazing operation consists of a stainless steel table equipped with an adjustable water spray to impart a uniform frozen-water glaze.

PACKAGING

- Following freezing and glazing, the finished product is conveyed to the weigh/pack/and label station. At this point, a computerized system weighs the correct amount of product and bags it in prelabeled bagging material. Each primary container will be identified by the production date code and lot number.
- Following weigh/pack/label, all primary containers or packages are mastercased as required by the customer or the company. Each mastercase is marked with identical production date codes and lot numbers as used on the primary containers or packages. As each mastercase is packed, it is palletized immediately in accordance with customer or company criterion. Once a pallet load is completed, it is conveyed to the storage freezer.

STORAGE

- All finished product is placed into frozen storage without delay. All product is stored on a first-in, first-out basis.

MODEL SANITATION STANDARD OPERATING PROCEDURES (SSOP)

In addition to a processing narrative, it is strongly recommended that seafood firms should have written sanitation standard operating procedures (SSOPs). The following model SSOP addresses the sanitation concerns for the fictional shrimp company, the ABC Shrimp Co. (Table 1). This SSOP model is organized to address the eight key sanitation conditions specified by FDA's seafood HACCP regulation for mandated sanitation control procedures.

Continued

Notes:

Instructor's Notes:

Example of a Process Flow Diagram for ABC Shrimp Co.

Figure 1. **Basic processing flow diagram**

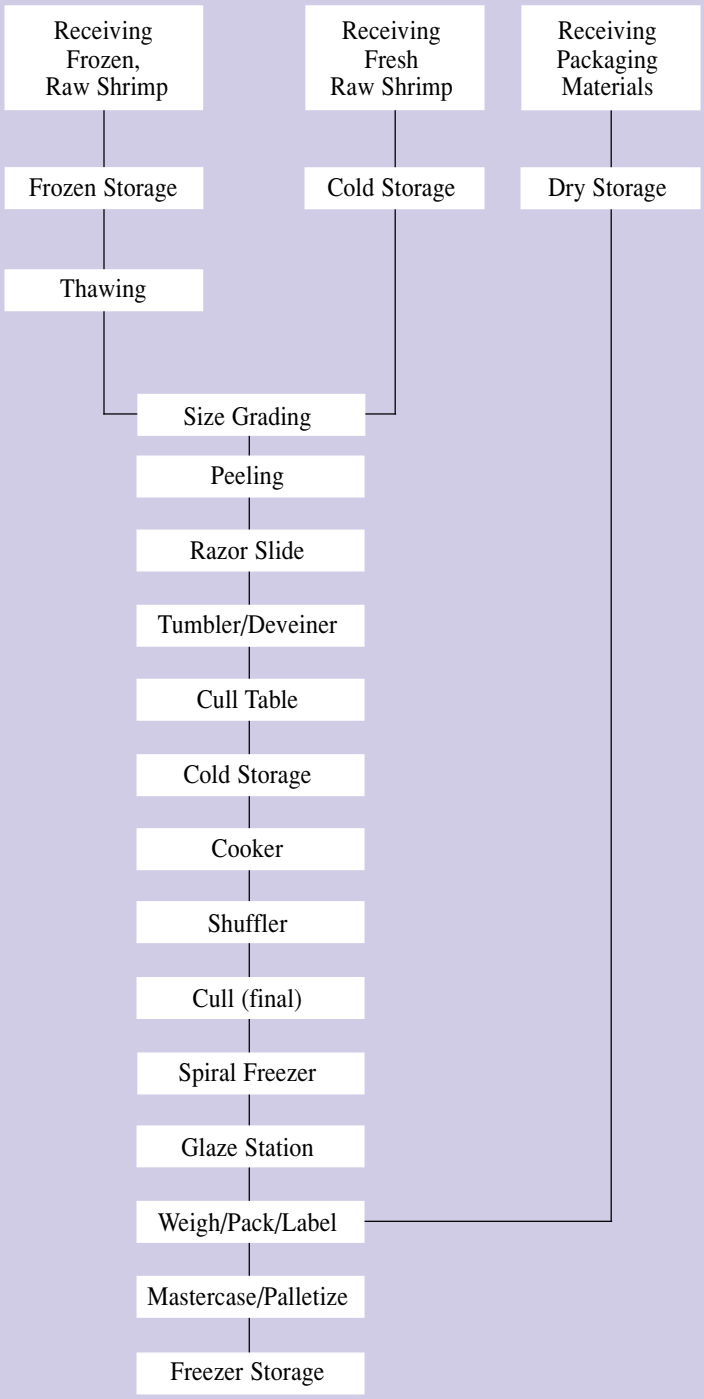


Table 1. Model SSOP Plan

Sanitation Standard Operating Procedure

1. Safety of Processing Water and Ice (FDA Key Sanitation Condition No. 1)

Controls and Monitoring:

a. All water used in the plant is from a reliable municipal water system. Municipal water bills indicate that the water source is safe. **Monitoring Frequency: Annually.**

b. The water system in the plant was designed and installed by a licensed plumbing contractor, and meets current community building codes. All modifications to the plumbing system will be completed by a licensed plumbing contractor and will be inspected to ensure conformance with local building codes. Copies of building inspection reports indicate that the plumbing system is properly constructed. **Frequency: When plumbing is installed or modified.**

c. All water faucets and fixtures inside and outside the plant have antisiphoning devices installed. Water faucets and fixtures are inspected for the presence of antisiphoning devices. **Monitoring Frequency: Daily before processing.**

Corrections:

a. In the event of municipal water treatment failure, the plant will stop production, determine when the failure occurred, and hold produ cts produced during the failure until product safety can be assured. Production will resume only when water meets state and federal water quality standards.

b. Corrections will be made to the plumbing system, if necessary, to correct problems. Production will resume only when water meets state and federal water quality standards.

c. Water faucets and fixtures without antisiphoning devices will not be used until antisiphoning devices have been installed.

Records:

a. Municipal water bill and periodic sanitation record.

b. Building plumbing inspection report and periodic sanitation record.

c. Daily Sanitation Control Record

2. Condition and Cleanliness of Food Contact Surfaces, Including Utensils, Gloves, and Outer Garments (FDA Key Sanitation Condition No. 2)

Controls and Monitoring:

a. Food contact surfaces are adequately cleanable (do not have cracks, cavities, crevices, overlapping joints, mineral scale, etc. that are not possible to adequately clean and sanitize). The sanitation supervisor inspects food-contact surfaces to determine if they are adequately cleanable.
Monitoring Frequency: Daily

b. Food-contact surfaces are cleaned and sanitized:

1) Before operations begin, food-contact surfaces are rinsed with cold water and sanitized with a 100 ppm sodium hypochlorite sanitizer. The sanitation supervisor inspects food-contact surfaces to determine if they are sanitized. **Monitoring Frequency: Before operations begin.**

2) During breaks, major solids are physically removed from floors, equipment, and food-contact surfaces. All surfaces are rinsed with cold water. Equipment and food-contact surfaces are scrubbed, using brushes with a chlorinated alkaline cleaner in warm (120ºF) water. All surfaces and floors are rinsed with cold water. Check sanitizers and food contact surfaces. Food contact surfaces are sani tized with a 100 ppm sodium hypochlorite sanitizer solution. Floors are sanitized with a 400 ppm quaternary ammonium chloride sanitizer. Utensils are cleaned in a deep sink with a chlorinated alkaline cleaner, rinsed in hot water (190ºF), soaked in a 100 ppm sodium hypochlorite sanitizer for at least 10 minutes, and rinsed in hot water (190ºF) prior to use. The sanitation supervisor checks sanitizers before use and inspects food-contact surfaces to determine if they are clean and sanitized. **Monitoring Frequency: At the 4 and 8-hour breaks.**

3) At the end of daily operations, major solids are physically removed from floors, equipment, and food contact surfaces. Equipment is disassembled as required for adequate cleaning. All surfaces are rinsed with cold water. Equipment and food-contact surfaces are scrubbed using brushes with a chlorinated alkaline cleaner in warm (120ºF) water. All surfaces and floors are rinsed with cold water. Floors and walls are sprayed with a 400 ppm quaternary ammonium chloride sanitizer solu tion. Utensils are cleaned in a deep sink with a chlorinated alkaline cleaner in warm (120ºF) water, rinsed in hot water (190ºF), soaked in a 100 ppm sodium hypochlorite sanitizer for at least 10 minutes, and air dried. The sanitation supervisor inspects food-contact surfaces to determine if they are clean and sanitized. **Monitoring Frequency: At the end of operations.**

c. Workers wear clean gloves and outer garments.

1) Workers working with raw and cooked product wear clean gloves, clean outer garments, waterproof aprons, and waterproof boots. Waterproof aprons are cleaned and sanitized twice each day, at the midday break and at the end of the shift.

2) Administrative personnel wear smocks and waterproof boots when in processing areas. Smocks are laundered in-house as needed.

3) Maintenance workers wear gray uniforms and waterproof boots. Uniforms are laundered in house as needed.

4) Production supervisors monitor the use of gloves and the cleanliness of workers' outer garments. **Monitoring Frequency: Before operations and after each break.**

Corrections:

a. Food-contact surfaces that are not adequately cleanable are repaired or replaced.

b. Adjust sanitizer concentration. Food-contact surfaces that are not clean are cleaned and sanitized.

c. Gloves that become a potential source of contamination are cleaned and sanitized or replaced. Outer garments that become a potential source of contamination are cleaned and sanitized or replaced.

Records:

a-c. Daily Sanitation Control Record

3. Prevention of Cross-Contamination (FDA Key Sanitation Condition No. 3)

Controls and Monitoring:

a. Production supervisors have received basic food sanitation training. Plant manager schedules basic food sanitation courses for new production supervisors. **Monitoring Frequency: When production supervisors are hired.**

b. Employee practices do not result in food contamination (hair restraints, glove use, hand washing, personal belonging storage, eating and drinking, boot sanitizing).

1) Workers wear hairnets, headbands, caps, beard covers, or other effective hair restraints and do not wear jewelry or other objects that might fall into the product, equipment, or containers.

2) Workers wear disposable gloves and replace them as needed.

3) Workers wash their hands and gloves thoroughly and sanitize them before starting work, after each absence from their workstation, and anytime they have become soiled or contaminated.

4) Clothing and personal belongings are not stored in production areas.

5) Workers do not eat food, chew gum, drink beverages, or use tobacco in production areas.

6) Workers wear color-coded aprons (blue in raw product areas and white in cooked product areas) and are not allowed to enter or pass through other processing areas.

7) Workers sanitize their boots in boot baths containing 800-ppm quaternary ammonium chloride sanitizer solution before entering processing areas.

8) Production supervisors monitor employee practices. **Monitoring Frequency: Before operations and every four hours during production.**

c. Boot sanitizing solutions are checked every four hours during production. Sanitation supervisor checks boot sanitizing solutions. **Monitoring Frequency: Before operations and every four hours during production.**

d. Plant grounds are in a condition that protects against contamination of food. Sanitation supervisor inspects plant grounds. **Monitoring Frequency: Daily before operations.**

e. Waste is removed from processing areas during production. Sanitation supervisor monitors removal of waste. **Monitoring Frequency: Every 4 hours.**

f. Floors are sloped to facilitate drainage. Processing area floors are inspected for adequate drainage. **Monitoring Frequency: Daily before operations.**

g. Plant buildings are maintained in good repair. Raw-product processing and cooked-product processing areas are separated. Coolers, including the evaporators, are cleaned annually, or more often if needed. Nonfood-contact surfaces in processing and packaging areas are cleaned daily at the end of the shift. Raw and cooked products are physically separated in coolers. Packaging materials are protected from contamination during storage. Sanitation supervisor inspects plant. **Monitoring Frequency: Daily before operations.**

h. Cleaning and sanitizing equipment is color-coded for specific plant areas: blue for raw-product processing areas, white for cooked-product processing areas, and yellow for toilet facilities and general plant cleaning. Sanitation supervisor observes that proper equipment is used. **Monitoring Frequency: At each cleanup period.**

Corrections:

a. New production supervisors receive basic sanitation instruction.

b. Workers correct deficiencies in hair restraint use, jewelry use, glove use, hand washing, personal belonging storage, eating and drinking in processing areas, and boot sanitizing before working with raw or cooked products.

c. Boot sanitizing solution is changed.

d. Sanitation supervisor initiates correction of potentially contaminating condition.

e. Waste is removed.

f. Floors with standing water will have the drains unplugged, or, if necessary, consultations will be held with plumbing or general contractors and corrections will be made to correct floor drainage problems.

g. Sanitation supervisor initiates correction of potentially contaminating condition, including assessment of product quality.

h. Sanitation equipment that is being used in the wrong plant area is cleaned and sanitized and exchanged for correct equipment. Sanitation supervisor initiates correction of potentially contaminating condition.

Records:

a. Periodic Sanitation Control Record or training record

b-h. Daily Sanitation Control Record

4. Hand Washing/Sanitizing, and Toilet Facilities (FDA Key Sanitation Condition No. 4)

Controls and Monitoring:

a. Toilet facilities are provided off the workers' dressing room, physically separated from processing areas. Toilet facilities have self-closing doors, are maintained in good repair, and are cleaned and sanitized daily at the end of operations. Sanitation supervisor inspects the toilet facilities and hand washing facilities. **Monitoring Frequency: Daily before operations and every 4 hours during operations.**

b. Handwashing/sanitizing facilities are provided in raw and cooked processing areas and in the toilet facility. Hand washing facilities have: hot and cold running water with foot activated valves; liquid sanitizing hand soap; hand sanitizer solutions that are changed every 4 hours during production; sanitary towel service; signs directing workers to wash their hands and gloves thoroughly. Hands should be washed and sanitized before starting work, after each absence from their workstation, and anytime they have become soiled or contaminated. Sanitation supervisor inspects the hand washing facilities and checks hand sanitizer strength. **Monitoring Frequency: Daily before operations and every 4 hours during operations**.

Corrections:

a. Sanitation supervisor initiates cleaning of dirty toilet facilities and correction of any potentially contaminating condition. Repairs are made as needed.

b. Sanitation supervisor restocks facilities or adjusts sanitizers.

Records:

a-b. Daily Sanitation Control Record

5. Protection of Food, Food-Packaging Material, and Food-Contact Surfaces from Adulteration

(FDA Key Sanitation Condition No. 5)

Controls and Monitoring:

a. Cleaning compounds, sanitizers, and lubricants used in processing and packaging areas are approved for use in food plants. Receiving manager checks invoices at receiving before food-grade chemicals are stored. **Monitoring Frequency: When cleaning compounds, sanitizers, and lubricants are received.**

b. Food-grade and nonfood-grade chemicals and lubricants are stored separately outside processing and packaging areas. Sanitation supervisor inspects chemical storage areas. **Monitoring Frequency: Daily before operations.**

c. Food, food-packaging materials and food-contact surfaces are protected from adulteration from biological, chemical and physical contaminants. Safety-type light fixtures are used in processing and packaging areas. Sanitation supervisor inspects processing and packaging areas. **Monitoring Frequency: Daily before operations and every 4 hours.**

d. Equipment is in good repair with no loose or missing metal parts. Sanitation supervisor inspects processing and packaging equipment. **Monitoring Frequency: Daily before operations.**

e. Drip or condensate does not contaminate food or packaging materials. **Monitoring Frequency: Pre-op and at 4 and 8-hour breaks.**

Corrections:

a. Unapproved chemicals are returned or used in nonprocessing areas.

b. Improperly stored chemicals are moved to the correct storage area.

c. Safety of the product is examined.

d. Repairs are made as needed.

e. Sanitation supervisor corrects any condensation problems.

Records:

a. Periodic Sanitation Control Record

b-c. Daily Sanitation Control Record

6. Labeling, Storage, and Use of Toxic Compounds (FDA Key Sanitation Condition No. 6)

Controls and Monitoring:

a. All toxic compounds used in the plant are labeled with the manufacturer's name, use instructions, and the appropriate EPA approval, or have documentation with the necessary information. Receiving manager verifies that this information is present before toxic compounds are stored. **Monitoring Frequency: When toxic compounds are received.**

b. Cleaning compounds, sanitizing agents, lubricants, pesticide chemicals, and other toxic compounds are properly labeled and stored in a closed and locked cage in dry storage outside processing and packag ing areas and separately from food-grade chemical, food-grade lubricant, and packaging material storage. Only authorized personnel have access to the cage. Sanitation supervisor checks cage for cleanliness and container leakage. **Monitoring Frequency: Daily before operations.**

c. All manufacturers' instructions and recommendations are followed. Only authorized personnel fill small working containers, such as containers of hand sanitizing compounds. These containers are properly marked with the common name of the chemical and are not stored in any way that may cause the chemical to fall or drip onto food or food-packaging materials. Sanitation supervisor verifies proper procedures and labeling. **Monitoring Frequency: Daily before operations.**

Corrections:

a. Toxic compounds without proper information are placed on hold until information is obtained. Toxic compounds without documentation are returned to the supplier.

b. Improperly stored chemicals are moved to the correct storage area. Leaking containers are resealed or replaced as necessary. Storage cage will be cleaned by the next working day.

c. Misuse of toxic compounds results in disciplinary action or retraining. Potentially contaminated food is discarded or destroyed. Improper labeling of working containers is corrected.

Records:

a. Periodic Sanitation Control Record

b-c. Daily Sanitation Control Record

7. Employee Health (FDA Key Sanitation Condition No. 7)

Controls and Monitoring:

a. Workers report to their immediate supervisor any health condition that might result in food contamination. Supervisors report suspected health problems to the plant manager. The plant manager decides if a potential food contamination situation exists. **Monitoring Frequency: Daily before operations.**

b. Supervisors check for infected lesions that might contaminate food. **Monitoring Frequency: Daily before operations.**

Corrections:

a. Workers who represent a potential risk are sent home or reassigned to non-food-contact jobs.

b. Cover lesion with impermeable bandage, reassign, or send worker home.

Records:

a-b. Daily Sanitation Control Record

8. Pests (FDA Key Sanitation Condition No. 8)

Controls and Monitoring:

a. A pest management firm treats the outside of the building. They also inspect the interior of the building and treat as necessary with appropriate chemicals. **Monitoring Frequency: Every other month.**

b. Plant grounds and interior areas are kept free of litter, waste, and other conditions that might attract pests. Outer plant doors are kept closed, processing areas are screened with plastic curtains, and electric bug-killing devices are located outside entrances to processing areas. No pets are allowed in the plant. Supervisors report any pest problems to the plant manager. The sanitation supervisor inspects for the presence of pests. **Monitoring Frequency: Daily before operations.**

Corrections:

a. Conditions that may cause pest problems are corrected.

b. The pest management firm is notified of any pest problem and treats the problem. Pest treatments are more frequent if problems are identified.

Records:

a. Periodic Sanitation Control Record

b. Daily Sanitation Control Record

Table 2.

Daily Sanitation Control Record	Date:			
Firm:	Mark S/U			
Address:				
Products being processed: (?)	Pre-Op	4-Hour	8-Hour	Post-Op
Condition	Time:	Time:	Time:	Time:
1. Safety of Water and Ice:				
c. Water faucets and fixtures have anti-siphoning devices.				
2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments:				
a. Equipment and utensils are adequately cleanable.				
b. Sanitation strength (ppm)/food contact surfaces and utensils are clean and sanitized.				
c. Gloves/garments contacting food are clean and sanitary.				
3. Prevention of cross-contamination:				
b. Employee practices do not result in food contamination (hair restraints, glove use, hand washing, personal belonging storage, eating and drinking, boot sanitizing).				
c. Boot sanitizer strength is adequate (ppm).				
d. Plant grounds are in good condition.				
e. Waste is removed from processing areas.				
f. Floors have adequate drainage.				
g. Plant buildings in good repair.				
Raw and cooked-product processing areas separated.				
No drip over food or packaging materials.				
Safety-type lighting used.				
Coolers and evaporators are clean.				
Nonfood-contact surfaces are clean.				
Cooked and raw products physically separated in coolers.				
Packaging materials protected from contaminants.				
h. Proper color-coded sanitation equipment is used.				

Table 2. (Continued)

Daily Sanitation Control Record	Date:			
Firm:	Mark S/U			
Address:				
Products being processed: (?)	Pre-Op	4-Hour	8-Hour	Post-Op
Condition	Time:	Time:	Time:	Time:
4. Hand Washing Sanitizing, and Toilet Facilities:				
a. Toilets facilities are clean, sanitary and in good repair.				
b. Hand sanitizer strength (ppm)/hand washing and sanitizing supplies.				
5. Adulteration:				
b. Food-grade chemicals identified and stored properly.				
c. Food, food-packaging materials and food-contact surfaces are protected from adulteration.				
d. Equipment is in good repair.				
e. Drip and surface condensate.				
6. Toxic compounds:				
b. Toxic compounds identified and stored properly.				
c. Proper containers and procedures are used.				
7. Employee Health:				
a. Employee health conditions are acceptable.				
b. Employees do not have infected lesions.				
8. Pests:				
a. No pests in plant.				
Comments & Corrections:				
Report by:				
S = Satisfactory / U = Unsatisfactory.				

Table 3.

Periodic Sanitation Control Record	Date:		
Firm Name: **Firm Address:**			
Condition	**S**	**U**	**Comments/Corrections**
1. Safety of Water and Ice:			
a. Municipal water bill (annually).			
b. Building plumbing inspection report (when plumbing is modified).			
3. Prevention of cross-contamination:			
a. Production supervisors have received basic food sanitation training (when hired).			**Name(s)**
5. Adulteration:			
a. Invoices for food-grade chemicals checked before chemicals are stored (when received).			
6. Toxic compounds:			
a. Labels or documents for toxic compounds checked before compounds stored (when received).			
8. Pests:			
a. Pest management firm's report is satisfactory (every other month).			
Comments and Corrections:			
Report by: S = Satisfactory / U = Satisfactory			

Notes:

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.
- Likekihood 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.

Continued

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).

Notes:

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.

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.

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

Continued

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.

Continued

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 *Salmonella*.	A cook step follows that assumes a high bacterial load.	
	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.				
	CHEMICAL Sulfiting agent	Yes	Sulfiting agents may cause an allergic-type reaction.	Labeling control based on product screening.	
	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.				
	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	BIOLOGICAL Bacterial pathogens CHEMICAL Sulfiting agent PHYSICAL None	Yes Yes	Frozen seafoods can be natural reservoirs for marine vibrios and, depending on the quality of the harvest, can harbor terrestrial pathogens such as *Salmonella*. Sulfiting agents may cause an allergic-type reaction.	A cook step follows that assumes a high bacterial load. Labeling control based on supplier declaration.	
Frozen Storage	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Receiving Packaging Material	BIOLOGICAL Bacterial pathogen contamination CHEMICAL Chemical contaminants PHYSICAL None	No No	Not likely to occur • Not likely to occur • No history of occurrence		
Dry Storage	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Thawing	BIOLOGICAL • Bacterial pathogen growth • Bacterial pathogen contamination CHEMICAL None PHYSICAL None	Yes No	If not properly controlled, bacterial pathogens can grow during thawing. Controlled by SSOP	A cook step follows that assumes a high bacterial load.	

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	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur because of the continuous process.		
	• Bacterial pathogen contamination	No	Controlled by SSOP		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Peeling	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Razor Slide	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL Metal fragments	No	Subsequent processing removes any fragments. No historical problem.		
Tumbler/Deveiner	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cull Table	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				

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	No	Controlled by SSOP		
	PHYSICAL None				
Cooker	BIOLOGICAL Bacterial pathogen survival	Yes	Without proper processing time and temperature, bacterial pathogens such as *Listeria monocytogenes*, *Salmonella* spp. and *Vibrio* spp. may survive.	Adequate cooking time and temperature	
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Shuffler	BIOLOGICAL • Recontamination with bacterial pathogens	No	Controlled by SSOP		
	Note: Companies that DO NOT have SSOPs in place would need to control post-processing contamination with appropriate HACCP sanitation CCPs.				
	• Bacterial pathogen growth	No	Not likely to occur because of the continuous process		
	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.				
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cull	BIOLOGICAL • Recontamination with bacterial pathogens	No	Controlled by SSOP		
	• Bacterial pathogen growth	No	(See remarks for shuffler)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None identified				
Spiral Freezer	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur due to rapid freezing rate		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None identified				

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	BIOLOGICAL • Recontamination with bacterial pathogens	No	Use potable water and equipment cleaned per SSOP.		
	• Bacterial pathogen growth	No	(See shuffler)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Weigh/Pack/Label	BIOLOGICAL • Recontamination with bacterial pathogens	No	(See shuffler)		
	• Bacterial pathogen growth	No	(See shuffler)		
	CHEMICAL Sulfiting agent	Yes	Potential allergic-type reaction (accurate label declaration)	Accurate label declaration	
	Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None identified				
Mastercase/Palletize	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur because frozen		
	CHEMICAL None				
	PHYSICAL None				
Freezer Storage	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur because frozen		
	CHEMICAL None				
	PHYSICAL None				

Chapter 6: **Principle 2:** Determine the Critical Control Points

Notes:

Overhead 1

Objective:
In this module, you will learn:
- The definition of a critical control point (CCP).
- The relationship between a significant hazard and a CCP.
- A CCP may change for product formulations and processing lines.
- The use of a decision tree to select a CCP.
- Examples of CCPs.

For every significant hazard identified during the hazard analysis (Principle 1), there must be one or more CCPs where the hazard is controlled. The CCPs are the points in the process where the HACCP control activities will occur.

Overhead 2

Definition:
Critical Control Point: 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.

A CCP should be a specific point in the process flow where application of a control measure effectively prevents, eliminates or reduces the hazard to an acceptable level.

Overhead 3

Points may be identified as CCPs when hazards can be prevented.

In some products and processes, the following may be true:
- Introduction of pathogens or drug residue can be prevented by control at the receiving step (e.g., supplier declaration).
- A chemical hazard can be prevented by control at the formulation or ingredient-addition step.
- Pathogen growth in the finished product can be prevented by control at the formulation or ingredient-addition step (e.g., pH adjustment or addition of preservatives).
- Pathogen growth can be controlled by refrigerated storage or chilling.

Continued

Notes:

Overhead 4

Points may be identified as CCPs when hazards can be eliminated.

In some products and processes, the following may be true:
- Pathogens can be killed during cooking.
- Metal fragments can be detected by a metal detector and eliminated by removing the contaminated product from the processing line.
- Parasites can be killed by freezing (e.g., *Anisakis* in fish destined for raw consumption).

Overhead 5

Points may be identified as CCPs when hazards are reduced to acceptable levels.

In some products and processes, the following may be true:
- The occurrence of foreign objects can be minimized by manual sorting and automatic collectors.
- Some biological and chemical hazards can be minimized by obtaining shellfish from approved waters.

It may not be possible to fully eliminate or prevent a hazard. In some processes and with some hazards, minimization may be the only reasonable goal of the HACCP plan. For example, when producing a product that will be consumed raw or partially cooked, no lethal treatment may exist to eliminate a pathogen hazard or no technology may exist to detect and prevent a chemical or physical hazard. In these cases, it may be necessary to select CCPs that allow significant hazards to be reduced to acceptable levels.

Although hazard minimization is acceptable in some instances, it is important that all food-safety hazards be addressed and that any limitations of the HACCP plan to control those hazards be understood.

Overhead 6

Definition:
Control Point: Any step at which biological, physical or chemical factors can be controlled.

Overhead 7

CCPs vs. Control Points

• ***CCPs vs. Control Points***

Many points in the flow diagram not identified as CCPs may be considered control points. These may address control of quality factors such as color or flavor or non-HACCP regulatory requirements such as standards of fill. A HACCP plan can lose focus if points are unnecessarily identified as CCPs.

Only points at which food-safety hazards can be controlled are considered to be CCPs. A tendency exists to control too much and to designate too many CCPs. A CCP should be limited to that point or those points at which control of the hazards can best be achieved. For example, a metal hazard can be controlled by ingredient sourcing, magnets, screens and a metal detector, all in one line. However, sourcing, magnets and screens would not be considered CCPs if the metal hazard is best controlled by use of metal detection and product rejection.

Overhead 8

Multiple CCPS and Hazards

• ***Multiple CCPs and Hazards***

A CCP can be used to control more than one hazard. For example, refrigerated storage might be a CCP to control pathogen growth and histamine formation. Likewise, more than one CCP may be needed to control a hazard. In controlling pathogens in cooked hamburger patties, the cook and the patty-forming steps could both be identified as CCPs if cooking time is based on a maximum patty thickness.

Continued

Notes:

Explanatory Note:

In some cases, FDA will allow products to be grouped into a single HACCP plan as long as the products have similar hazards and CCPs (critical limits can differ). An example of this is cooked shrimp. Processors can have one plan to cover the different size classes even though the cook time (critical limit) may differ for each size.

Overhead 9

CCPS are Product- and Process-Specific.

They may change with differences in:
- plant layout,
- formulation,
- process flow,
- equipment,
- ingredient selection and
- sanitation and support programs.

• *CCPs are Product- and Process-Specific*

CCPs identified for a product on one processing line may be different for the same product on another line. This is because the hazards and the best points for controlling them may change with differences in:
- plant layout,
- formulation,
- process flow,
- equipment,
- ingredient selection and
- sanitation and support programs.

Although HACCP models and generic HACCP plans can be useful in considering CCPs, the HACCP requirements of each formulation and processing line must be considered separately.

• *CCP Decision Tree*

In Principle One, you learned how to determine where hazards enter a process or may be enhanced during the process. Often the best place to control a hazard is at the point of entry. But this is not always true. The CCP can be several process steps away from the point where the significant hazard is introduced. A series of questions can help to identify CCPs for a process ***(see Figure 1)***. The questions are referred to as a CCP Decision Tree and are asked at each process step identified in Principle 1 with a significant hazard. Properly used, a CCP decision tree can be a helpful tool in identifying CCPs, but it is not a perfect tool. Although application of a CCP decision tree can be useful in determining if a particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of HACCP. The CCP decision tree is not a substitute for expert knowledge, since complete reliance on the decision tree can lead to false conclusions.

The CCP decision tree in Figure 1 is but one example of numerous other decision trees that have been developed to assist in the appropriate determination of CCPs. Appendix IV has another example of a decision tree from the NACMCF.

Question 1. Does a control measure(s) exist at this step or subsequent steps in the process flow for the identified hazard?

If your answer is yes, ask Question 2.

If you cannot identify a control measure in the process for the hazard, answer no. If the answer is no, then ask*:* Is control at this step necessary for safety? If this answer is no too, the step is not a CCP for that hazard. Move to the next hazard at that step or to the next step with a food-safety hazard. If the answer is yes, then you have identified a significant hazard that is not being controlled. In this case, the step, process or product must be redesigned to include a control measure. Sometimes there is no reasonable control measure available. In such cases, HACCP does not provide assurance that food products are safe.

Question 2. Does this step eliminate or reduce the likely occurrence of a significant hazard to an acceptable level?

To answer this question, consider if this is the **best** step at which to control the hazard? If the answer is yes, then the step is a CCP; move to the next food-safety hazard. If the answer is no, ask Question 3.

Question 3. Could contamination with an identified hazard or hazards occur in excess of acceptable levels, or could these increase to unacceptable levels?

The question refers to contamination that exists, occurs or increases at this step. If the answer is no, then the step is not a CCP for that hazard. Move to the next hazard at that step or the next step with a food-safety hazard.

If the answer is yes, then ask the fourth question.

Question 4. Will a subsequent step eliminate the identified hazard or hazards or reduce the likely occurrence to an acceptable level?

If you answer no, then this step is a CCP. If you answer yes, then this step is not a CCP for this hazard. In this case, be sure the hazard is controlled by a subsequent processing step.

In Chapter 5, eight significant hazards were identified for the IQF cooked shrimp. In Table 1, the CCP decision tree is applied for these hazards.

Continued

Instructor's Note:

Appendix IV demonstrates another example of a CCP decision tree.

Explanatory Note:

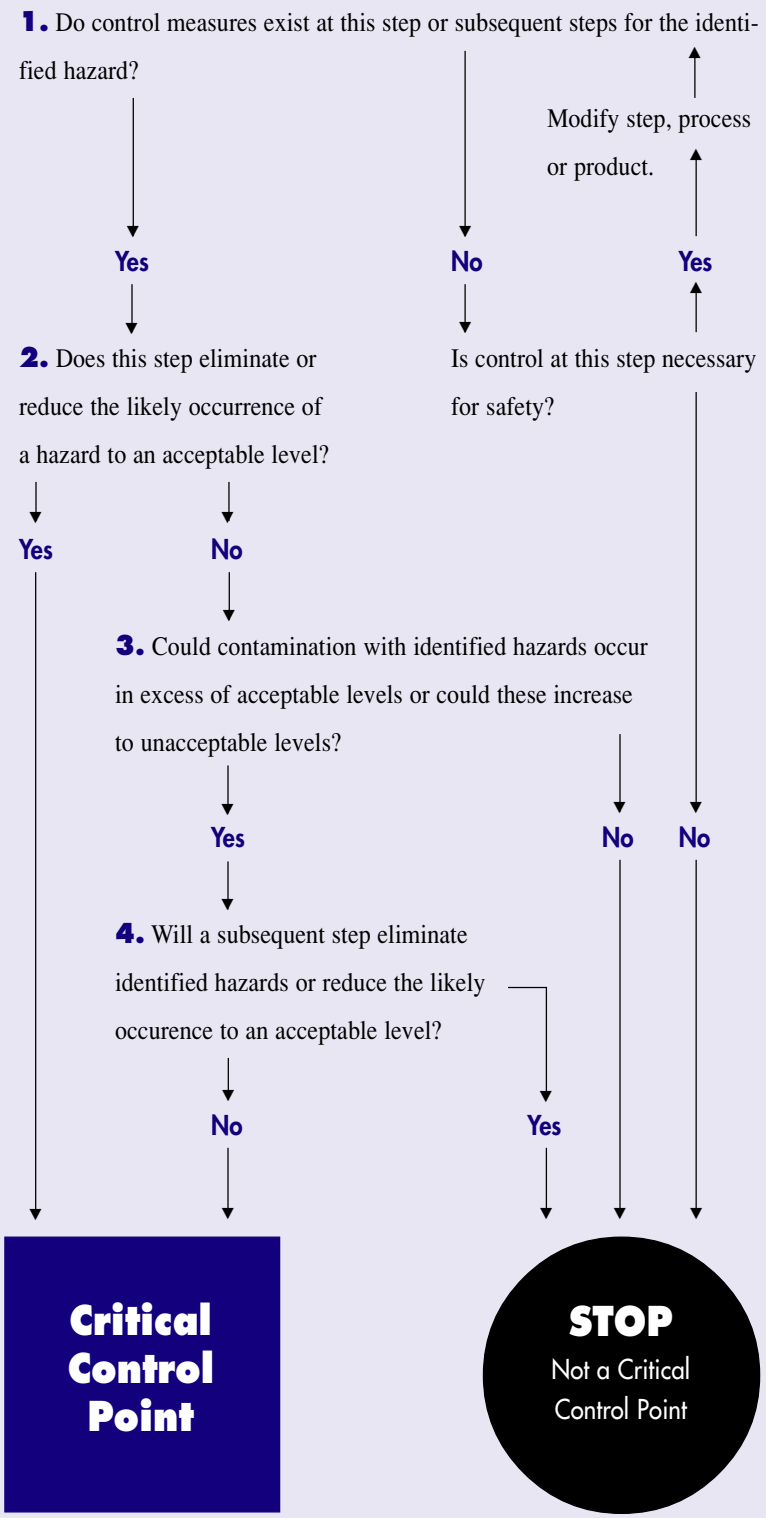
Reintroduce the IQF cooked shrimp example. Use the decision tree to fill in the sixth column in the hazard-analysis worksheet. On this worksheet, we previously noted for receiving of fresh (and frozen) shrimp in column 5 that a subsequent step can be applied to control the hazard of bacterial pathogens on raw shrimp. Thus the answer to Question 1 on the decision tree is yes.

Explanatory Note:

In the IQF cooked-shrimp example, bacterial pathogens were identified as a significant hazard at the receiving-fresh-shrimp step. In some cases, supplier guarantees or raw material handling can minimize pathogen levels at a receiving step. However, those measures are not likely to reduce the hazard of pathogens, such as *Salmonella* or *Listeria*, to acceptable levels in the finished product. Therefore, the receiving step cannot be used in this plant to "eliminate or reduce the likely occurrence of a hazard to an acceptable level." The answer to Question 2 is no.

Overhead 10

Figure 1: CCP Decision Tree Table



Decision Tree adapted from NACMCF.

Overhead 11

Table 1

CCP Decision Tree Table for IQF Cooked Shrimp Example

Process Step/Hazard	Q1	Q2	Q3	Q4	CCP
Receiving Fresh Shrimp: bacterial pathogens	Yes	No	Yes	Yes	No
Receiving Fresh Shrimp: sulfiting agent	Yes	No	Yes	Yes	No
Receiving Frozen Shrimp: bacterial pathogens	Yes	No	Yes	Yes	No
Receiving Frozen Shrimp: sulfiting agent	Yes	No	Yes	Yes	No
Thawing: bacterial pathogens	Yes	No	Yes	Yes	No
Cold Storage: bacterial pathogens	Yes	No	Yes	Yes	No
Cooker: pathogen survival	Yes	Yes	-	-	Yes
Weigh/Pack/Label: sulfiting agent	Yes	Yes	-	-	Yes

Explanatory Note:

In the cooked-shrimp example, pathogenic microorganisms can be introduced at the receiving-fresh-shrimp step in excess of acceptable levels. The answer to Question 3 is yes.

Explanatory Note:

In the cooked-shrimp example, the cook step will reduce pathogen occurrence to an acceptable level and will be the best point to control the hazard. For the receiving-fresh-shrimp step, the answer to Question 4 is yes. The receiving-fresh-shrimp step is, therefore, not a CCP for bacterial pathogens.

Explanatory Note:

Review the answers to the CCP decision-tree questions. Note that once the answers make it clear that a step is or is not a CCP, it is not necessary to continue with the questions for that step (e.g., cooker).

Explanatory Note:

For the hazard due to sulfite residuals in fresh shrimp, the control measure is to screen each lot of product with a rapid sulfite test to determine the presence of any chemical residual in excess of 10 ppm, which requires appropriate product labeling. Similarly, supplier declarations are required to determine any residuals and labeling requirements for frozen shrimp.

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 *Salmonella*.	A cook step follows that assumes a high bacterial load.	No
	Note: If this product is 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.				
	CHEMICAL Sulfiting agent	Yes	Sulfiting agents may cause an allergic-type reaction.	Labeling control based on product screening	No
	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.				
	PHYSICAL None				
Cold Storage	BIOLOGICAL Bacterial pathogen growth CHEMICAL None PHYSICAL None	Yes	Without controlled temperatures, bacterial pathogens may increase in numbers.	A cook step followas 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	BIOLOGICAL Bacterial pathogens	Yes	Frozen seafoods can be natural reservoirs for marine vibrios and, depending on the quality of the harvest, can harbor terrestrial pathogens such as *Salmonella*.	A cook step follows that assumes a high bacterial load.	No
	CHEMICAL Sulfiting agent	Yes	Sulfiting agents may cause an allergic-type reaction.	Labeling control based on supplier declaration	No
	PHYSICAL None				
Frozen Storage	BIOLOGICAL None				
	CHEMICAL None				
	PHYSICAL None				
Receiving Packaging Material	BIOLOGICAL Bacterial pathogen contamination	No	Not likely to occur		
	CHEMICAL Chemical contaminants	No	• Not likely to occur • No history of occurrence		
	PHYSICAL None				
Dry Storage	BIOLOGICAL None				
	CHEMICAL None				
	PHYSICAL None				
Thawing	BIOLOGICAL • Bacterial pathogen growth	Yes	If not properly controlled, bacterial pathogens can grow during thawing.	A cook step follows that assumes a high bacterial load.	No
	• Bacterial pathogen contamination	No	Controlled by SSOP		
	CHEMICAL None				
	PHYSICAL None				

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	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur because of the continuous process		
	• Bacterial pathogen contamination	No	Controlled by SSOP		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Peeling	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Razor Slide	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL Metal fragments	No	Subsequent processing removes any fragments. No historical problem.		
Tumbler/Deveiner	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cull Table	BIOLOGICAL • Bacterial pathogen growth	No	Not likely to occur (See size grading)		
	• Bacterial pathogen contamination	No	(See size grading)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				

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.	No
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cooker	BIOLOGICAL Bacterial pathogen survival	Yes	Without proper processing time and temperature, bacterial pathogens such as *Listeria monocytogenes*, *Salmonella* spp. and *Vibrio* spp. may survive	Adequate cooking time and temperature	Yes
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Shuffler	BIOLOGICAL • Recontamination with bacterial pathogens	No	Controlled by SSOP		
	Note: Companies that DO NOT have SSOPs in place would need to control post-processing contamination with appropriate HACCP sanitation CCPs.				
	• Bacterial pathogen growth	No	Not likely to occur because of the continuous process		
	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.				
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Cull	BIOLOGICAL • Recontamination with bacterial pathogens	No	Controlled by SSOP		
	• Bacterial pathogen growth	No	(See remarks for shuffler)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None identified				
Spiral Freezer	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur due to rapid freezing rate		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None identified				

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	BIOLOGICAL • Recontamination with bacterial pathogens	No	Use potable water and equipment cleaned per SSOP.		
	• Bacterial pathogen growth	No	(See shuffler)		
	CHEMICAL Sanitizer residues	No	Controlled by SSOP		
	PHYSICAL None				
Weigh/Pack/Label	BIOLOGICAL • Recontamination with bacterial pathogens	No	(See shuffler)		
	• Bacterial pathogen growth	No	(See shuffler)		
	CHEMICAL Sulfiting agent	Yes	Potential allergic-type reaction (accurate label declaration)	Accurate label declaration	Yes
	Sanitizer Residues	No	Controlled by SSOP		
	PHYSICAL None identified				
Mastercase/Palletize	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur because frozen		
	CHEMICAL None				
	PHYSICAL None				
Freezer Storage	BIOLOGICAL Bacterial pathogen growth	No	Not likely to occur because frozen		
	CHEMICAL None				
	PHYSICAL None				

Chapter 7: **Principle 3:** Establish Critical Limits

Notes:

Overhead 1

Objective:
In this module, you will learn:
- How to define critical limits.
- How to set critical limits for a CCP.
- How to find sources of critical limit information.
- How to determine the relationship between critical limits and operating limits.

Critical limits must be established for each CCP identified in the hazard analysis.

Overhead 2

Principle 3:
Establish critical limits.

Overhead 3

Definition:
Critical Limit: A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food-safety hazard.

A critical limit represents the boundaries that are used to ensure that an operation produces safe products. Each CCP must have one or more critical limits for each food-safety hazard. When the process deviates from the critical limit, a corrective action must be taken to ensure food safety. Examples of critical limits are listed in Table 1.

Establishing Critical Limits

In many cases, the appropriate critical limit may not be readily apparent or available. Tests may need to be conducted or information gathered from sources such as scientific publications, regulatory guidelines, experts or experimental studies (Table 2).

Continued

Overhead 4

Table 1. Examples of Critical Limits

Hazard	*CCP*	*Critical Limit*
bacterial pathogens (biological)	pasteurizer	≥ 161 F for ≥ 15 seconds for elimination of pathogens from milk
bacterial pathogens (biological)	drying oven	Drying schedule — oven temperature: ≥ 200 F, drying time: ≥ 120 min., air flow rate: ≥ 2 cuft/min, product thickness: ≤ 0.5 inches (to achieve a_w ≤ to 0.85 to control pathogens in dried foods)
bacterial pathogens (biological)	acidification	Batch schedule — product weight: ≤ 100 lbs., soak time: ≥ 8 hrs., acetic acid concentration: ≥ 3.5 percent, volume ≤ 50 gal. (to achieve maximum pH of 4.6 to control *Clostridium botulinum* in pickled foods)

Explanatory Note:

These critical limits are for illustrative purposes only. They do not relate to any specific product but demonstrate how critical limits could apply at CCPs utilizing different control parameters for bacterial pathogens. In actual practice, critical limits must be scientifically based.

Overhead 5

Table 2. Sources of Information on Critical Limits

General Source	Examples
scientific publications	journal articles, food science texts, microbiology texts
regulatory guidelines	state and local guidelines, tolerances and action levels; USDA guidelines, tolerances and action levels; FDA guidelines, tolerances and action levels
FDA	FDA Fish and Fisheries Products Hazards and Controls Guidance Manual (referenced in Chapter 13)
experts	NACMCF (National Advisory Committee on Microbiological Criteria for Foods), thermal process authorities; consultants, food scientists/microbiologists, equipment manufacturers, sanitarians, university extension, trade associations
experimental studies	in-house experiments; contract labs

If the information needed to define the critical limit is not available, a conservative value should be selected. The rationale and reference material used to establish a critical limit should become part of the support documentation for the HACCP plan.

Often a variety of options exist for controlling a particular hazard. The control options usually necessitate the establishment of different critical

limits. The selection of the best control option and the best critical limit is often driven by practicality and experience. The following examples suggest control options and critical limits that could be applied at the fryer step to control bacterial pathogens in fried fish patties.

Notes:

Overhead 6

Option No. 1
Monitoring for Pathogens
Hazard — presence of pathogens (microbiological)
CCP — fryer
Critical limit — no pathogens detected

(Not typically the best option)

Setting a microbial limit as a critical limit for an in-process CCP is rarely practical. Microbiological limits are difficult to monitor, and testing to determine critical limit deviations may require several days. Therefore, microbiological limits cannot be monitored on a timely basis. Microbiological contamination is often sporadic, and samples may need to be large to be meaningful. In this example, sampling and microbiological tests of the fish patties are unlikely to be sensitive enough or practical.

Overhead 7

Option No. 2
Controlling Internal Temperature
Hazard — presence of pathogens (microbiological)
CCP — fryer
Critical limit — minimum internal temperature of 150 F for one minute

Setting a microbial critical limit is not necessary in this example as long as an appropriate critical limit can be set that is based on the conditions needed to inactivate the microorganisms of concern. Pathogens of concern in fish patties are destroyed by cooking the patties to an internal temperature of 150 F for one minute. In this option, the product temperature at the end of frying is used as a critical limit. This option is typically more practical and sensitive than finished-product pathogen testing.

Continued

Notes:

Overhead 8

Option No. 3
Controlling Factors that Affect Internal Temperature
Hazard — presence of pathogens (microbiological)
CCP — fryer
Critical limit — minimum fryer oil temperature of 350 F
Critical limit — maximum patty thickness of 1/4 inch
Critical limit — minimum cook time in the oil of one minute

In many cases, it is not practical to continually monitor the internal temperature of the food product to ensure conformance with a critical limit. As an alternative, critical limits may be set that establish conditions necessary to ensure that the cooking process achieves the necessary minimum product temperature. In this option, the oil temperature, the fish patty thickness and the time that the patty stays in the hot oil are all factors that affect the final patty temperature. Tests must be performed to ensure that controlling these factors within the critical limits will always result in an internal product temperature that will inactivate the microorganisms of concern. Typically, this option is easier to control and to monitor than the previous two. In addition, the cooker temperature and cooking time can be monitored continually, which gives greater confidence that every item has been adequately cooked.

The process should be capable of operating within the bounds set by the critical limit. The parameters for the fryer — minimum fryer-oil temperature, maximum patty thickness and minimum cook time — become the critical limits for the CCP. The critical limits should not be confused with the operating parameters of the equipment.

Establishing Operating Limits

Overhead 9

Definition:
Operating Limits: Criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation.

If monitoring shows a trend toward lack of control at a CCP, operators should take action to bring the CCP under control before the critical limit is exceeded. The point where operators take such an action is called the operating limit. Operating limits should not be confused with critical limits. Operating limits are established at a level that would be reached before the critical limit is violated.

Overhead 10

Definition:
Process Adjustment: An action taken by the firm to bring the process back within operating limits.

The process should be adjusted when the operating limit is reached to avoid violating critical limits. These actions are called process adjustments. A processor may use these adjustments to avoid loss of control and the need to take corrective action. Spotting a trend toward loss of control early and acting on it can save product rework, or worse yet, product destruction. Corrective action is only required when the critical limit is exceeded.

Operating limits may be selected for various reasons:

- For quality reasons (e.g., higher cooking temperatures for flavor development or to control organisms that can cause spoilage).
- To avoid exceeding a critical limit (e.g., a cooking temperature higher than the critical limit could be used as an alarm point to warn the operator that the temperature is approaching the critical limit and needs adjusting).
- To account for normal variability (e.g., a fryer with a 5 F variability should be set at least 5 F above the critical limit to avoid violating it).

Figures 1 and 2 are graphical representations of several important points: 1) operating limits and process adjustments, 2) critical limits and corrective actions, and 3) implications of lot size. In this example of a generalized cooking process, an operating limit is established at 200 F and a critical limit at 190 F. Somewhere in the 10 F range between these two points, wise processors will make a process adjustment to bring the cook temperature back above 200 F. Because an adjustment is made before the temperature drops below the critical limit of 190 F, no HACCP record is required. However, if an adjustment is not taken until after the temperature drops below the critical limit, as shown in Figures 1 and 2, appropriate corrective actions must be taken and a corrective action report must be placed in the HACCP records file (corrective actions and records will be discussed in subsequent chapters).

When a corrective action is necessary, processors must be able to identify and segregate the affected lots. If lot sizes are big, large quantities of product may require segregation and corrective action despite the fact that only a small amount of product was produced when critical limits were exceeded. Coding production into smaller lots means far less product may be involved when violation of a critical limit occurs. Therefore, wise processors should change codes often during the production day and match monitoring frequency with code changes.

Notes:

Notes:

Overhead 11

Figure 1

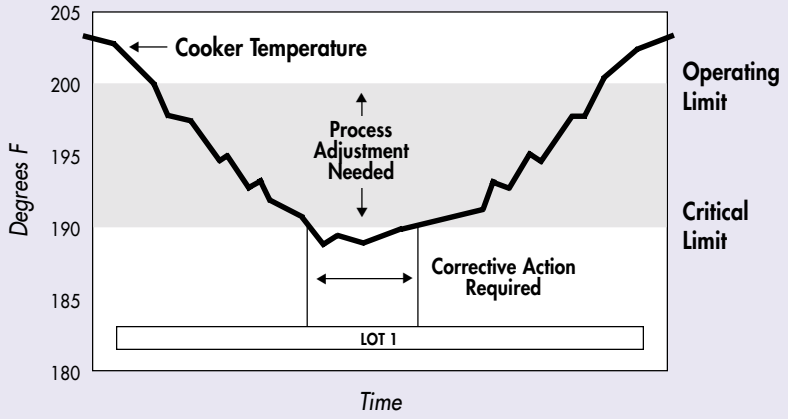
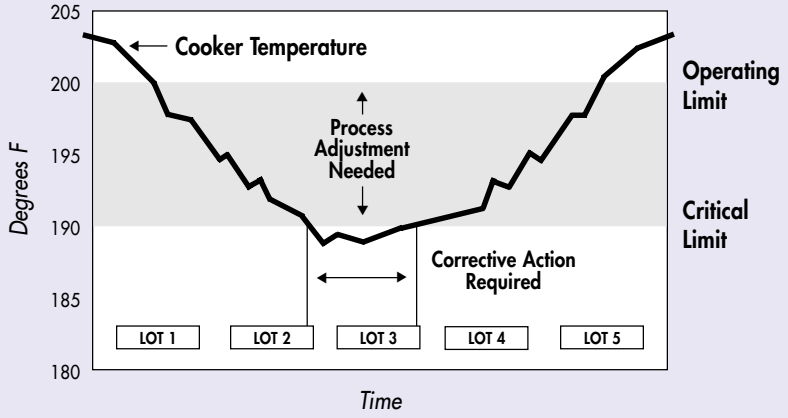


Figure 2



Critical Limits for ABC Shrimp Co.

The hazard-analysis worksheet for the IQF cooked-shrimp example identifies two CCPs: cooker and weigh-pack-label. The following table lists examples of critical limits for these CCPs.

Overhead 12

Table 4. Establishment of Critical Limits

Critical Control Point	*Critical Limit*
CCP — Cooker	Cook at ≥212 F for three minutes (to achieve minimum internal temperature of 145 F for 15 sec.)
CCP — Weigh/Pack/Label	All product containing sulfiting agent must declare presence

Overhead 13

HACCP Plan Form

Critical Limits:

1. CCP	2. Hazard	3. Critical Limits	4. 5. 6. 7. Monitoring (What How Frequency Who)	8. Corrective Action(s)	9. Verification	10. Records

The CCP, hazards and critical limits should be recorded in columns 1, 2 and 3 on the HACCP plan form.

Notes:

Explanatory Note:

For the purpose of this example, we have assumed that a study was performed to determine the worst case (e.g., largest shrimp, lowest initial temperature). The shrimp would be heated to an internal temperature of 145 F for 15 seconds by cooking for at least three minutes at 212 F or greater. In practice, processors may choose to vary process times depending on shrimp size. Therefore, shrimp size grading would likely become a CCP.

Explanatory Note:

Since residuals of sulfiting agents may trigger allergic-type reactions, labeling is required on product with detectable residues. Detection levels range above 10ppm.

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4)	(5) Monitoring	(6)	(7)	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Cooker	Survival of bacterial pathogens	Cook at 212 F for three minutes (to achieve minimum internal temperature of 145 F for 15 seconds)							
Weigh/Pack/ Label	Allergic-type reaction for undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence							

Firm Name: *ABC Shrimp Co.*

Firm Address: *Anywhere, USA*

Signature:

Date:

Product Description: *Cooked and frozen, headless, peeled and deveined shrimp*

Method of Storage and Distribution: *Frozen*

Intended Use and Consumer: *Thaw and serve, general public*

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

Chapter 8: **Principle 4:** Critical Control Point Monitoring

Overhead 1

Objective:
In this module, you will learn:
- How monitoring is defined.
- Why monitoring is needed.
- How to design a monitoring system.
- What methods and equipment are used for monitoring critical limits.
- How often monitoring should be performed.
- Who should monitor.

Monitoring is important to ensure that the critical limits are consistently met.

Overhead 2

Principle 4:
Establish monitoring procedures.

Overhead 3

Definition:
Monitor: to conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Notes:

Continued

Notes:

• ***Purpose for Monitoring***

Overhead 4

MONITORING

Purpose of Monitoring:

- To track the operation of the process and enable the identification of trends toward a critical limit that may trigger process adjustments,
- To identify when there is loss of control (a deviation occurs at a CCP).
- To provide written documentation of the process control system.

Monitoring is the process that the operator relies upon to maintain control at a CCP. Accurate monitoring indicates when there is a loss of control at a CCP and a deviation from a critical limit. When a critical limit is compromised, a corrective action is needed. The extent of the problem needing correction can be determined by reviewing the monitoring records and finding the last recorded value that meets the critical limit.

Monitoring also provides a record that products were produced in compliance with the HACCP plan. This information is useful in the verification of the HACCP plan as discussed in Principle 7.

• ***Design of a Monitoring System***

The control measures discussed in Principle 1 and the critical limits discussed in Principle 3 are intended to control the hazards at each CCP. The monitoring procedures are used to determine if the control measures are being enacted and the critical limits are being met. Monitoring procedures must identify:

- What will be monitored. (Column 4)
- How the critical limits and control measures will be monitored. (Column 5)
- How frequently monitoring will be performed. (Column 6)
- Who will perform the monitoring. (Column 7)

Overhead 5

HACCP Plan Form

Monitoring:

1. CCP	2. Hazard	3. Critical Limits	4. 5. 6. 7. Monitoring (What How Frequency Who)	8. Corrective Action(s)	9. Verification	10. Records

Specify the monitoring procedures for each CCP.

Overhead 6

MONITORING

- **What:** usually a measurement or observation to assess if the CCP is operating within the critical limit.
- **How:** usually physical or chemical measurements (for quantitative critical limits) or observations (for qualitative critical limits). Needs to be real-time and accurate.
- **When (frequency):** can be continuous or intermittent.
- **Who:** someone trained to perform the specific monitoring activity.

Overhead 7

What will be Monitored?

• ***What will be Monitored***

Monitoring may mean measuring a characteristic of the product or of the process to determine compliance with a critical limit.

Examples include:
- Measurement of cold-storage compartment temperature when critical for temperature-sensitive ingredients.
- Measurement of the pH of an acidifying ingredient when critical for the production of an acidified food.
- Measurement of line speed when critical to adequate cooking or chilling processes.

Continued

Notes:

Notes:

Monitoring may also involve observing if a control measure at a CCP is being performed.

Examples include:
- Checking that a vendor's certificate accompanies a lot of raw material.
- Checking the harvest area listed on a tag attached to a container of raw molluscan shellfish to ensure harvest from approved waters.

What will be monitored is listed in column 4 of the HACCP plan form.

Overhead 8

How Critical Limits and Control Measures will be Monitored

Explanatory Note:

The length of time between monitoring checks will directly affect the amount of rework or product loss when a critical-limit deviation is found.

• How Critical Limits and Control Measures will be Monitored

Monitoring must be designed to provide rapid (real-time) results. There is no time for lengthy analytical testing because critical limit failures must be detected quickly and an appropriate corrective action instituted before distribution.

Microbiological testing is seldom effective for monitoring CCPs. Very often the analytical methods are lengthy. Additionally, to do a statistically adequate job of finding pathogenic organisms at levels that may cause illness, large sample sizes are usually needed.

Physical and chemical measurements are preferred monitoring methods because testing can be done rapidly. Physical and chemical measurements (e.g., pH, time, temperature) can often be related to the microbiological control as illustrated by the fried-fish example in Principle 3. Examples of physical- and chemical-measurement monitoring at a CCP follow:

- Time and temperature. This combination of measurements is often used to monitor the effectiveness for destroying or controlling the growth of pathogenic bacteria. By processing a food at a set temperature for a set time, pathogenic bacteria can be destroyed. For example, pasteurized crabmeat (in a 401 x 301 can) should be heated to a container-core temperature of 185 F for one minute. This is usually assured by monitoring the temperature of a heated water bath and by monitoring the time that the product is held therein. In addition, pathogens can be controlled by minimizing exposure of a food to the critical pathogen growth temperatures between 40 F and 140 F. This can be achieved through rapid heating and/or cooling of the product through these critical temperatures and maintaining temperatures below 40 F or above 140 F during storage. For example, monitoring should be performed to determine the cumulative exposure of crabmeat to temperatures between 40 F and 140 F during the processing.

- Water Activity (a_w). Pathogen growth can be controlled by limiting water activity — the amount of water available for microbial growth. For example, drying products to a water activity below 0.85 stops pathogen growth. In this case, samples may be collected during the drying process and tested for water activity. The process is completed when a_w falls below 0.85. Processors may monitor temperature, time and flow if the rate of drying under these conditions is known to achieve an 0.85 a_w at the end of the process.
- Acidity (pH). Pathogen growth can be controlled by limiting the pH of the product to a level that does not allow growth. For instance, the growth of *Clostridium botulinum*, which leads to botulism, is controlled in acidified products by adding acid to lower the pH to 4.6 or below. In this case, the pH of an acidifying agent may be monitored before it is added to a batch. Recording the pH of the finished product is not a good monitoring tool because a few days must pass before the finished product's pH reaches equilibrium.
- Sensory examination. This is a means of testing for decomposition that may result in food-safety hazards such as histamine development. The type and intensity of the odor gives the examiner an indication of the time/temperature abuse that could result in histamine development.

The selection of the monitoring equipment is a major consideration during development of a HACCP plan. Equipment used for monitoring CCPs varies with the attribute being monitored. Examples of monitoring equipment include:

- thermometers,
- clocks,
- scales,
- pH meters,
- water activity meters and
- chemical analytical equipment.

The equipment chosen for monitoring at the CCP must be accurate to ensure control of the hazard. The variability of the monitoring equipment should be considered when setting the critical limit. For example, if a minimum internal temperature of 145 F is necessary to kill pathogens in a product and the thermometer has an accuracy of ± 2 F, then the critical limit should be set no lower than 147 F. Periodic calibration or standardization is necessary to ensure accuracy. This is further discussed in Chapter 11.

How monitoring will be performed is recorded in column 5 of the HACCP plan form.

Continued

Notes:

Notes:

Overhead 9

Monitoring Frequency

• ***Monitoring Frequency***

Monitoring can be continuous or noncontinuous. Where possible, continuous monitoring should be used. Continuous monitoring is possible for many types of physical and chemical parameters. Examples of continuous monitoring include:

- The time and temperature of a batch pasteurization process for crabmeat may be continuously monitored and recorded on a tempera ture-recording chart.
- Each package of frozen, mechanically-cut fish blocks may be passed under a metal detector.

A monitoring instrument that produces a continuous record of the measured value will not control the hazard on its own. The continuous record needs to be observed periodically and action taken when needed. This too is a component of monitoring. The length of time between checks will directly affect the amount of rework or product loss when a critical-limit deviation is found. In all cases, the checks must be performed in time to ensure that irregular product is isolated before shipment.

When it is not possible to monitor a CCP on a continuous basis, it is necessary for the monitoring interval to be short to detect possible deviations from critical limits or operating limits.

The frequency of noncontinuous monitoring should be partially determined from historical knowledge of the product and process. Questions that will help determine the correct frequency include:

- How much does the process normally vary (i.e., how consistent is the data)? If the data varies considerably, the time between monitoring checks should be short.
- How close are the normal values to the critical limit? If the normal values are close to the critical limit, the time between monitoring checks should be short.
- How much product is the processor prepared to risk if the critical limit is exceeded?

Examples of potential noncontinuous monitoring include:

- Temperature checks of batter on a breading line at specified time intervals.
- Routine, daily checks for properly iced fish.
- Periodic sensory examination for decomposition in histamine-forming seafood.

Overhead 10

Who will Monitor?

• ***Who will Monitor?***

Assignment of the responsibility for monitoring is an important consideration when developing a HACCP plan.

Individuals assigned to CCP monitoring can be:
- Line personnel,
- Equipment operators,
- Supervisors,
- Maintenance personnel or
- Quality-assurance personnel.

Monitoring by line personnel and equipment operators can be advantageous since they are continuously viewing the product and/or equipment and can readily observe changes from the norm. Also, including line personnel in HACCP activities has the advantage of building a broad base of understanding and commitment to the HACCP program.

Those responsible for monitoring a CCP should:
- Be trained in the CCP monitoring techniques.
- Fully understand the importance of CCP monitoring.
- Have ready access to the monitoring activity.
- Accurately report each monitoring activity.
- Immediately report critical-limit infractions so that immediate corrective actions (Principal 5) can be taken.

The monitor's duties should require that all unusual occurrences and deviations from critical limits be reported immediately to make sure adjustments and corrective actions are made in a timely manner. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

The monitoring procedures for each of the critical limits identified in Principle 3 for the IQF cooked-shrimp are contained in the attached HACCP plan.

Who will perform the monitoring will be recorded in column 7 of the HACCP plan form.

Notes:

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Cooker	Survival of bacterial pathogens	Cook at 212 F for three minutes (to achieve minimum internal temperature of 145 F for 15 seconds)	Cook temperature	• Monitor temperature with a continuous temperature recorder	• Temperature monitored continuously with hourly visual checks.	•Quality-control supervisor will program the continuous-recording thermometer.			
			Cook time	• Monitor cook time by timing the movement of a block placed on belt through cooker.	• Cook time monitored hourly.	• Cook will perform the hourly checks.			

Firm Name: *ABC Shrimp Co.*

Firm Address: *Anywhere, USA*

Signature:

Date:

Product Description: *Cooked and frozen, headless, peeled and deveined shrimp*

Method of Storage and Distribution: *Frozen*

Intended Use and Consumer: *Thaw and serve, general public*

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

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	**How**	**Frequency**	**Who**			
Weigh/Pack Label	Allergic-type reaction from undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence	• At weigh/pack/ label stage, check for "contains sulfite" declaration.	• Examine all labels issued at packing line and match declaration with product identity.	• One label each time a label roll is replaced	• Packing supervisor			
			• At receiving, sample each vessel of fresh shrimp to test for presence of sulfites.	• Rapid sulfite test	• Fresh shrimp, three-grab samples per vessel	• Dock master			
			• At receiving, supplier declaration for absence of sulfites for frozen shrimp.	• Observation of supplier declaration	• Frozen shrimp, check every shipment	• Dock master			
Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliance with weigh/pack/label critical limits.									

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

Notes:

Chapter 9: **Principle 5:** Corrective Actions

Overhead 1

Objective:
In this module, you will learn:
- The definition of corrective actions,
- Procedures for corrective action and
- Record-keeping requirements for corrective actions.

Overhead 2

Principle 5:
Establish corrective actions.

Corrective actions must be taken when critical limits at a CCP have been compromised. When possible, these actions should be predetermined when developing the HACCP plan.

Overhead 3

Definition:
Corrective Action: Procedures to be followed when a deviation occurs.

When critical limits are violated at a CCP, the predetermined, documented corrective actions should be instituted. These corrective actions should state procedures to restore process control and determine the safe disposition of the affected product. It may be possible, and is always desirable, to correct the problem on the spot.

Corrective action options include:
- isolating and holding product for safety evaluation.
- diverting the affected product or ingredients to another line where deviation would not be considered critical.
- reprocessing.
- destroying product.

Continued

Explanatory Note:

Corrective actions are implemented when monitoring results indicate a deviation from critical limits. Effective corrective actions depend heavily on an adequate monitoring program.

Notes:

The primary objective is to establish a HACCP program that permits rapid identification of deviations from a critical limit. The sooner the deviation is identified, the more easily corrective actions can be taken and the greater the potential for minimizing the amount of noncompliant product. An individual who has a thorough understanding of the process, product and HACCP plan and who has the authority to make decisions needs to be assigned the responsibility of making corrective actions.

Effective corrective action plans must:
- Correct and eliminate the cause of the noncompliance to assure that the CCP is brought back under control.
- Segregate, assess and determine the disposition of the noncompliant product.

All corrective actions taken must be documented. Documentation will assist the firm in identifying recurring problems so that the HACCP plan can be modified. Additionally, corrective action records provide proof of product disposition.

Components of Corrective Actions

There are two components of corrective actions: 1) to correct and eliminate the cause of the deviation and restore process control and 2) to identify the product that was produced during the process deviation and determine its disposition.

Overhead 4

Corrective Action Components:
- To correct and eliminate the cause of the deviation and restore process control.
- To identify the product that was produced during the process deviation and determine its disposition.

- ***Correct and Eliminate the Cause of the Deviation and Restore Process Control***

Corrective actions must bring the CCP back under control. A corrective action should take care of the immediate (short-term) problem as well as provide long-term solutions. The objective is to implement a short-term fix so that control can be re-established and the process started again as soon as possible without further process deviation.

It may be necessary to determine the cause of the deviation to prevent future recurrence. A critical limit failure that was not anticipated or reoccurs should result in an adjustment to the product or process or a re-evaluation of the HACCP plan.

One outcome of the re-evaluation may be a decision to modify the HACCP plan. A permanent solution to eliminating or minimizing the initial cause or causes for the process deviation should be implemented if necessary. Specific instructions for corrective actions must be available to plant workers and should be part of the documented HACCP plan.

- ***Identify the Product that was Produced During the Process Deviation and Determine the Disposition***

When a deviation occurs, identify nonconforming product. There are four steps that may be used for determining product disposition and developing a corrective action plan.

Overhead 5

Four Steps:

A. Step One: Determine if the product presents a safety hazard:
   a. Based on expert evaluation.
   b. Based on physical, chemical or microbiological testing.
B. Step Two: If no hazard exists based on the evaluations in Step 1, the product may be released.
C. Step Three: If a potential hazard exists (based on the evaluations in Step 1), determine if the product can be:
   a. Reworked/reprocessed.
   b. Diverted for a safe use.
D. Step Four: If potentially hazardous product cannot be handled as described in Step 3, the product must be destroyed. This is usually the most expensive option and is usually regarded as the last resort.

Continued

Notes:

Explanatory Note:

If a product is to be tested and released, the sampling method is highly important. The use of a faulty sampling protocol can result in accepting, rather than rejecting, an undesirable product. The limits of sampling plans must be understood. It may be prudent to consult an expert.

Explanatory Note:

It is important to ensure that any reworking does not result in the creation of a new hazard. Of primary concern are toxic materials, including heat-stable biological toxins. It must be realized that reworked product is still subject to regulatory scrutiny and that reworking must result in a safe product.

Notes:

Corrective Action Format Examples

Corrective actions are usually written in an "if/then" format. The "if" part of the corrective action describes the condition and the "then" part describes the action taken. For example:

Overhead 6

IF *deviation:*	Temperature of milk at pasteurizer drops below critical limit.
THEN *corrective action:*	Milk flow is diverted until temperature recovers. Diverted product is repasteurized. Check the operation of the heating/cooling units to determine the reason for the temperature deviation that caused the flow diversion. Repair if necessary, re-establish control and resume production.

Explanatory Note:

During the process, it is possible to extend the cook time until the desired internal temperature is reached for the required time. However, this would be a "process adjustment" rather than a corrective action.

Overhead 7

IF *deviation:*	Product (e.g., hot smoked fish) does not reach required internal temperature for the required time.
THEN *corrective action:*	Recook or destroy product.

Overhead 8

IF *deviation:*	Mahi-mahi held at elevated temperature for excess time period (temperature limit exceeded, possible elevated histamine level).
THEN *corrective action:*	Bury product in ice, place on hold and conduct sensory analysis and histamine test. Determine the reason for the process delay. Prevent future occurrences.

Corrective Action Records

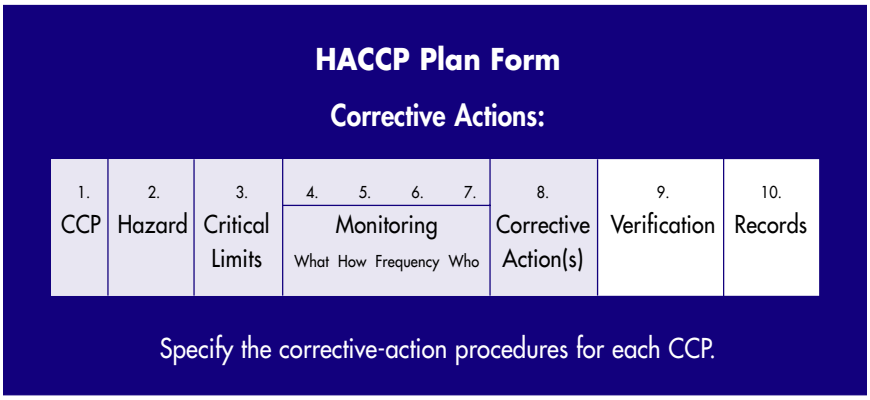
Predetermined corrective actions are written into the HACCP plan. When critical limits are exceeded and a corrective action occurs, it is recorded. A corrective-action report form is helpful.

The corrective-action report should contain the following:

a. Product identification (e.g., product description, amount of product on hold).
b. Description of the deviation.
c. Corrective action taken including final disposition of the affected product.
d. Name of the individual responsible for taking the corrective action.
e. Results of the evaluation when necessary.

HACCP plan records could contain a separate file in which all deviations and corresponding corrective actions are maintained in an organized fashion. Corrective actions are recorded in column 8 of the HACCP plan form. Following is the corrective actions for the IQF cooked-shrimp example.

Overhead 9



Explanatory Note:

The corrective action recording should be closely linked with the corresponding monitoring that recorded a deviation. Recommended approaches include recording the monitoring and corrective actions on the same form, piece of paper, or electronic record.

Continued

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4)	(5) Monitoring	(6)	(7)	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Cooker	Survival of bacterial pathogens	Cook at 212 F for three minutes (to achieve minimum internal temperature of 145 F for 15 seconds)	Cook temperature	• Monitor temperature with a continuous temperature recorder	• Temperature monitored continuously with hourly visual checks.	• Quality-control supervisor will program the continuous-recording thermometer.	If temperature or time parameters are not met, then processing line will be stopped and required adjustments made. All product produced during the deviation will be recooked or destroyed.		
			Cook time	• Monitor cook time by timing the movement of a block placed on belt through cooker.	• Cook time monitored hourly.	• Cook will perform the hourly checks.			

Firm Name: *ABC Shrimp Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Cooked and frozen, headless, peeled and deveined shrimp*

Method of Storage and Distribution: *Frozen*

Intended Use and Consumer: *Thaw and serve, general public*

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

EXAMPLE: For Illustrative Purposes Only* - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measures	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	**How**	**Frequency**	**Who**			
Weigh/Pack Label	Allergic-type reaction from undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence	• At weigh/pack/ label stage, check for "contains sulfite" declaration.	• Examine all labels issued at packing line and match declaration with product identity.	• One label each time a label roll is replaced	• Packing supervisor	If this product is mislabeled, then appropriately label.		
			• At receiving, sample each vessel of fresh shrimp to test for presence of sulfites.	• Rapid sulfite test	• Fresh shrimp, three-grab samples per vessel	• Dock master			
			• At receiving, supplier declaration for absence of sulfites for frozen shrimp.	• Observation of supplier declaration	• Frozen shrimp, check every shipment	• Dock master			
Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliance with weigh/pack/label critical limits.									

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

Notes:

Chapter 10: **Principle 6:** Verification Procedures

Overhead 1

Objective:
In this module, you will learn:
- How to define verification.
- What functions are part of HACCP plan verification.
- What functions are part of validation.

Overhead 2

Principle 6:
Establish verification procedures.

Overhead 3

Definition:
Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and that verify the system is operating according to the plan.

Verification

One of the more complex HACCP principles is verification. Although it is complex, the proper development and implementation of the verification principle is fundamental to the successful execution of the HACCP plan. HACCP has spawned the use of a new adage — "trust what you verify," which speaks to the heart of the verification principle. The purpose of the HACCP plan is to prevent food-safety hazards, and the purpose of verification is to provide a level of confidence that the plan is based on solid scientific principles, is adequate to control the hazards associated with the product and process, and is being followed.

Continued

Explanatory Note:

Routine monitoring activities for critical limits should not be confused with verification methods, procedures or activities. This could be a point of confusion, and the instructor should keep this in mind while addressing this chapter.

Notes:

Overhead 4

"Trust What You Verify"
Verification provides a level of confidence that the HACCP plan is based on solid scientific principles, is adequate to control the hazards associated with the product and process, and is being followed.

Perhaps one of the reasons verification has been difficult to understand is because there are several elements associated with this principle, including validation and reviews. Confusion also arises because the HACCP plan must include verification procedures for individual CCPs and for the overall plan. To facilitate understanding, each of these elements will be discussed.

Overhead 5

Elements of Verification:
- Validation
- CCP verification activities
  - Calibration of monitoring devices
  - Calibration record review
  - Targeted sampling and testing
  - CCP record review
- HACCP system verification
  - Observations and reviews
  - Microbiological end-product testing
- Regulatory agencies

- ***Validation***

Overhead 6

Definition:
Validation: The element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Validation is an essential component of verification and requires substantiation that the HACCP plan, if implemented effectively, is sufficient to control the food-safety hazards that are likely to occur. Validation of the plan occurs before the plan is actually implemented. The purpose of

validation is to provide objective evidence that all essential elements of the plan have a scientific basis and represent a "valid" approach to controlling the food-safety hazards associated with the specific product and process. There are several approaches to validating the HACCP plan, among them are: incorporation of fundamental scientific principles, use of scientific data, reliance on expert opinion or conducting in-plant observations or tests.

Notes:

Overhead 7

Validation of the HACCP plan, who does it?
- HACCP team
- Individual qualified by training or experience

What does validation involve?
- A scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy.

Validation can be performed by the HACCP team or by an individual qualified by training or experience. Validation activities may be similar in scope and time commitment to the original HACCP plan development. An in-plant validation should be performed initially before actual reliance on the HACCP plan and when factors warrant. These factors could include: changes to the raw materials, product or process; adverse review findings; recurring deviations; new scientific information about potential hazards or control measures; on-line observations; or new distribution or consumer-handling practices. Validation involves a scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy.

Overhead 8

Validation Frequency:
- Initially
- When factors warrant. The following may warrant validation of the plan:
  - changes in raw materials,
  - changes in product or process,
  - adverse review findings,
  - recurring deviations,
  - new information on hazards or control measures,
  - on-line observations, and
  - new distribution or consumer handling practices.

Continued

Notes:

Examples of Validation Activities:

1. One approach to controlling vegetative pathogens as a hazard in cooked hamburgers is to ensure that the hamburgers are cooked to an internal temperature that destroys pathogens. In the HACCP plan, parameters for maximum patty thickness, maximum belt speed and minimum oven temperature could be the critical limits to ensure that an adequate temperature is reached at the cook step. These criteria would be established after collecting enough data on-line to ensure that controlling those points would also control the minimum internal temperature of every hamburger patty as it is cooked.
2. An internal temperature of 145 F was determined as critical to destroy pathogens in cooked shrimp. The firm uses a process of 212 F for three minutes to provide an internal temperature of at least 145 F. The ability of the process time and temperature to achieve the internal temperature of the cooked shrimp should be validated by measuring the center temperature of a representative number of cooked shrimp. The cooking equipment should also be validated using temperature distribution tests to determine that adequate temperatures are delivered throughout the cooker during processing.

- ***Verification of CCPs***

Overhead 9

CCP Verification Activities:
- Calibration
- Calibration record review
- Targeted sampling and testing
- CCP record review

Verification activities developed for CCPs are essential to ensure that the control procedures used are properly functioning and that they are operating and calibrated within appropriate ranges for food-safety control. Additionally, CCP verification includes supervisory review of CCP calibration, monitoring and corrective action records to confirm compliance with the HACCP plan. CCP verification may also include targeted sampling and testing.

- ***Calibration***

Verification activities at CCPs include calibration of monitoring devices to assure the accuracy of the measurements taken. Calibration is conducted to verify that monitoring results are accurate.

Calibration of CCP monitoring equipment is fundamental to the successful implementation and operation of the HACCP plan. If the equipment is out of calibration, then monitoring results will be unreliable. If this happens, the CCP should be considered out of control since the last documented acceptable calibration. This situation should be given ample consideration when establishing the frequency of calibration. Frequency of calibration should also be influenced by equipment sensitivity.

Overhead 10

Calibrations are performed:
- On equipment and instruments used in monitoring or verification.
- At a frequency to ensure accuracy of measurements.
- By checking accuracy against a recognized standard at or near the condition that the instrument or equipment will be used.

Examples of calibration activities:

1. A thermometer used to monitor temperature at a cook CCP may be checked for accuracy by comparing it against a certified thermometer in a hot-water bath.
2. The continuous temperature chart recorder on a pasteurizer may be compared during each batch against a certified accurate thermometer.
3. A pH meter is calibrated against pH buffer standards of 7.0 and 4.0 when it is used to test products with a final pH of 3.8 to 4.2.

- ***Calibration Record Review***

Reviewing the equipment calibration records involves checking the dates and methods of calibration and the test results (e.g., equipment passing or failing). Calibration records are kept and reviewed. This review may be conducted as part of an audit (audits are discussed later in this chapter).

Example of calibration record review:

1. A review of the thermometer records indicates that the thermometer was checked for accuracy against a certified thermometer at a frequency specified in the HACCP plan. The records also indicate that the thermometer performed within established limits and did not need adjustment. This review disclosed no problems in the MIG calibrations.

- ***Targeted Sampling and Testing***

Verification may also include targeted sampling, testing and other periodic activities. Vendor compliance may be checked by targeted sampling when receipt of material is a CCP and purchase specifications are relied

Continued

Notes:

on as critical limits. Typically, when a monitoring procedure is not as stringent as desired, it should be coupled with a strong verification strategy.

Examples of targeted sampling and testing:

1. In the cooked-shrimp example, the firm may purchase frozen shrimp under a supplier's guarantee for a sulfite-free product. A quarterly sample is collected for laboratory analysis to verify that the product being tested is sulfite-free.
2. In the cooked-shrimp example, verification of sulfite residual control at receiving of fresh shrimp may involve quarterly analysis of samples to ensure that the results obtained through the original monitoring procedure are accurate. Records should indicate any deviations.
3. Egg white is used as an ingredient in meringue-pie topping. Historically, egg whites have been associated with a risk of *Salmonella*. Since the meringue is not cooked or otherwise treated to kill *Salmonella*, the preventive measure could be to ensure that all egg whites received are *Salmonella*-free. The CCP would be egg-white receiving, and the critical limit would be "every lot has a guarantee ensuring it is pasteurized and *Salmonella*-free." The adequacy of the supplier's certificate could be periodically verified by collecting samples from a lot and testing for *Salmonella*.

When critical limits are set for equipment operation, product samples may be taken to ensure that the equipment settings are appropriate for product safety. For example, the firm processing cooked shrimp may collect in-line samples of selected product after cooking to measure internal temperature.

- ***CCP Record Review***

At least two types of records are generated at each CCP: monitoring and corrective action. These records are valuable management tools, providing documentation that CCPs are operating within established safety parameters and that deviations are handled in a safe and appropriate manner. However, records alone are meaningless unless someone in a supervisory capacity reviews them on a periodic basis to "verify" that the HACCP plan is being followed. Current seafood HACCP regulations mandate a second review of monitoring records within one week after the initial records were taken.

HACCP System Verification

In addition to the verification activities for CCPs, strategies should be developed for scheduled verification of the complete HACCP system. The frequency of the system-wide verification should be yearly (at a mini-

mum) or whenever there is a system failure or a significant change in the product or process. The HACCP team is responsible for ensuring that this verification function is performed. Often, the HACCP team will contract an independent third party to conduct the system-wide verification activities.

Overhead 11

HACCP System Verification Frequency:
- Annually
- Occurrence of a system failure or significant change in product or process

- ***System Verification Activities***

Systematic verification activities include on-site observations and record reviews. Reviews are usually performed by an unbiased person who is not responsible for performing the monitoring activities.

System verification should occur at a frequency that ensures the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and product.

Overhead 12

Verification Activities of the HACCP System:
- Check the accuracy of the product description and flow chart.
- Check that CCPs are monitored as required by the HACCP plan.
- Check that processes are operating within established critical limits.
- Check that records are completed accurately and at the time intervals required.

Overhead 13

Record Review:
- Monitoring activities have been performed at the locations specified in the HACCP plan.
- Monitoring activities have been performed at the frequencies specified in the HACCP plan.
- Corrective actions have been performed whenever monitoring indicated deviation from critical limits.
- Equipment has been calibrated at the frequencies specified in the HACCP plan.

Continued

Explanatory Note:

The frequency of verification activities will likely change over time. A history of review findings that indicate that the processes are consistently in control may justify safely reducing the frequency. On the other hand, adverse findings, such as inconsistent monitoring activities, inconsistent record keeping and improper corrective actions warrant correcting the problems and more frequent verification reviews. Adverse findings may indicate a need for subsequent validation of the HACCP plan. FDA's seafood HACCP regulation requires "reassessment" of the HACCP plan on an annual basis. This is a process that includes a technical review of the hazard analysis and each element of the HACCP plan as well as on-site review of all flow diagrams and appropriate records from the operation of the plan. The purpose of the reassessment is to ensure that the HACCP plan accurately identifies and controls relevant hazards.

Notes:

- ***End-Product Microbiological Testing in HACCP Verification***

As explained in Chapter 2, microbiological testing is ineffective for routine monitoring but can be used as a verification tool. Microbiological testing can be used to determine (e.g., during verification audits or on periodic basis that the overall operation is under control.

Example of microbiological testing:

1. Several years ago, NACMCF recommended a microbiological criteria for *Staphylococcus aureus* in cooked, ready-to-eat crabmeat. The recommended criteria for plants operating under a HACCP plan and following GMPs are as follows: for every five sample units (n=5), no more than two units (c = 2) can exceed 100 organisms per gram (m = 100/g), and no unit can exceed 1,000 organisms per gram (M = 1,000/g). Obviously, analysis for this organism would not be useful for routine CCP monitoring. However, it may be useful for periodically verifying the effectiveness of the HACCP system.

- ***Company Verification Schedule***

Table 1 is an example of company-established HACCP verification schedule.

Table 1 and Overhead 14

Example of a Company-Established HACCP Verification Schedule

Activity	*Frequency*
Initial validation of HACCP plan	Prior to and during initial implementation of plan
Subsequent validation of HACCP plan	When critical limits changed, significant changes in process occurred, equipment failed, system failed, etc.
Verification of CCP monitoring as described in the plan (e.g., monitoring of shrimp cook time and temperature)	According to HACCP plan (e.g., daily record review)
Review of monitoring and corrective action records to show compliance with the plan	Weekly
Reassessment of HACCP plan	Yearly

The Role of Regulatory Agencies in HACCP Plan Verification

The major role of regulatory agencies in a HACCP system is to verify that HACCP plans are effective and are being followed. Verification normally will occur at the inspected facility; however, some aspects of verification may be conducted at other appropriate locations.

HACCP plans are unique documents prepared by a processor to ensure the control of a specific process or procedure. The plans may contain proprietary information and must be appropriately protected by the regulatory agency. Agency personnel must have access to records that pertain to CCPs, deviations, corrective actions and other information pertinent to the HACCP plan that may be required for verification.

Overhead 15

Verification procedures by an agency include:

- Review of the HACCP plan and any modification.
- Review of CCP monitoring records.
- Review of corrective action records.
- Review of the verification records.
- Visual inspections of operations to determine if the HACCP plan is followed and records are properly maintained.
- Random sample collection and analysis.

Notes:

EXAMPLE: For Illustrative Purposes Only - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4) Monitoring		(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Verification	(10) Records
			What		How	Frequency	Who			
Cooker	Survival of bacterial pathogens	Cook at 212 F for 15 minutes (to achieve minimum internal temperature of 145 F for 15 seconds)	Cook temperature	Cook time	• Monitor temperature with a continuous temperature recorder • Monitor cook time by timing the movement of a block placed on belt through cooker.	• Temperature monitored continuously with hourly visual checks. • Cook time monitored hourly.	• Quality-control supervisor will program the continuous-recording thermometer. • Cook will perform the hourly checks.	If temperature or time parameters are not met, then processing line will be stopped and required adjustments made. All product produced during the deviation will be recooked or destroyed.	• Daily record review • Quarterly calibration of thermometer • Semi-annual finished-product microbial testing • Process validation study of time and temperature of cook and its effect on the final internal temperature of various sizes of shrimp and initial temperature (on file) • Cooking equipment validation study (on file)	

Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliance with weigh/pack/label critical limits.

Firm Name: *ABC Shrimp Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Cooked and frozen, headless, peeled and deveined shrimp*

Method of Storage and Distribution: *Frozen*

Intended Use and Consumer: *Thaw and serve*

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

EXAMPLE: For Illustrative Purposes Only - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	**How**	**Frequency**	**Who**			
Weigh/Pack Label	Allergic-type reaction from undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence	• At weigh/pack/ label stage, check for "contains sulfite" declaration.	• Examine all labels issued at packing line and match declaration with product identity.	• One label each time a label roll is replaced	• Packing supervisor	If this product is mislabeled, then appropriately label.	• Daily record review	
			• At receiving, sample each vessel of fresh shrimp to test for presence of sulfites.	• Rapid sulfite test	• Fresh shrimp, three-grab samples per vessel	• Dock master		• Daily record review • Quarterly lab report for sulfite (fresh shrimp)	
			• At receiving, supplier declaration for absence of sulfites for frozen shrimp.	• Observation of supplier declaration	• Frozen shrimp, check every shipment	• Dock master		• Daily record review • Quarterly lab report for sulfite (frozen shrimp)	

Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliance with weigh/pack/label critical limits.

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

Notes:

Chapter 11: **Principle 7:** Record-Keeping Procedures

Notes:

Overhead 1

Objective:
In this module, you will learn:
- What kinds of records are needed in a HACCP system.
- When to record monitoring information.
- How computerized records can be used.
- How to conduct a record review.

Accurate record keeping is an essential part of a successful HACCP program. Records provide documentation that the critical limits have been met or that appropriate corrective actions were taken when the limits were exceeded. Likewise, they provide a means of monitoring so that process adjustments can be made to prevent a loss of control.

Overhead 2

Principle 7:
Establish record-keeping and documentation procedures.

Types of Records Needed

Overhead 3

Four kinds of categories are kept as part of the HACCP system.
1. HACCP plan and support documentation used in developing the plan
2. Records of CCP monitoring
3. Records of corrective action
4. Records of verification activities

Continued

Explanatory Note:

Although not required by the seafood HACCP regulation, it is advisable to maintain HACCP-plan support documentation described in this chapter.

- ***1. HACCP-Plan Support Documents***

HACCP-support documents include the information and data used to develop the HACCP plan. This includes the written hazard-analysis worksheet (Chapter 5) and records of any information used in performing the hazard analysis and establishing the critical limits.

Support documents may include: sufficient data used to establish the adequacy of any barriers to bacterial pathogen growth, to establish the safe shelf life of the product (if age of the product can affect safety), and to establish the adequacy of a heating process in destroying bacterial pathogens. In addition to data, support documents may also include correspondence with consultants or other experts.

Support documents should also include:
- A list of the HACCP team and their responsibilities.
- A summary of the preliminary steps taken in the development of the HACCP plan.
- Prerequisite programs.

- ***2. Monitoring Records***

HACCP monitoring records are primarily kept to demonstrate control at CCPs. HACCP records provide a useful way to determine if critical limits have been violated. Timely record review by a management representative ensures that the CCPs are being controlled in accordance with the HACCP plan. This was discussed in Chapter 10. Monitoring records also provide a means by which regulators can determine whether a firm is in compliance with its HACCP plan.

By tracking the values recorded on monitoring records, an operator or manager can determine if a process is approaching its critical limit. Trends can be identified through record review to make necessary process adjustments. If timely adjustments are made before the critical limit is violated, processors can reduce or eliminate the labor and material costs associated with corrective actions.

Overhead 4

All HACCP monitoring records should be on forms that contain the following information:
- Form title,
- Firm name and location,
- Time and date,
- Product identification (including product type, package size, processing line and product code, where applicable),
- Actual observation or measurement,
- Critical limits,
- Operator's signature or initials,
- Reviewer's signature or initials, and
- Date of review.

Examples of CCP monitoring records may include:
- Storage temperature records for temperature-sensitive ingredients, in-process materials and finished products where temperature control is necesssary to ensure product safety.
- Container-seal examination records where the hermetic seal affects product safety.
- Salometer-measurement records where salt brine is used to establish a barrier to bacterial pathogen growth in the finished product

- ***3. Corrective Action Records***

Corrective action records were discussed in Chapter 9.

- ***4. Verification Records***

Verification records (Chapter 10) should include:
- Modifications to the HACCP plan (e.g., changes in ingredients, formulations, processing, packaging and distribution);
- Processor audit records verifying supplier compliance with guarantees or certifications;
- Verification of the accuracy and calibration of all monitoring equipment;
- Results of microbiological challenge tests, environmental microbiological tests, and periodic in-line and finished-product microbiological, chemical and physical tests if applicable;
- Results of in-house, on-site inspections; and
- Results of equipment-evaluation tests.

Examples of verification records include:
- Temperature distribution studies for thermal processes.
- Metal detector challenges.

Continued

Notes:

Record-Monitoring Information

Monitoring information should be recorded at the time the observation is made. False or inaccurate records filled out before the operation takes place or ones that are completed later are inappropriate for a HACCP system.

Computerized Records

Computerized records are an option to manual record keeping. When using computerized records, include controls to ensure that records are authentic, accurate and protected from unauthorized changes.

Record Review

Monitoring records for CCPs and critical-limit deviations must be reviewed in a timely manner by a representative of plant management. All records should be signed or initialed and dated by the reviewer. This subject is discussed more in Chapter 10.

ABC Shrimp Company IQF Cooked-Shrimp Example

• ***Monitoring Records***

Sample records are included for each of the monitoring activities identified in columns 4 to 7 of the HACCP plan for IQF cooked shrimp. The names of these forms should be entered in column 10 of the HACCP plan form. These records include:

Figure 1. Raw material evaluation sheet.
This form records the presence or absence of sulfiting agents detected in incoming raw shrimp at the receiving-raw-shrimp step. It is also used to record the vendor's name and the presence or absence of a supplier's certificate for incoming frozen shrimp at the receiving-frozen-shrimp step.

Figure 2. Supplier's guarantee.
This document indicates that the shrimp from this vendor does not contain sulfiting agents.

Figure 3. Shrimp cooker log.
This form is used to record the time and temperature of cooking at the cooker step.

Figure 4. Pack-room inspection record.
The form is used to note that shrimp treated with sulfiting agents are appropriately labeled.

• ***Additional Records***

Figure 5. Laboratory results - sulfite residuals.
This document indicates the results of a laboratory analysis for sulfite residual, which is used as a quarterly verification of the supplier's certification.

Figure 6. Cooking process validation letter.
This document confirms that the cooking critical limits are scientifically sound.

Figure 7. Cooking equipment validation letter.
This document confirms that the temperature throughout the cooking equipment is at or above the critical limit when the equipment is properly operated.

Figure 8. Equipment calibration log.
This form records the results of the quarterly calibration of the MIG thermometers used on the cookers.

Figure 9. Laboratory report - product microbiology.
This document indicates the results of finished product laboratory analyses for total plate count (TPC), coliform bacteria, *Escherichia coli, Staphylococcus aureus* and *Salmonella*.

Figure 10. Sample corrective action record.
This record relates to the cooking process records that have been previously discussed. This form is used to document the action taken when a critical limit is exceeded.

Figure 11. Employee Training Record.
This document indicates the training courses completed by each employee.

Overhead 5

HACCP Plan Form

Records:

1. CCP	2. Hazard	3. Critical Limits	4.–7. Monitoring (What, How, Frequency, Who)	8. Corrective Action(s)	9. Verification	10. Records

Specify the record-keeping procedures for each CCP.

Notes:

Continued

Explanatory Note:

Figure 1 also includes information for a variety of nonsafety attributes in addition to the sulfiting agent information. It exemplifies the use of existing forms for HACCP purposes. Some firms may choose to separate their HACCP records from nonsafety control records. Note the critical limits at the bottom of the form.

Figure 1 and Overhead 6

Raw-Material Evaluation Sheet
ABC Shrimp Co., Smithville, GA

Date: _____ **Time of Examination:** _____
Lot Number: _____ Declared Wt: _____
Actual Wt: _____
Brand: _____ Country of Origin: _____
Packer: _____ Shrimp Type: _____
Vendor: _____ Process Type: _____

Sample No.	*1*	*2*	*3*	*4*	*5*	*6*
Actual Color						
Frozen Wt.						
Drained Wt.						
No./Pkg.						
Ct./Lb.						
% Peel						
% Pieces						
% Shell Spots						
Foreign Mat.						
% Meat Spots						
Dehydrated						
% Swimmerets						
% Missing Tail						
Sulfites						
Veins						
Phosphate						
% Spines						
Bleaching						
% Discolored						
Salt						
Bilge Odor						
Stale						

Certificate for Sulfite Use (Yes/No): _____
Operator: _____
Reviewed By: _____ **Date:** _____

(Items in bold are part of HACCP record.)

Figure 2 and Overhead 7

Supplier's Guarantee
East Bay Fishing Co., Yourtown, LA

December 25, 1995

ABC Shrimp Co.
P.O. Box 54
Smithville, GA 43898

Dear Mr. Smith,
This certifies that, in accordance with your purchasing specification, this shipment of frozen shrimp has not been treated with any sulfite compounds — East Bay Lot Number 12345.

Yours truly,
Ira M. Honest
QC Director, East Bay Fishing Co.

Figure 3 and Overhead 8

Shrimp Cooker Log
ABC Shrimp Co., Smithville, GA

Date: 3/4/96 Critical Limits: ≥ 212 F for ≥ 3 minutes

Line: Number 1 Product: IQF cooked shrimp

Operator: Jamie Good

Line Number	Lot Number	Time of Day	Steam Temp. (F)	Temp. from Recorder (F)	Cook Time (Min.)	Critical Limits Met	Comments
1	034	2:34 p.m.		214	3.2	Yes	
1	043	3:30 p.m.		214	3.2	Yes	
1	053	4:28 p.m.		**210**	3.1	No	*See corrective actions*
1	053	4:29 p.m.		212		Yes	Steam valve adjusted
1	053	5:01 p.m.	213	212	3.1	Yes	

Temperature/time to be checked hourly during operation.

Reviewer:_____ Date: _____

If critical limits are exceeded, notify the shift supervisor, and separate and identify the batch involved.

Notes:

Explanatory Note:

Figure 3: Continuous temperature monitoring is performed by a recording thermometer. Manual time and temperature checks are performed every hour, and the operator confirms that the critical limit was continually met since the last reading. Time checks are performed by determining how long it takes a block to move through the steam tunnel using a stopwatch. A comparison between the standard thermometer and the recording thermometer is made daily. A deviation occurred at 4:28 p.m., triggering a corrective action that is documented in Figure 10. Note that during the 5:01 p.m. temperature check, the recording thermometer was reading lower than the standard thermometer. This condition is acceptable as long as the two instruments are as close as reasonably possible. However, it would not be acceptable for the recording thermometer to read higher than the standard thermometer.

Notes:

Figure 4 and Overhead 9

Pack-Room Inspection Record
ABC Shrimp Co., Smithville, GA

Date: 3/4/95

Line: Number 1 Product: IQF cooked shrimp

Label Room Supervisor: Betty Smith

Lot Number	Time of Day	Presence of Sulfiting Agents Yes/No	Sulfite Statement on Label Yes/No	Label Type & Comments
043	3:45 p.m.	Yes	Yes	ABC 8 oz.
044	4:45 p.m.	Yes	Yes	Smith Brothers 12 oz.

Reviewer: _____ Date of Review: _____

Critical Limits: *All shrimp treated with sulfiting agents must be accurately labeled.*

Figure 5 and Overhead 10

A-One Laboratory Report for:
ABC Shrimp Co., Smithville, GA

Date: 3/5/95 Sample Number: ABC Shrimp lot# 002

Vendor: East Bay Sulfites, ppm: < 10 ppm

Examined by: Sheila Good

Remarks:

The above sample was analyzed for the presence of sulfites using official AOAC recognized methods.

Irvine R. Wright
Laboratory Director
A-One Laboratories
Jonestown, PA 25418

Figure 6 and Overhead 11

Cooking-Process Validation Letter
Seafood Processing Research and Extension Unit
Your State University

January 5, 1996

ABC Shrimp Co.
P.O. Box 54
Smithville, GA 43898

Dear Mr. Smith:

Various published studies document that a process which provides an internal temperature of 145 F in shrimp is adequate for pasteurization. This supports our studies revealing that pathogenic organisms are destroyed by processing the shrimp at 212 F for three minutes. This process provides an internal temperature above 145 F for a minimum of 15 seconds.

Sincerely,
I.M. Helpful
Seafood Processing Research and Extension Unit
Your State University

Notes:

Explanatory Note:

Figure 7: Emphasize that all thermal-processing equipment should be tested to verify that it will perform the required process.

Figure 7 and Overhead 12

Cooking-Equipment Validation Letter
Seafood Processing Research and Extension Unit
Your State University

January 5, 1996

ABC Shrimp Co.
P.O. Box 54
Smithville, GA 43898

Dear Mr. Smith:

On Dec. 20, 1995, during a visit to your firm, temperature distribution tests were performed in your shrimp steam cooker on line number one using a portable data logger and 12 thermocouple leads. Test results from three production runs indicated that the temperature distribution in your steam cooker, when operated at a mercury-in-glass reading of 212 F, ranges from 212 F to 214 F. These studies indicate that your steam cooker continues to operate as designed.

On this same date, the internal temperature of six shrimp from individual lots of large (3.5 to 5.0 shrimp per oz.), medium (5.0 to 9.0 shrimp per oz.) and small (9.0 to 17.0 shrimp per oz.) shrimp were measured in the cooker during production runs at 212 F for three minutes. The internal temperature of the large shrimp exceeded 150 F; the medium shrimp, 160 F; and the small shrimp, 165 F. The internal temperatures noted during these tests exceed your firm's HACCP critical limits of an internal temperature of 145 F for 15 seconds.

Sincerely,
I.M. Helpful
Seafood Processing Research and Extension Unit
Your State University

Figure 8 and Overhead 13

Equipment-Calibration Log
Temperature Measurement
Instrument/Equipment
ABC Shrimp Co., Smithville, GA

Instrument/Equipment: Standard thermometer

Location in Plant: Shrimp Cooker Line Number One

Serial Number: B546

Model Number: Always Right 140 F to 260 F

Date Received in Plant: 3/2/95

Date Calibrated	Calibration Results	Method of Calibration	Employee	Reviewer Date
3/15/95	Thermometer was in calibration.	Tested in steam flow 215 F using certified thermometer S.N. 07569	Sam Smith	Becky Allen 3/18/95
6/12/95	Thermometer scale adjusted 1 F down to match standard thermometer.	Tested in steam flow 215 F using certified thermometer S.N. 07569	Stan Jones	Becky Allen 6/15/95
9/10/95	Thermometer was in calibration.	Tested in steam flow 215 F using certified thermometer S.N. 56432	Sam Smith	Joe Noble 9/15/95
12/2/95	Thermometer was reading 5 F below the standard thermometer scale. Adjusted.	Tested in steam flow 215 F using certified thermometer S.N. 56432	Sam Smith	Becky Allen 12/6/95
2/29/96	Thermometer was in calibration.	Tested in oil bath 215 F by laboratory using certified thermometer S.N. 56432	Jean Jones	Joe Noble 3/3/96

Explanatory Note:

Figure 8: Emphasize that all monitoring equipment such as thermometers and scales should be checked against a standard. In some cases, this standard may be a boiling-water bath, an ice slush or a known weight, depending upon the instrument and the accuracy requirements for the critical limit being monitored. Note that on the 6/12/89 calibration, the thermometer was 1 F above the standard. This could have an impact on the previously produced product and could have resulted in critical limit deviations. These should be evaluated, and appropriate corrective action should be taken and recorded.

Explanatory Note:

There are situations when the results of a verification activity would necessitate a corrective action. For example, with the positive *Salmonella* result in Batch 1, it would be appropriate for the processor to hold any of the affected lot still in storage and recall any of the product that was no longer under the processor's control. Then the processor could recook or destroy the lot. It would also be appropriate to re-evaluate the HACCP plan and its implementation to determine how the defect could have occurred.

Explanatory Note:

Figure 9: Finished product analyses may often be included as part of a firm's periodic verification efforts. Firms should establish specifications for the microbiological tests that are performed as part of verification.

Figure 9 and Overhead 14

A-One Laboratory Report
ABC Shrimp Co., Smithville, GA

Date: 4/5/96 Sample No.: ABC Shrimp Lot # 0112

Vendor: East Bay Analyst: Sheila Good

The results of the analyses of sample 0112 consisting of 6/8 oz. samples of shrimp identified as batch 1 to 6 are as follows:

Batch	T.P.C./ g	Coliforms/ 10g	E. Coli/ 10g	Staph/ g	Salmonella/ sample
1	40	0	0	Negative	Positive
2	48	0	0	Negative	Negative
3	20	0	0	Negative	Negative
4	56	0	0	Negative	Negative
5	40	0	0	Negative	Negative
6	20	2	0	Negative	Negative

Remarks:

The above sample was analyzed using methods found in the FDA Bacteriological Analytic Manual, 7th Edition.

Irvine R. Wright
Laboratory Director
A-One Laboratories
Jonestown, PA 25418

Figure 10 and Overhead 15

Corrective-Action Report
ABC Shrimp Co., Smithville, GA

Date: 3/4/96 Lot I.D.: 053

Description of Problem:

At 4:28 p.m., the temperature dropped to 210 F for 30 seconds according to the recorder.

Action Taken:

Temperature drop was noted immediately. Steam valve was adjusted and the product exiting the cooker for the next five minutes was destroyed.

Date Problem Solved: 3/4/96

Current Status:

Remainder of lot is acceptable.

Supervisor: Ollie K. Fellows

Reviewer: Seymour Samples Date: 3/4/96

Explanatary Note:

See Figure 3 for corresponding monitoring record showing process deviation.

Explanatory Note:

Figure 10: The critical limit failure in the first corrective action report would not likely have been noted without the continuous monitoring provided by the recording thermometer. In a continuous cooker, when a temperature drop occurs, the product in the cooker at the time of the deviation must be held and evaluated, recooked, destroyed or shifted to some other acceptable use unless the line can be stopped to give a still cook.

Notes:

Figure 11 and Overhead 16

Employee-Training Record
ABC Shrimp Co.

Employee: Richard J. Smith

Training Course	Date of Course
Sanitation in the processing plant, 4-hour course, state inspection service.	July 6, 1994
Computer operation of the pasteurizer, Best Yet Pasteurizer Co., John Jones, customer representative. three days on-the-job training.	Feb. 2-5, 1995
Sanitation in the processing plant, 4-hour course, state inspection service, update.	Aug. 3, 1995

EXAMPLE: For Illustrative Purposes Only - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Cooker	Survival of bacterial pathogens	Cook at 212 F for three minutes (to achieve minimum internal temperature of 145 F for 15 seconds)	Cook temperature	• Monitor temperature with a continuous temperature recorder	• Temperature monitored continuously with hourly visual checks.	• Quality-control supervisor will program the continuous-recording thermometer.	If temperature or time parameters are not met, then processing line will be stopped and required adjustments made. All product produced during the deviation will be recooked or destroyed.	• Daily record review • Quarterly calibration of thermometer • Semi-annual finished-product microbial testing • Process validation study of time and temperature of cook and its effect on the final internal temperature of various sizes of shrimp and initial temperature (on file) • Cooking equipment validation study (on file)	• Cooker log • Recording charts
			Cook time	• Monitor cook time by timing the movement of a block placed on belt through cooker.	• Cook time monitored hourly.	• Cook will perform the hourly checks.			

Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliance with weigh/pack/label critical limits.

Firm Name: *ABC Shrimp Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Cooked and frozen, headless, peeled and deveined shrimp*

Method of Storage and Distribution: *Frozen*

Intended Use and Consumer: *Thaw and serve*

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

EXAMPLE: For Illustrative Purposes Only - HACCP Plan Form

ABC Shrimp Co.

Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Weigh/Pack Label	Allergic-type reaction from undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence	• At weigh/pack/ label stage, check for "contains sulfite" declaration.	• Examine all labels issued at packing line and match declaration with product identity.	• One label each time a label roll is replaced	• Packing supervisor	If this product is mislabeled, then appropriately label.	• Daily record review	• Pack-room inspection sheet
			• At receiving, sample each vessel of fresh shrimp to test for presence of sulfites.	• Rapid sulfite test	• Fresh shrimp, three-grab samples per vessel	• Dock master		• Daily record review • Quarterly lab report for sulfite (fresh shrimp)	• Raw-material evaluation sheets
			• At receiving, supplier declaration for absence of sulfites for frozen shrimp.	• Observation of supplier declaration	• Frozen shrimp, check every shipment	• Dock master		• Daily record review • Quarterly lab report for sulfite (frozen shrimp)	• Supplier guarantees
Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliance with weigh/pack/label critical limits.									

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

Chapter 12: The Seafood HACCP Regulation

Notes:

Overhead 1

Objective:
In this module, you will learn:
- What are the requirements of the seafood HACCP regulation.
- How to reference the specific requirements.

In December 1997, the FDA initiated a seafood regulation based on the seven principles of HACCP called "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products." This regulation has become known as "the seafood HACCP regulation." It will be referred to in this chapter as "the regulation." A copy of the regulation is provided in Appendix I.

- ***Regulation Format***

The regulation is part of Title 21 of the Code of Federal Regulations (CFR), Part 123, and is subdivided into three subparts and 13 sections.

Overhead 2

Regulation Format

Subpart A — General provisions
- 123.3 Definitions
- 123.5 Current GMPs
- 123.6 HACCP plan
- 123.7 Corrective actions
- 123.8 Verification
- 123.9 Records
- 123.10 Training
- 123.11 Sanitation control procedures
- 123.12 Special requirements for imported products

Subpart B — Smoked and smoke-flavored fishery products
- 123.15 General
- 123.16 Process controls

Subpart C — Raw molluscan shellfish
- 123.20 General
- 123.28 Source controls

Continued

Explanatory Note:

The terms "fish" and "fishery product" together define the products that are subject to this regulation.

- ***Definitions 123.3***

Twenty important terms are used throughout the regulation. They are:

Overhead 3

Definitions 123.3

- certification number
- critical control point
- critical limit
- fish
- fishery product
- hazard
- importer
- molluscan shellfish
- preventive measure
- process-monitoring instrument
- processing
- processor
- scombroid toxin-forming species
- shall
- shellfish-control authority
- shellstock
- should
- shucked shellfish
- smoked or smoke-flavored fishery products
- tag

Of the terms listed above, a few definitions need to be emphasized.

Fish means freshwater or saltwater finfish, crustaceans, aquatic animal life (including alligators, frogs, aquatic turtles, jellyfish, sea cucumbers, sea urchins and roe) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

Fishery product means any human food product where fish is a characterizing ingredient. [Note: This definition exempts products from the mandatory HACCP requirements that contain inconsequential amounts of fish. For example, Worcestershire sauce contains some anchovy paste but is not characterized by that ingredient.]

Overhead 4

Who must comply?

Importer
Processor — domestic and foreign

Importer means either the U.S. owner/consignee or the U.S. agent/representative of the foreign owner/consignee at the time of the product's entry into the United States. This person is responsible for ensuring that goods being offered for entry are in compliance with all laws affecting the importation. Ordinarily, the importer is not the custom-house broker, freight forwarder, carrier or steamship representative. [Note: The ownership of an imported product can change many times in a short period of time after entry into the United States. However, the person who is the owner or consignee at the time that the product is offered for entry is identified as the importer because: 1) that person has the ability to decide whether to offer the product for entry, and 2) that person is in a position to ensure that the product is processed under appropriate controls and to demonstrate this to FDA.]

Processor means any person engaged in commercial, custom or institutional processing of fish or fishery products either in the United States or in a foreign country.

Processing means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading or holding fish or fishery products. [Note: Eviscerating done by an aquaculture grower before delivery to a processing plant would make it necessary for the grower to comply with the requirements of this regulation. Fishing vessels and carriers may be affected by this regulation indirectly through the controls that processors may impose on them to meet HACCP obligations. However, vessels are not directly affected by the regulation, except for factory trawlers and similar vessels. Retail establishments must follow state and local government regulations. The Food Code (FDA's model food ordinance that many state and local regulatory authorities use in developing their food laws and regulations) requires that raw materials for retail establishments come from approved sources.]

Overhead 5

This regulation does not apply to:
- The harvest or transport of fish or fishery products.
- Practices such as heading, eviscerating or freezing intended solely to prepare a fish for holding on a harvest vessel.
- The operation of a retail establishment.

Shall is used to state mandatory requirements.

Should is used to state recommended or advisory procedures or to identify recommended equipment.

Continued

Explanatory Note:

The terms importer, processor and processing together define who is subject to this regulation.

Explanatory Note:

Products that do not move in interstate commerce are not subject to the regulation. However, products are considered to have entered into interstate commerce if raw materials, ingredients, packaging, etc. have originated outside the state.

Explanatory Note:

The use of the term "should" in the FDA regulation may differ from its use in Chapters 5 through 11 of this manual. Chapters 5 through 11 are designed to teach the principles of HACCP, including certain activities that need to be carried out to properly implement HACCP plans. Identifying these activities as those that "should" be enacted means they are important for the HACCP program to be effective. Many of these activities may be mandatory elements of the regulation.

Notes:

- ***Current Good Manufacturing Practices (CGMPs) 123.5***

Overhead 6

Current Good Manufacturing Practices 123.5

- Regulations found in Title 21, Part 110 of the Code of Federal Regulations
- Proper practices for the safe and sanitary handling of all foods

The Food Drug and Cosmetic Act deems food to be adulterated if processed under insanitary conditions. The Current Good Manufacturing Practices describe the conditions and practices that must be followed to avoid producing adulterated food product. Part 110 applies to the processing of all FDA-regulated food products including fish and fishery products because it is the basis for determining whether the facilities, methods, practices and controls used to process these products are safe and whether the products have been processed under sanitary conditions. The purpose of the seafood HACCP regulation is to set out requirements specific to the processing of fish and fishery products.

- ***Hazard Analysis 123.6(a)***

Overhead 7

Hazard Analysis 123.6(a)

Every processor shall conduct or have conducted a hazard analysis.

The regulation requires that every processor perform a hazard analysis. It outlines two major steps in a hazard analysis:
- Determine whether there are hazards that are reasonably likely to occur.
- Identify preventive measures to control the identified hazards.

Overhead 8

Hazards that are "reasonably likely to occur:"

Those "for which a prudent processor would establish controls"

This means a prudent processor would establish controls because there is a reasonable possibility that a hazard will occur. To make this decision, examine:

- Experience,
- Illness data,
- Scientific reports and
- Other information
  (e.g., FDA's Fish and Fishery Products Hazards and Control Guide).

The criteria for including a food-safety hazard in a processor's HACCP plan should be the likelihood that the hazard will occur or develop in that product without proper controls (e.g., based on the processing technique, the harvest location, the species).

An example of a hazard that is reasonably likely to occur is histamine in certain fish species. Histamine reaction is one of the most frequently reported illnesses from seafood. The relationship between time and temperature abuse after harvest and the formation of the toxin is well-established.

It is the end product of the hazard analysis — the HACCP plan and its implementation — that will be judged by the regulator and not the hazard analysis itself. For this reason, the regulation does not require that the hazard analysis be performed in any particular way or that it be documented in writing for regulatory review. However, a written hazard analysis will help the processor remember the thought process used to identify the hazards and develop the HACCP plan. This will be useful when periodic plan reassessments are conducted and when the plan is reviewed by regulators.

- ***HACCP Plan 123.6(b)***

Overhead 9

HACCP Plan 123.6(b)

Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food-safety hazards that are reasonably likely to occur.

Overhead 10

A HACCP plan shall be specific to:

- Each processing location.
- Each species of fish and type of fishery product.

When HACCP plan components are similar, some fish and fishery products may be grouped under a single HACCP plan.

Continued

Notes:

Notes:

- ***HACCP Plan Contents 123.6(c)***

Overhead 11

The HACCP plan shall:

- List the food-safety hazards that are reasonably likely to occur.
- List the CCPs.
- List the critical limits.
- List the monitoring procedures.
- List predetermined corrective-action plans.*
- List the verification measures.
- Provide for a system of monitoring records.

** Processors are not required to predetermine corrective actions.*

Food-safety hazards can include: natural toxins, microbiological contamination, chemical contamination, pesticides, drug residues, decomposition that is related to safety (e.g., scombroid toxin-forming species), parasites that are related to safety (e.g., fish used for raw consumption), unapproved food and color additives, and physical hazards. They can be hazards that are introduced inside the processing plant or hazards that occur before, during or after harvest.

The frequencies of the monitoring and verification procedures must be included in the HACCP plan. Monitoring records must provide the actual values or observations noted during monitoring.

- ***Signing and Dating the HACCP Plan 123.6(d)***

Overhead 12

The HACCP plan shall be signed and dated by:

The most responsible individual at the processing facility or a higher level official of the processor.

This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

Overhead 13

The HACCP plan shall be signed and dated:

- Upon initial acceptance.
- Upon any modification.*
- At least annually.*

** This is a verification requirement.*

- ***Low Acid Canned Foods and Acidified Foods 123.6(e)***

Processors who must comply with the requirements of part 113 or 114 (acidified and low-acid canned foods) of the CFR do not need to address the hazard of *Clostridium botulinum* in their HACCP plans. Their HACCP plans do not need to include controls to prevent that hazard, but they must continue to comply with 113 or 114. Other hazards may be reasonably likely to occur in an acidified or low-acid canned fishery product (e.g., histamine in canned tuna), and these must be addressed in the HACCP plan as appropriate.

- ***Sanitation Controls and the HACCP Plan 123.6(f)***

FDA recognizes that sanitation controls may be troublesome to manage in a HACCP plan. It is often difficult to determine appropriate critical limits and corrective actions for sanitation controls, particularly those relating to personnel hygiene (e.g., hand washing). For this reason, the regulation does not require that sanitation controls be included in the HACCP plan. However, sanitation controls that are not in the plan must be monitored according to the sanitation provisions of the regulation. Sanitation is discussed in section 123.11.

- ***Legal Basis 123.6(g)***

FDA's application of HACCP is primarily based on the Federal Food Drug and Cosmetic Act. This section of the act makes it unlawful to process food under conditions that may render it injurious to health. Any fish or fishery products processed or imported in violation of this regulation can be considered adulterated and subject to regulatory action.

Continued

Notes:

Explanatory Note:

HACCP plans will not be preapproved by FDA before they are implemented by the processor. They should not be submitted to the agency for review. FDA reached this decision because:

- HACCP plans should be evaluated on-site, a process best accomplished during inspections of processing facilities.
- FDA does not have sufficient resources to review HACCP plans from all domestic and foreign seafood processors in advance of HACCP implementation by processors.

Notes:

- ***Corrective Action 123.7***

Overhead 14

Corrective Action 123.7

Whenever a deviation from a critical limit occurs, a processor shall take corrective action.

The regulation requires that a corrective action take place whenever a critical limit is not met at a CCP.

Overhead 15

Corrective Actions — Two Choices

- Predetermined
- Alternate Procedure
    - Segregate and hold product.
    - Determine product acceptability.
    - Apply corrective action to product and process.
    - Reassess the HACCP plan.

Processors have a choice of developing a predetermined corrective-action plan in advance as part of their HACCP plans or of following the alternate procedure for corrective actions provided in the regulation. When a processor develops a plan in advance, he/she follows the plan that is appropriate when the deviation occurs. These corrective-action plans become part of their HACCP plans as previously described in section 123.6(c).

A predetermined corrective-action plan provides a processor with benefits such as faster action when a deviation occurs and less need to justify to management the appropriateness of the corrective action after it has been taken. But unusual situations may arise that may not be addressed in predetermined corrective-action plans. Processors may choose not to predetermine their corrective actions. In these cases, the alternate corrective-action procedure must be followed.

A proper corrective-action plan describes the steps that are to be taken and assigns responsibility for taking those steps. It is designed to ensure that:

- No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.
- The cause of the deviation is corrected.

The alternate corrective-action procedure involves:

- Segregating and holding the affected product until the next two requirements are met.
- Determining whether the product is safe for distribution. This decision must be made by someone who has suitable training or experience. This training or experience must be in the field(s) of science that is necessary for the person to understand the public health consequences of the critical-limit deviation.
- Take corrective action, as necessary, to ensure no unsafe product enters commerce.
- Take corrective action, as necessary, to fix the problem that caused the deviation.
- Determine whether the HACCP plan needs to be modified to reduce the risk that the deviation will happen again and modify the HACCP plan as necessary. This decision must be made by someone who has met the training requirements covered in section 123.10.

All corrective actions must be fully documented in records.

- ***Verification 123.8***

Overhead 16

Every processor shall verify:

- That the HACCP plan is adequate to control the food-safety hazards that are reasonably likely to occur.
- That the HACCP plan is implemented effectively.

Every processor must verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification must include, at a minimum, reassessment of the HACCP plan, ongoing verification activities, and record reviews.

The HACCP plan must be reassessed at least once per year and whenever any changes occur that could affect the hazard analysis or the HACCP plan in any way. This could include changes in:

- Raw materials or source of raw materials.
- Product formulation.
- Processing methods or systems.
- Finished product distribution systems.
- The intended use or consumers of the finished product.

The purpose of the reassessment is to ensure that the HACCP plan is adequate to control the food-safety hazards which are reasonably likely to occur. It must be performed by an individual who meets the training requirements described in section 123.10. If a processor has no HACCP plan because no significant hazards were identified, then the hazard analysis must be reassessed whenever any changes occur that could affect the hazard analysis.

Continued

Notes:

Notes:

The regulation requires ongoing verification activities in addition to periodic reassessment. These ongoing activities are in keeping with the HACCP principle that verification must ensure that the HACCP plan is being implemented on a day-to-day basis. These ongoing verification procedures must be listed in the HACCP plan.

Overhead 17

Ongoing verification:
- Consumer complaint review.
- Calibration of process-monitoring instruments.
- Periodic end-product and in-process testing (processor's option).

Records must be kept of the calibration procedures and end-product or in-process testing that is performed as part of a processor's HACCP activities.

Consumer complaints must be reviewed by the processor to determine whether they relate to problems at a CCP. The regulation does not give regulators access to consumer complaints but does give them access to corrective action records that relate to problems identified by consumer complaints.

Overhead 18

Review of records:
- CCP monitoring records.
- Corrective-action records.
- Calibration records.
- In-process and end-product testing records.

Explanatory Note:

Importer and sanitation records are not required to be reviewed.

The regulation requires that processors review certain records as part of verification. The purpose of these reviews is to ensure that the records are complete and that the activities occurred in accordance with the processor's written procedures. The records must be reviewed by someone who meets the training requirements described in section 123.10.

Monitoring and corrective-action records must be reviewed within one week of when the record was made. Calibration and in-process or end-product testing records must be reviewed in a timely manner.

Sometimes the review of a consumer complaint or the performance of verification procedure will indicate a potential public-health problem. When this happens, the processor must follow the corrective-action procedures described in section 123.7.

• ***Records 123.9***

Overhead 19

Records required by the regulation:
- Monitoring records.
- Corrective-action records.
- Verification records.
- Sanitation-control records.
- Importer-verification records.

The records required by the regulation must:
- Contain certain information.
- Be completed at the time of the activity.
- Be signed or initialed by the operator or observer.
- Be retained for specified periods of time.
- Be available for review and copying by regulatory authorities.

Overhead 20

Required information on each record:
- Name and location of the processor or importer.
- Date and time of the activity being recorded.
- Signature or initials of the person making the record.
- Identity of the product and the production code where appropriate.

Overhead 21

Record retention:
- One year for refrigerated products.
- Two years for frozen or preserved products.

If permanent storage at the processing facility is not practical (e.g., a remote processing site or a processing vessel), the records may be transferred to some other facility at the end of the season. But the records must be able to be promptly returned when requested by a regulatory agency.

Notes:

Continued

Notes:

A key feature of the HACCP verification process is access by government inspectors to the the HACCP plan, monitoring records and corrective-action records. Examination of HACCP records enables an inspector to see how the processing facility operates over time rather than just on the day of the inspection. Additionally, it enables the inspector to review the adequacy of the processor's preventive-control system.

FDA has concluded that records and plans should be protected to the extent possible to promote the implementation of HACCP across the seafood industry. The regulation generally states that HACCP plans and records which come into FDA's possession will be treated as either trade secrets or commercial confidential materials.

- ***Training 123.10***

The regulation requires that certain activities and functions be performed by an individual trained in HACCP.

Overhead 22

The HACCP-trained individual shall:
- Develop the HACCP plan.
- Reassess and modify the HACCP plan and hazard analysis.
- Review HACCP records.

Processors can use a trained employee or a trained third party to perform these functions. The jobs may be done by one person or by several as long as they have been properly trained. The regulation defines a "HACCP-trained individual" as one "who has successfully completed training in the application of HACCP principles to fish and fishery product processing that is at least equivalent to that received under a standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify if it has provided knowledge at least equivalent to that provided through the standardized curriculum." This course material, developed by the National Seafood HACCP Alliance, is the standardized curriculum that has been recognized by FDA.

- ***Sanitation Control Procedures (SCP) 123.11***

Sanitation is a prerequisite program that is necessary for the effective implementation of HACCP. In writing the seafood HACCP regulation, FDA concluded that the GMP regulations (21 CFR 110) had not proven fully effective in encouraging seafood processors to take full responsibility for ensuring that sanitation in their plants consistently met minimum standards. For these reasons, the regulation requires that processors take certain actions to control sanitation conditions and practices.

These actions must be taken even if a processor determines there is no need for a HACCP plan. The sanitation requirements of the regulation may be made part of the processor's HACCP plan or may be managed separately. Some processors may choose to use a combination of these approaches.

Overhead 23

General Requirement
- Current GMP regulations are the standard for proper sanitation conditions and practices.
- Eight key sanitation conditions and practices.
- Mandatory sanitation monitoring with record keeping.
- Mandatory corrections with record keeping.
- Recommended SSOP.

The SCP regulation encourages, but does not require, that each processor develops a Sanitation Standard Operating Procedures (SSOP). The SSOP should describe how the processor will ensure that certain key sanitation conditions and practices will be met. It should also describe how the plant operations will be monitored to ensure that the conditions and practices will be met.

Whether or not a processor chooses to write an SSOP, the key sanitation conditions and practices that are relevant to the plant must be monitored.

Overhead 24

Eight key sanitation conditions and practices:
- Safety of water.
- Condition and cleanliness of food-contact surfaces.
- Prevention of cross-contamination.
- Maintenance of hand-washing, hand-sanitizing and toilet facilities.
- Protection from adulterants.
- Labeling, storage and use of toxic compounds.
- Employee health conditions.
- Exclusion of pests.

The purpose of the monitoring is to ensure that the requirements of the current GMP regulations are met. Monitoring frequencies are not specified but must be sufficient to ensure that the current GMP requirements are met.

Continued

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When the conditions and practices contained in the current GMP regulations are not met, they must be corrected in a timely manner. Records must be kept of the monitoring and the corrections. These records are subject to the same requirements as the HACCP records, except plant-verification review.

- ***Imported Products 123.12***

It has always been the importer's responsibility to offer for entry into this country products that are not adulterated under U.S. law. FDA's surveillance system for imports has traditionally consisted of: reviews of customs entry forms for fish and fishery products being offered for entry into the United States, sensory analyses (wharf examinations) and sample collections for laboratory anlysis of products awaiting entry, and automatic detention of products with a history of problems. As with traditional processing-plant inspections, this method is a "snapshot" approach that is not preventive.

Under the seafood HACCP regulation, HACCP controls are required for imported fish and fishery products as well as for domestic products. The definition of processor explicitly includes those who process seafood in foreign countries. Additionally, the regulation requires that importers take certain steps to verify that their foreign suppliers meet the requirements of the regulation.

Overhead 25

Importer Verification:
- Import from countries with a memorandum of understanding (MOU) or
- Implement verification procedures.

Importers may meet their obligation in one of two ways. They may import fish and fishery products that are covered by memorandums of understanding between the United States and a foreign country. In this case, they do not need to take any other action to meet the requirements of the regulation.

Otherwise, the importer must have and implement written verification procedures for ensuring that the fish and fishery products offered for import into the United States were processed in accordance with the requirements of the regulation.

Notes:

Overhead 26

Importer Verification Procedures:
- Product specifications and
- Affirmative steps.

Product specifications should cover those characteristics of the product that would be useful in providing assurance that the product is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act. This section relates to contaminants that may render the food injurious to health and to insanitary processing conditions. It may be appropriate for a specification for frozen tuna steaks to include a maximum limit for histamine of 50 ppm.

Overhead 27

Importer Verification Procedures

Affirmative steps may include any of the following:
- Obtain foreign processor's HACCP and sanitation monitoring records for the lot being entered.
- Obtain continuing or lot-by-lot certificate from competent third party.
- Regularly inspect foreign processor.
- Obtain foreign processor's HACCP plan and written guarantee that regulation is being met.
- Test the product and obtain written guarantee that regulation is being met.
- Perform other verification procedures that provide equivalent level of assurance.

An importer may hire a competent third party to perform verification activities. However, the importer remains responsible for demonstrating to FDA that the requirements have been met.

The importer must keep records in English that document that the affirmative steps have been performed. The records must describe the results of the steps. These records are subject to the records requirements described in section 123.9. Importers that also process fish or fishery products must also meet the HACCP and sanitation requirements of the regulation for their processing operations.

Continued

Notes:

- ***Smoked and Smoke-Flavored Fishery Products 123.15 and 123.16***

Overhead 28

Smoked and Smoke-Flavored Fishery Products
- HACCP plan must include controls for *Clostridium botulinum* toxin formation for the shelf life of the product under normal and moderate abuse conditions.
- Where product is subject to 21 CFR 113 or 114, the HACCP plan need not include such controls.

Smoked fish has been linked to a few cases of botulism. *Clostridium botulinum*, the bacteria that causes botulism, is prevented from growing in properly smoked fish by a combination of barriers, including salt, smoke, nitrite and, in the case of hot-smoked fish, heat. Careful control of these parameters is necessary to ensure the safety of the finished product. Such controls must be included in the HACCP plans of these products, unless the product is preserved by the addition of acid or heat under the controls required by the acidified or low-acid canned food regulations (21 CFR 113 and 114).

It is important to note that if there are other significant hazards, they must be included in the HACCP plan.

- ***Raw Molluscan Shellfish 123.20 and 123.28 and Control of Communicable Diseases 1240.60***

Overhead 29

Raw Molluscan Shellfish 123.20
- HACCP plans must include a means for controlling the origin of the raw molluscan shellfish.
- Where processing includes a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern, the HACCP plan need not include controls on sources of origin.

The largest number of reported illnesses from consumption of seafood is caused by raw molluscan shellfish (oysters, clams and mussels). These hazards are primarily introduced before the molluscan shellfish are harvested. The risk of occurrence of these hazards is reduced by ensuring that the molluscan shellfish come from sanitary growing waters. In most cases, the sanitary quality of molluscan-shellfish growing waters is determined by a state or national agency called a shellfish-control authority.

The regulation provides very specific requirements for controlling the source of origin for raw molluscan shellfish. It is important to note, however, that other hazards may also be reasonably likely to occur in these products, and they must be identified in the HACCP plan.

Overhead 30

Raw Molluscan Shellfish 123.28
Processors shall only process molluscan shellfish from:
- Growing waters approved by a shellfish-control authority.
- Federal growing waters not closed by an agency of the federal government.

Overhead 31

Raw Molluscan Shellfish 123.28
Shellstock Receiving
- If source is a harvester, harvester must be in compliance with any license requirement.
- If source is another processor, processor must be certified by a shellfish-control authority.
- Containers of shellstock must be properly tagged.

Overhead 32

Raw Molluscan Shellfish 1240.60
Required information on tag:
- Date and place shellfish were harvested (state and site).
- Type and quantity of shellfish.
- Harvester identification number, name of harvester or name or registration number of harvester's vessel.

Continued

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Overhead 33

Raw Molluscan Shellfish 123.28
Records for shellstock receiving must document:
- Date of harvest.
- Location of harvest by state and site.
- Quantity and type of shellfish.
- Date of receipt by the processor.
- Name of harvester, name or registration number of the harvester's vessel or harvester's identification number.

Overhead 34

Raw Molluscan Shellfish 123.28
Shucked molluscan shellfish containers must bear a label that contains:
- Name of packer or repacker.
- Address of packer or repacker.
- Certification number of packer or repacker.

Overhead 35

Raw Molluscan Shellfish 123.28
Records for shucked product must document:
- Date of receipt.
- Quantity and type of shellfish.
- Name and certification number of the packer or repacker.

Chapter 13: Sources of Information on Preparing HACCP Plans

Overhead 1

Objective:
In this module, you will learn:
- What sources of information exist to help you identify seafood safety hazards and establish control measures.
- How to use the *Fish and Fishery Products Hazards and Controls Guide* to identify hazards and establish control measures.

Overhead 2

Sources of Information:
- Seafood processors
- Government inspectors
- Trade associations
- Suppliers and buyers
- Sea Grant/Cooperative Extension
- Publications
  - *Fish and Fishery Products Hazards and Control Guide*
  - Compliance policy guides
  - Import alerts
  - National Shellfish Sanitation Program manuals
  - U.S. Department of Agriculture
  - Model Seafood Surveillance Project (National Marine Fisheries Service)
  - Seafood Safety (National Academy of Sciences)
  - Morbidity and Mortality Weekly Report (Centers for Disease Control and Prevention)
  - Recommended International Code of Practice (CODEX)
  - Food Safety Enhancement Program (Agriculture Canada)
  - Quality Management Program (Fisheries and Oceans Canada)

Explanatory Note:

Although not required by the seafood HACCP regulation, it is advisable to maintain HACCP plan supporting documentation described in this chapter.

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Sources of Information on Seafood Hazards and Control Measures

Appendix III introduced the hazards that are common in fish and fishery products. It also provided some information about how these hazards can be controlled. You will need to perform a hazard analysis to decide whether these or other hazards are reasonably likely to occur in your products. Also, control measures need to be devised that make sense for your operations. To do this, gather information from a variety of sources and choose the information that best applies to your situation. Some of the most useful sources are described in this chapter.

- ***The Seafood Processor***

You and your employees know your operation better than anyone. Experience is an excellent source of information. You may already have knowledge about hazards that can affect your product, and you may have already implemented suitable controls.

- ***Government Inspectors***

Federal, state and local inspectors that visit your plant can be a good source of information. Inspectors may point out potential hazards, but it will usually be your responsibility to implement effective control measures.

- ***Trade Associations***

Trade associations can also provide useful information. Trade journals often provide general information on potential hazards and controls. Articles on specific processes or products also can be useful. Some trade organizations provide services such as consulting, educational programs and publications that can help identify hazards and control measures.

- ***Suppliers and Buyers***

Suppliers of cleaning materials, processing equipment and packaging materials can provide information on potential hazards and control measures. A buyer's specification may point to a hazard in one of your products. For example, a buyer may require a *Salmonella*-free product. It is important to note, however, that not all buyer's specifications relate to safety.

- ***Sea Grant/Cooperative Extension***

Many universities have Sea Grant or Cooperative Extension programs. These programs provide continuing education and technical assistance to industry. Extension specialists and agents can assist in identifying potential hazards and control measures. For a listing, visit *http://seafood.ucdavis.edu/organize/org-sg.htm*

• ***Publications***

Textbooks, government publications and scientific literature provide general and specific HACCP information. These publications usually include a list of references that can be used to get further information.

Scientific journals are available in most libraries, especially university libraries. Summaries of information from scientific journals are also available in FDA, Sea Grant and other publications. Following is a listing of organizations that produce publications that may be helpful.

• ***U.S. FDA Fish and Fishery Products Hazards and Controls Guide***

This guide was developed to help seafood processors identify and control hazards in their operations. The guide provides information on seafood hazards and suggested control measures that can be incorporated into seafood HACCP plans. The guide was also developed as a tool that regulators can use to assist them in evaluating seafood processors' HACCP plans.

• Available as bound manual from University of Florida, IFAS-Extension Bookstore, P.O. Box 110011, Gainesville, FL 32611-0011.
• Available as electronic source on FDA website,
http://vm.cfsan.fda.gov/~dms/haccp-2.html

• ***FDA Compliance Policy Guides (CPGs) and Import Alert***

The FDA CPGs provide information on FDA compliance policy. The FDA Import Alerts are notices from FDA headquarters to district offices concerning new or unusual problems affecting import products. The CPGs and import alerts can be obtained by contacting: FDA, Freedom of Information (HFI-35), 5600 Fishers Lane, Rockville, MD 20857. Alternately, you may purchase the Import Alerts Manual and the Compliance Policy Guides Manual from: U.S. Department of Commerce, Technology Administration, National Technical Service (NTIS), Sales Desk, 5285 Port Royal Road, Springfield, VA 22161 (Phone: 703/487-4650). In addition, the import alerts can be obtained on the World Wide Web at *http://www.fda.gov* (then under FDA Activities click on Imports, where you will find information on current Import Alerts).

• ***FDA National Shellfish Sanitation Program (NSSP) Manuals***

The NSSP is a cooperative federal/state/industry program established in 1925 to ensure the safety of molluscan shellfish. The program is described in the *National Shellfish Sanitation Program Manual of Operations*, Parts I and II. Part I is entitled "Sanitation of Shellfish Growing Areas," and Part II is entitled "Sanitation of the Harvesting, Processing and Distribution of Shellfish." The manuals are available from FDA regional offices.

• Additional information
http://www.issc.org

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• ***U.S. Department of Agriculture (USDA) HACCP***

The USDA Food Safety and Inspection Service conducted a 1990 study to determine how to implement the HACCP system in meat and poultry inspection operations. The project resulted in the development of model HACCP plans. Two generic HACCP models deal with refrigerated foods and cooked sausage. They are available from: USDA, Food Safety and Inspection Service, Washington, DC 20250. For additional USDA information visit *http://www.fsis.usda.gov/*

• ***National Marine Fisheries Service (NMFS) Model Seafood Surveillance Program (MSSP)***

The NMFS developed the MSSP in response to a Congressional mandate to "design a program of certification and surveillance to improve the inspection of fish and seafood consistent with the hazard analysis critical control point system." As a result of this project, NOAA/NMFS developed HACCP models for 14 types of products and for wholesalers/distributors/seafood auctions and fishing vessels. These models include product safety, plant/food hygiene and economic fraud hazards. They may be obtained from: National Marine Fisheries Service, P.O. Box 1207, Pascagoula, MS 39568. Web site for HACCP manual, visit *http://seafood.nmfs.noaa.gov/manual.html*

• ***National Advisory Committee on Microbiological Criteria for Foods (NACMCF)***

NACMCF provides advice and recommendations to the secretaries of the Department of Agriculture and the Department of Health and Human Services concerning the development of microbiological criteria used to evaluate the safety and wholesomeness of food, including criteria for microorganisms that indicate whether food has been processed using GMPs. Web address: *http://www.usda.gov/*

• ***National Academy of Sciences (NAS)***

The NAS received its congressional charter in 1863, which established it as a private, nonprofit organization designated as an official advisor to the federal government on science and technology matters. Its members include experts from many disciplines, including scientists, engineers, doctors, lawyers and corporate executives. The NAS *Seafood Safety* publication provides a good source of information about seafood hazards. NAS publications can be obtained from the National Academy Press (phone:800/624-6242).

• ***Centers for Disease Control and Prevention (CDC)***

The CDC is responsible for characterizing risk factors and prevention strategies for diseases that impact on public health. In addition, the CDC assists local health agencies in epidemiologic investigations of foodborne illness outbreaks. Certain diseases are reported to the CDC by state epidemiologists. The *Morbidity and Mortality Weekly Report* contains summaries of this information. It can be obtained by contacting CDC at: *Morbidity and Mortality Weekly Report*, Mailstop C-08, CDC, 1600 Clifton Road N.E., Atlanta, GA 30333 (Phone: 404/332-4555).

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• ***Codex Alimentarius (CODEX)***

The Codex Alimentarius Commission is sponsored by the Food and Agriculture Organization and the World Health Organization of the United Nations. Its purpose is to facilitate international trade by establishing uniform food standards. The commission has developed many standards and guidelines, including *Recommended International Code of Practice for Fresh Fish*. Information may be obtained from the U.S. Coordinator for Codex Alimentarius, USDA, Food Safety and Inspection Service, Washington, D.C. 20250.

• ***Canadian Food Inspection Agency***

The agency has developed a Food Safety Enhancement Program (FSEP), a HACCP-based program for food manufacturing operations. Guidance manuals for the FSEP, including *Guidelines and Principles for the Development of HACCP Generic Models*, are available from Agriculture Canada, Food Protection and Inspection Branch, 59 Camelot Dr., Nepean, Ontario, Canada K18 0Y9. Web site: http://www.inspection.gc.ca/english/ppc/psps/haccp/haccpe.shtml

• ***Fisheries and Oceans Canada Quality Management Program (QMP)***

This HACCP-based program is designed for seafood processing plants. Publications are available from Fisheries and Oceans Canada, Inspection Directorate, 200 Kent St., 7th Floor, Ottawa, Canada K1A 0E6 (phone: 613/993-6930).

Computer-Accessible Information Sources

• ***FDA's Home Page***

The FDA home page Internet address is: *http://www.fda.gov.* From there, you can easily locate consumer education materials, industry guidance, bulletins for health professionals and other documents and data from FDA's centers and offices. The World Wide Web enables you to download and print the documents you want. In addition, FDA's Office of Seafood maintains a question-and-answer document regarding HACCP issues. Web address: *http://vm.cfsan.fda.gov/~dms/qa2haccp.html*

FDA seafood information is located on the Center for Food Safety and Applied Nutrition (CFSAN) home page. Use the search option found on the FDA home page to find CFSAN.

• ***Regulatory Fish Encyclopedia: http://www.cfsan.fda.gov/~frf/rfe0.html***

• ***AquaNIC***

AquaNIC (Aquaculture Network Information Center) is a gateway to electronic resouces on aquaculture. AquaNIC is maintained at Perdue University, West Lafayette, Indiana. Access to AquaNIC is free. Information on AquaNIC can be viewed on your computer monitor, downloaded

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via modem or sent to your e-mail address. AquaNIC also contains an image directory that holds hundreds of pictures, short videos and slides in a variety of common image formats. AquaNIC is linked to other aquaculture databases on the Internet. Information on accessing AquaNIC can be obtained from Purdue University. Web address: *http://aquanic.org*

• ***USDA***

USDA Food and Nutrition Information Center has a database on training programs and resource materials. Web address: *http://www.nal.usda.gov/fnic/foodborne/haccp/index.shtml*

• ***Seafood Discussion Group (Mailing List)***

An Internet seafood discussion group has been established to facilitate seafood technology information exchange. The National Seafood HACCP Alliance sends network subscribers new information on seafood HACCP implementation, upcoming seafood technology meetings and other seafood technology information. Subscriptions are free and available to anyone with access to e-mail. To subscribe, address your request to listproc@ucdavis.edu and in the message text write only: subscribe seafood (your first name) (your last name). *http://seafood.ucdavis.edu/listserv/listinfo.htm*

Information on the seafood discussion group can be obtained from: Robert J. Price, Extension Specialist, Seafood Products, Food Science and Technology Department, University of California, One Shields Ave., Davis CA 95616 (phone:530/752-2194, e-mail: rjprice@ucdavis.edu).

• ***SeafoodNIC (http://seafood.ucdavis.edu)***

SeafoodNIC (Seafood Network Information Center) is a Web database containing information on the National Seafood HACCP Alliance plus seafood-related guidelines and regulations, sanitation information, organizations, publications, and meetings. SeafoodNIC is linked to other seafood databases on the Internet. Information on the SeafoodNIC discussion group mailing is on *http://seafood.usdavis.edu/listserv/listinfo.htm*

• ***Compendium of Fish and Fishery Processes, Hazards, and Controls***

The compendium includes sections on seafood processes and controls, plus biological, chemical and physical hazards and controls. It provides the seafood industry with information on documented seafood process parameters, federal guidelines and tolerances for seafood contaminants, bacterial-growth parameters and recommended hazard-control operations. The compendium will assist the seafood industry in developing effective HACCP plans by providing scientific information on food-safety hazards and controls. It is available for viewing or downloading on the Internet. Web address: *http://seafood.ucdavis.edu/haccp/compendium/compend.htm*

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• ***Selected Additional References***

FDA/DHHS. 1994. "Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products," Government Printing Office, Washington, DC 20402 (202/512-2357), Jan. 28, 1994. Federal Register, pages 4142-4214. *http://www.access.gpo.gov/su_docs/aces/aaces002.html* - 1) from the "individual database" scroll down and highlight "Federal Register, Volume 59 (1994)," 2) in the search terms box, type the terms, processing importing fish, 3) hit the submit button and then select the corresponding article.

Lee, J.S. and K.S. Hilderbrand Jr., 1992. "Hazard Analysis and Critical Control Point Applications to the Seafood Industry," ORESU-H-92-001, Oregon Sea Grant, Oregon State University, Corvallis, OR. *http://nsgd.gso.uri.edu/oresu/oresuh92001.pdf* (Requires Adobe Acrobat Reader)

Microbiology and Food Safety Committee, National Food Processors Association (NFPA). 1989. "Guidelines for the Development of Refrigerated Foods," NFPA Bulletin 42-L, 1989. *http://www/nfpa-food.org/Pub_Catalog/pubcat00_alpha.pdf* (Requires Acrobat Reader)

NACMCF. 1992. National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis, and Critical Control Point System Adopted March 20, 1992, (NAS), "HACCP: Principles and Applications," Van Nostrand Reinhold.

Subcomittee on Microbiological Criteria, Committee on Food Protection, Food and Nutrition Board, National Research Council, NAS. 1985. "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients," National Academy Press.

How to Use the Fish and Fishery Products Hazards and Controls Guide

Overhead 3

Preliminary Steps:
- General information
- Describe the food
- Describe the method of distribution and storage
- Identify the intended use and consumer
- Develop a flow diagram

Instructor's Note:

Use Chapter 2 of the guide to explain the kind of assistance that it can provide for plan development. In particular, highlight the potential species-related and process-related hazards tables contained in Chapter 3, the sample plans at the end of each of the hazard chapters, and the appendices to the guide. It may be helpful to select a product of interest to the students to run through the process as an example.

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Overhead 4

Hazard-Analysis Worksheet
- Set up the hazard-analysis worksheet
- Identify the potential species-related hazards
- Identify the potential process-related hazards
- Complete the hazard-analysis worksheet
- Understand the potential hazard
- Determine if the potential hazard is significant
- Identify the critical control points

Overhead 5

Complete the HACCP Plan Form
- Set the critical limits
- Establish monitoring procedures
  - What?
  - How?
  - Who?
- Establish corrective action procedures
- Establish a record-keeping system
- Establish verification procedures

The guide is designed so that a processor or regulator can look up the fish species and finished-product form of interest and identify potential food-safety hazards. It is structured around the same hazard-analysis worksheet and HACCP plan form that has been used throughout this course. In this way, the user is lead through a series of decisions such as: whether a potential hazard is a significant hazard; what is the proper CCP; what critical-limit monitoring programs, corrective-action procedures and verification procedures are appropriate; and what records are necessary.

The recommendations included in the guide are not, for the most part, binding FDA requirements. Use of the guide in developing HACCP plans is not mandatory. The guide provides useful guidance, but seafood processors and importers are free to choose other control measures that provide an equivalent level of safety assurance to those listed in the guide. There may also be circumstances where a hazard identified in the guide may not apply to a product or species because of conditions specific to the processor.

Food-safety hazards can be introduced to a product because of the nature of the product (e.g., the species) or because of the way it is processed. The guide refers to the first type as species-related hazards. It refers to the second type as process-related hazards. The guide is set up in a way that

lets you look up the species of interest (among the more than 350 listed) in a table. The table lists the potential species-related hazards that FDA has reason to believe exist for each species. You can also find the finished product of interest in another table. This table lists the potential process-related hazards that FDA has reason to believe exist for each finished product form. Processors must control both types of hazards.

The guide then provides information to help processors and regulators decide if these potential hazards are reasonably likely to occur in any given circumstance. It further provides information about how the hazard might be controlled. These control options are not intended to be all inclusive. Rather they represent the mechanisms that FDA is aware of that should prove effective in eliminating or minimizing the risk of a hazard developing in a product. In particular, the guide provides information about critical limits that may be appropriate in certain circumstances. In some cases, the suggested critical limits are derived from existing tolerances or action levels. In other cases, they are derived from a review by FDA of the scientific and technical literature, conducted for the specific purpose of assisting in the development and review of HACCP plans.

You have been provided a copy of the latest edition of the guide along with your other training materials. You should use it as a reference tool during the practical exercise on the last day of the course.

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Appendix I: FDA's Seafood HACCP Rule

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Subpart A — General Provisions

§ *123.3 Definitions*

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

(a) Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b) Critical control point means a point, step or procedure in a food process at which control can be applied, and a food-safety hazard can be prevented, eliminated, or reduced to acceptable levels.

(c) Critical limit means the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food-safety hazard.

(d) Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to alligators, frogs, aquatic turtles, jellyfishs, sea cucumbers, sea urchins and roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e) Fishery product means any human food product in which fish is a characterizing ingredient.

(f) Food-safety hazard means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

(g) Importer means either the U.S. owner or consignee at the time of entry into the United States or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom-house broker, the freight forwarder, the carrier or the steamship representative.

(h) Molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, scallops or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i) Preventive measure means physical, chemical or other factors that can be used to control an identified food safety hazard.

(j) Process-monitoring instrument means an instrument or device used to indicate conditions during processing at a critical control point.

(k) (1) Processing means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading or holding.

(2) The regulations in this part do not apply to:

(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.

(ii) Practices such as heading, eviscerating or freezing intended solely to prepare a fish for holding on a harvest vessel.

(iii) The operation of a retail establishment.

(l) Processor means any person engaged in commercial, custom or institutional processing of fish or fishery products either in the United States or in a foreign country. A processor includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m) Scombroid toxin-forming species means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

(n) Shall is used to state mandatory requirements.

(o) Shellfish control authority means a federal, state or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p) Shellstock means raw, in-shell molluscan shellfish.

(q) Should is used to state recommended or advisory procedures or to identify recommended equipment.

(r) Shucked shellfish means molluscan shellfish that have one or both shells removed.

(s) Smoked or smoke-flavored fishery products means the finished food prepared by:

(1) Treating fish with salt (sodium chloride), and

(2) Subjecting it to the direct action of smoke from burning wood, sawdust or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t) Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

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§ *123.5 Current Good Manufacturing Practice*

(a) Part 110 of this chapter applies in determining whether the facilities, methods, practices and controls used to process fish and fishery products are safe and whether these products have been processed under sanitary conditions.

(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

§ *123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan*

(a) Hazard analysis. Every processor shall conduct or have conducted a hazard analysis to determine whether there are food-safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food-safety hazards can be introduced both within and outside the processing plant environment, including food-safety hazards that can occur before, during and after harvest. A food-safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b) The HACCP plan. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food-safety hazards that are reasonably likely to occur as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together or group kinds of production methods together if the food-safety hazards, critical control points, critical limits and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food-safety hazards that are reasonably likely to occur as identified in accordance with paragraph (a) of this section, and that must be controlled for each fish and fishery product. Consideration should be given to whether any food-safety hazards are reasonably likely to occur as a result of the following:
  (i) Natural toxins;
  (ii) Microbiological contamination;
  (iii) Chemical contamination;
  (iv) Pesticides;
  (v) Drug residues;
  (vi) Decomposition in scombroid toxin-forming species or in any other species where a food-safety hazard has been associated with decomposition;
  (vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels or intends for the product to be so consumed;
  (viii) Unapproved use of direct or indirect food or color additives; and
  (ix) Physical hazards;

(2) List the critical control points for each of the identified food-safety hazards, including as appropriate:
  (i) Critical control points designed to control food-safety hazards that could be introduced in the processing plant environment; and
  (ii) Critical control points designed to control food-safety hazards introduced outside the processing plant environment, including food-safety hazards that occur before, during and after harvest;

(3) List the critical limits that must be met at each of the critical control points;

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with § 123.7(b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with § 123.8(a);

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

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(d) Signing and dating the HACCP plan.

(1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance

(ii) Upon any modification and

(iii) Upon verification of the plan in accordance with § 123.8(a)(1).

(e) Product subject to other regulations. For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food-safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food-safety hazard. A HACCP plan for such fish and fishery products shall address any other food-safety hazards that are reasonably likely to occur.

(f) Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with § 123.11(b) they need not be included in the HACCP plan and vice versa.

(g) Legal basis. Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

§ *123.7 Corrective Actions*

(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with § 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not have a corrective-action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with § 123.10;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with § 123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with § 123.8(a)(3)(ii) and the recordkeeping requirements of § 123.9.

§ *123.8 Verification*

(a) Overall verification. Every processor shall verify that the HACCP plan is adequate to control food-safety hazards that are reasonably likely to occur and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1) Reassessment of the HACCP plan. A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of § 123.6(c).

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(2) Ongoing verification activities. Ongoing verification activities including:
  (i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;
  (ii) The calibration of process-monitoring instruments; and,
  (iii) At the option of the processor, the performing of periodic end-product or in-process testing.

(3) Records review. A review, including signing and dating, by an individual who has been trained in accordance with § 123.10, of the records that document:
  (i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;
  (ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with § 123.7. This review shall occur within one week of the day that the records are made; and
  (iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b) Corrective actions. Processors shall immediately follow the procedures in § 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food-safety hazard now exists. Such changes may include, but are not limited to changes in: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with § 123.10.

(d) Recordkeeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of § 123.9.

§ *123.9 Records*

(a) General requirements. All records required by this part shall include:

(1) The name and location of the processor or importer;
(2) The date and time of the activity that the record reflects;
(3) The signature or initials of the person performing the operation; and
(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b) Record retention.

(1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least one year after the date they were prepared in the case of refrigerated products and for at least two years after the date they were prepared in the case of frozen, preserved or shelf-stable products.
(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least two years after their applicability to the product being produced at the facility.
(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(c) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

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(d) Public disclosure.

(1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e) Tags. Tags as defined in § 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of § 123.28(c).

(f) Records maintained on computers. The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

§ *123.10 Training*

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of § 123.6(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in § 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in § 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in § 123.8(c); and

(c) Performing the record review required by § 123.8(a)(3);
The trained individual need not be an employee of the processor.

§ *123.11 Sanitation Control Procedures*

(a) Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b) Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food-contact surfaces, or is used in the manufacture of ice;
(2) Condition and cleanliness of food-contact surfaces, including utensils, gloves and outer garments;
(3) Prevention of cross-contamination from insanitary objects to food, food-packaging material and other food-contact surfaces, including utensils, gloves and outer garments, and from raw product to cooked product;
(4) Maintenance of hand washing, hand sanitizing and toilet facilities;
(5) Protection of food, food-packaging material and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;
(6) Proper labeling, storage and use of toxic compounds;
(7) Control of employee health conditions that could result in the microbiological contamination of food, food-packaging materials and food-contact surfaces; and
(8) Exclusion of pests from the food plant.

The processor shall correct in a timely manner, those conditions and practices that are not met.

(c) Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of § 123.9.

(d) Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by § 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section, they need not be included in the HACCP plan and vice versa.

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§ *123.12 Special Requirements for Imported Products*

This section sets forth specific requirements for imported fish and fishery products.

(a) Importer verification. Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,

(ii) Affirmative steps that may include any of the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 123.9.

(d) Determination of compliance. There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B—Smoked and Smoke-Flavored Fishery Products

§ *123.15 General*

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

§ *123.16 Process Controls*

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food-safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

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Subpart C—Raw Molluscan Shellfish

§ *123.20 General*

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

§ *123.28 Source Controls*

(a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the federal government.

(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in § 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in § 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

(1) The date of harvest;
(2) The location of harvest by state and site;
(3) The quantity and type of shellfish;
(4) The date of receipt by the processor; and
(5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with § 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

(1) The date of receipt,

(2) The quantity and type of shellfish, and

(3) The name and certification number of the packer or repacker of the product.

Part 1240—Control of Communicable Diseases

2. The authority citation for 21 CFR part 1240 continues to read as follows:

AUTHORITY: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

3. Section 1240.3 is amended by revising paragraph (r), and by adding new paragraphs (s), (t), and (u) to read as follows:

§ *1240.3 General Definitions*

(r) Molluscan shellfish. Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

(s) Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(t) Shellfish control authority means a federal, state, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(u) Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

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4. Section 1240.60 is amended by revising the section heading, by redesignating the existing text as paragraph (a) and adding the word "molluscan" before the word "shellfish" the two times that it appears, and by adding new paragraphs (b), (c), and (d) to read as follows:

§ 1240.60 Molluscan Shellfish

(b) All shellstock shall bear a tag that discloses the date and place they were harvested (by state and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

(c) All containers of shucked molluscan shellfish shall bear a label that identifies the name, address and certification number of the packer or repacker of the molluscan shellfish.

(d) Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

Appendix II: HACCP Worksheets

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HACCP Worksheets

Worksheets are recommended to document the hazard analysis and final HACCP plans. The hazard analysis should contain certain information to justify the identification of the proper critical control points. Information in the HACCP plan must explain the details for each HACCP step. There is no standardized or mandated format for the worksheets, but the information should be arranged in a progressive manner that clearly explains the thought process for the hazard analysis and the individual steps in the HACCP plan.

The following worksheets are provided as recommended examples. The information is arranged in a similar manner, but the layouts are in either a landscape or portrait form to suit individual preferences.

SPECIAL NOTE: These recommended worksheets can be copied for routine use, but if they are used for official use they must include details that identify the commercial firm and related activity. The additional information must include:

- Form title
- Firm name and location
- Time and dates
- Product identification
- Signature and date (HACCP Plan)

Hazard Analysis Worksheet

(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 hazards?	(6) Is this step a critical control point? (Yes/No)
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				

Hazard Analysis Worksheet

(1) Ingredient or Processing Step	(2) Identify potential Hazards introduced, controlled or enhanced at this step.	(3) Are any potentiial food hazards significant? (Yes/No)	(4) Justify your decision for 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)

HACCP Plan Worksheet

		CCP 1	CCP 2	CCP 3
(1) Critical Control Point (CCP)				
(2) Significant Hazard				
(3) Critical Limits				
Monitoring	(4) What			
	(5) How			
	(6) When			
	(7) Who			
(8) Corrective Action				
(9) Verification				
(10) Records				

HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4)	(5) Monitoring	(6)	(7)	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			

Appendix III: Hazards Found in Seafood

Notes:

Overhead 1

Objective:
In this module, you will learn:
- The identity and characteristics of biological, chemical and physical safety hazards commonly identified with seafood.
- Control measures for hazards in seafood.

Biological Hazards

Biological safety hazards commonly found in seafood include bacterial pathogens, viral pathogens and parasites.

- ***Bacterial Pathogens***

Pathogen contamination and growth is often an important factor in food-borne illness.

Overhead 2

Bacterial Pathogens:
- *Bacillus cereus*
- *Campylobacter jejuni*
- *Clostridium botulinum*
- *Clostridium perfrigens*
- Pathogenic *Escherichia coli*
- *Listeria monocytogenes*
- *Salmonella spp.*
- *Shigella spp.*
- Pathogenic *Staphylococcus aureus*
- *Vibrio cholerae*
- *Vibrio parahaemolyticus*
- *Vibrio vulnificus*
- *Yersinia enterocolitica*

Bacillus cereus

Food poisoning caused by *B. cereus* may occur when foods are prepared and held without proper refrigeration for several hours before being served. *B. cereus* is an aerobic spore-forming bacterium. It is commonly found in soil, on vegetables, and in many raw and processed foods. Consumption of foods that contain 10^6/g may result in food poisoning. Foods incriminated in food poisoning outbreaks include cooked meat and vegetables, boiled or fried rice, vanilla sauce, custards, soups, and raw vegetable sprouts. Two types of illnesses have been attributed to *B. cereus*. The first is characterized by abdominal pain and diarrhea. It has an incubation period of 4-16 hours and symptoms that last for 12-24 hours. The second is characterized by an accute attack of nausea and vomiting. It has an incubation period of 1-5 hours. Diarrhea is not common with the second type of illness.

B. cereus is a common food contaminant. Effective control measures depend on destruction by a heat process and temperature control to prevent spore germination and multiplication of vegetative cells in cooked, ready-to-eat foods. Measures to reduce or eliminate the threat of food poisoning by *B. cereus* include: 1) Avoid preparing food too far in advance of planned service, 2) Avoid holding cooked foods at room temperature, 3) Use quick chill methods to cool foods below 45ºF (7.2ºC) within 4 hours of preparation; store in shallow pans/ small quantities with the food less than 4 inches deep; if food is especially thick (e.g., refried beans), store no more than 3 inches deep, 4) Hold/store hot foods above 140ºF (60ºC) until served, and 5) Reheat foods rapidly to 165ºF (74ºC) or above.

Campylobacter jejuni

C. jejuni is widely distributed in the intestinal tract of poultry, livestock, and warm-blooded domestic animals. It is a very common and important cause of diarrheal illness in humans. Symptoms include profuse diarrhea (sometimes bloody), abdominal pain (intensity and duration can be somewhat severe), headache, weakness, and fever. Many infections occur without symptoms. *C. jejuni* is transmitted through: contaminated foods, including raw clams, mussels and oysters; person-to-person contact; and contaminated water. Cross-contamination of foods by dirty food-contact surfaces, including cutting boards and hands, may be the most frequent route of transmission.

Hazards from *C. jejuni* can be controlled by thoroughly cooking seafood and by stressing the importance of proper (and frequent) hand and equipment washing and sanitary food-handling practices. Since the infective dose of *C. jejuni* is thought to be small, time/temperature abuse of food products is not necessary to result in this illness.

Clostridium botulinum

C. botulinum is found throughout the environment and has been isolated from soil, water, vegetables, meats, dairy products, ocean sediments, the intestinal tracts of fish, and the gills and viscera of crabs and other shellfish. *C. botulinum* is a spore-forming bacteria that grows in the absence of air. These characteristics allow it to survive normal cooking temperatures and to grow in a vacuum-packaged and modified-atmosphere environment. *C. botulinum* produces a powerful neurotoxin that causes botulism. Growth is necessary for *C. botulinum* to produce toxin. Symptoms include diarrhea, vomiting, abdominal pain, nausea and weakness. These are followed by double, blurred vision and dilated, fixed pupils. In severe cases, paralysis of the muscles responsible for breathing can cause death.

The type of *C. botulinum* Type E that is most common in fish and fishery products is of particular concern because it grows at temperatures as low as 38 F and produces little noticeable evidence of spoilage. *C. botulinum* Type A is the form of this bacteria that is most common in land-based products. It is a common contaminant on processing equipment. It will grow at tempera-

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tures no colder than 50 F and produces a putrid odor in products in which it grows. However, its spores are much more heat-resistant than the Type E form of the bacteria.

Because *C. botulinum* produces heat-resistant spores and requires the absence of oxygen for growth, botulism has been most commonly associated with improperly canned food (usually home canned). Semi-preserved seafood, including smoked, salted and fermented fish, have also been identified as causes of botulism.

Hazards from *C. botulinum* can be controlled by inhibiting growth of the bacteria or by destroying it in seafood. Proper thermal processes for canned seafood destroy the bacteria. Heavy salting or drying to reduce the water activity below 0.93 and fermentation or acidification to below pH 4.6 are effective means of preventing *C. botulinum* growth. Maintaining proper storage temperatures alone is not considered an adequate control measure for *C. botulinum* Type E because of its ability to grow at low temperatures and because of the severity of the illness. Nonetheless, in many products, it is an important second barrier to growth.

Clostridium perfringens

C. perfringens is commonly found in soil, dust, and the intestinal tract of animals. It is a spore forming, anaerobic (oxygen-free growth conditions) bacterium. Food poisoning caused by *C. perfringens* may occur when foods such as meat or poultry are cooked and held without maintaining adequate heat or refrigeration before serving. The illness is a self-limiting gastroenteritis with an incubation period of 8-15 hours and a duration of 12-24 hours. The symptoms, which include intense abdominal cramps, gas, and diarrhea, have been attributed to a protein enterotoxin produced during sporulation of the organism in the intestine.

The presence of small numbers of *C. perfringens* is not uncommon in raw meats, poultry, dehydrated soups and sauces, raw vegetables, and spices. Because the spores of some strains are resistant to temperatures as high as 100ºC for more than 1 hour, their presence in foods may be unavoidable. Furthermore, the oxygen level may be sufficiently reduced during cooking to permit growth of the clostridia. Spores that survive cooking may germinate and grow rapidly in foods that are inadequately refrigerated after cooking. Thus, when clinical and epidemiological evidence suggests that *C. perfringens* is the cause of a food poisoning outbreak, the presence of hundreds of thousands or more of these organisms per gram of food substantiates the diagnosis.

Control measures emphasize proper food preparation and storage techniques, especially temperature control. Control measures include:

1) Rapid, uniform cooling of cooked foods to <10ºC (50ºF) within 2-3 hours;
2) Hot holding of cooked foods at or above 60ºC (140ºF);
3) Reheating cooled or chilled foods to a minimum internal temperature of 75ºC (167ºF) immediately before serving;

4) Not leaving foods at room temperature or thawing frozen foods at room temperature;
5) Preventing cross-contamination of cooked foods with bacteria from raw foods by using separate food-contact surfaces for preparing raw and cooked foods items, or by thoroughly cleaning and sanitizing food-contact surfaces after being used for raw products;
6) Maintaining food preparation areas so that they are free of soil and dust;
7) Cleaning and sanitizing meat slicers, meat-cutting equipment, food contact surfaces, and other equipment after use; and
8) Using good personal hygiene methods, and thoroughly washing hands frequently when handling food products, especially after handling raw products and before handling cooked products.

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Escherichia coli

E. coli are naturally found in the intestinal tracts of all animals, including humans. Most forms of the bacteria are not pathogenic and serve useful functions in the intestine. Pathogenic strains of *E. coli* are transferred to seafood through sewage pollution of the coastal environment or by contamination after harvest. *E. coli* food infection causes abdominal cramping, water or bloody diarrhea, fever, nausea, and vomiting.

Hazards from *E. coli* can be prevented by: heating seafood sufficiently to kill the bacteria, holding chilled seafoods below 40 F, preventing post-cooking cross-contamination, and prohibiting people who are ill from working in food operations. The infective dose of *E. coli* is dependent upon the particular strain from only a few organisms to millions. For this reason, time/temperature abuse of food products may or may not be necessary to result in illness.

Listeria monocytogenes

L. monocytogenes is widespread in nature and has been isolated from soil, vegetation, marine sediments and water. In the early 1900s, *L. monocytogenes* was recognized as a bacterium that caused illness in farm animals. More recently, it has been identified as the cause of listeriosis in humans. Most healthy individuals are either unaffected by *L. monocytogenes* or experience only mild flulike symptoms. Victims of severe listeriosis are usually immunocompromised. Those at highest risk include: cancer patients, individuals taking drugs that affect the body's immune system, alcoholics, pregnant women, persons with low stomach acidity and individuals with AIDS. Severe listeriosis can cause meningitis, abortions, septicemia and a number of other maladies, some of which may lead to death.

The greatest threat of listeriosis is from ready-to-eat products that do not require further cooking at home. *L. monocytogenes* in raw food that will be cooked before consumption is less of a concern to the food industry since the bacteria are killed during cooking. *L monocytogenes* has been

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isolated from raw fish, cooked crabs, raw and cooked shrimp, raw lobster, surimi and smoked fish. One of its most significant characteristics is its ability to grow at temperatures as low as 31ºF.

Hazards from *L. monocytogenes* can be prevented by thoroughly cooking seafood and by preventing cross-contamination once the seafood is cooked. Since the infective dose of *L. monocytogenes* is thought to be small, time/temperature abuse of food products may not be necessary to result in illness.

Salmonella spp.

Salmonella is naturally found in the intestinal tracts of mammals, birds, amphibians and reptiles but not in fish, crustaceans or mollusks. *Salmonella* is transferred to seafood through sewage pollution of the harvest environment or by contamination after harvest.

Salmonella food infection causes nausea, vomiting, abdominal cramps and fever. Outbreaks of *Salmonella* food infection have been associated with raw oysters, salmon, tuna salad, shrimp cocktail, stuffed sole and gefilte fish.

Hazards from *Salmonella* can be prevented by: heating seafood sufficiently to kill the bacteria, holding chilled seafood below 40 F, preventing post-cooking cross-contamination and prohibiting people who are ill or are carriers of *Salmonella* from working in food operations. The infective dose of *Salmonella* is thought to be extremely variable, relatively high for healthy individuals and very low for at-risk individuals, such as the elderly or medically compromised. For this reason, illness could result even without time/temperature abuse, but abuse has been a contributing factor in many outbreaks.

Shigella spp.

Shigella is naturally found in the intestinal tract of humans. *Shigella* is transferred to seafood through sewage pollution of the coastal environment or by contamination after harvest. *Shigella* produces an illness called Shigellosis, which causes mild diarrhea, fever, abdominal cramps and severe fluid loss.

Hazards from *Shigella* can be prevented by eliminating human waste contamination of water supplies and by improved personal hygiene for people who are ill or are carriers of *Shigella* and work in food operations.

Staphylococcus aureus

Humans and animals are the primary reservoirs for *S. aureus*. *S. aureus* can be found in the nose and throat and on the hair and skin of 50 percent of healthy individuals. However, the bacteria can be found in air, dust, sewage and surfaces of food-processing equipment. *S. aureus* can produce a toxin if allowed to grow in food. The toxin is not destroyed by the cooking or canning processes. *S. aureus* has the ability to grow and

produce toxins in food with very little available water (.85 a_W, 10 percent salt), which would prevent the growth of other pathogens.

S. aureus food poisoning causes nausea, vomiting, abdominal cramping, watery or bloody diarrhea, and fever.

Hazards from *S. aureus* can be prevented by: minimizing time/temperature abuse of seafood, especially after cooking, and requiring that food handlers engage in proper hygiene.

Vibrio cholerae

V. cholerae is found in estuaries, bays, and brackish waters. It is naturally occurring and is not necessarily related to sewage contamination. *V. cholerae* tends to be more numerous in the environment during warmer months.

There are a number of types of *V. cholerae,* and these produce very different symptoms. One type, *Vibrio cholerae* 01, initially causes abdominal discomfort and mild diarrhea. As the illness progresses, the symptoms may include: watery diarrhea, abdominal cramps, vomiting and dehydration. Death can occur. Susceptibility to cholera is enhanced in people who have had gastric surgery, take antacids or have type O blood. Outbreaks of this type of cholera have been associated with oysters, crabs and shrimp from the Gulf of Mexico. *V. cholerae* 01 has also been recovered from Chesapeake Bay waters, although no illness has been reported from that area.

Another type of *V. cholerae*, non-01, causes diarrhea, abdominal cramps and fever. Nausea, vomiting and bloody diarrhea have also been reported. The severity of the symptoms is dependant, in part, upon the specific strain. In its most severe form, *V. cholerae* non-01 has resulted in septicemia (blood poisoning) in individuals with medical conditions that weaken their immune systems. The illness has been associated with consumption of raw oysters, but the bacterium has also been found in crabs.

Hazards from *V. cholerae* can be prevented by cooking seafood thoroughly and by preventing cross-contamination once the seafood is cooked.

Vibrio parahaemolyticus

V. parahaemolyticus is naturally occurring in estuaries and other coastal areas throughout most of the world. In most areas, *V. parahaemolyticus* is more numerous in the environment during the warmer months and, as a result, most outbreaks in the United States occur during the summer.

The most commonly experienced symptoms of *V. parahaemolyticus* illness include: diarrhea, abdominal cramps, nausea, vomiting and headache. Fever and chills are less frequently reported. The illness has been associated with consuming contaminated crabs, oysters, shrimp and lobster.

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Hazards from *V. parahaemolyticus* can be controlled by thoroughly cooking seafood and preventing cross-contamination after cooking. Control of time/temperature abuse is also an important preventative measure.

Vibrio vulnificus

V. vulnificus is a naturally occurring marine bacterium. *Vibrio vulnificus* requires salt for survival and is commonly isolated at salinities of 7 ppt to 16 ppt. It is primarily found in the Gulf of Mexico, but it has also been isolated from the Atlantic and Pacific oceans. The numbers of the bacterium in the environment are highest during the warmer months of April through October.

The most common symptoms include: skin lesions, septic shock, fever, chills and nausea. Abdominal pain, vomiting and diarrhea are less frequently reported. Death occurs in about 50 percent of the cases. A number of medical conditions make individuals more susceptible to the life-threatening effects of this bacterium, including: liver disease, alcohol abuse, cancer, diabetes, chronic kidney disease, immunosuppressive drug or steroid usage, low stomach acidity and AIDS. *V. vulnificus* sepsis has been associated with the consumption of certain molluscan shellstock.

Hazards from *V. vulnificus* can be controlled by thorough cooking of shellfish and by preventing cross-contamination once the seafood is cooked. The risk of *V. vulnificus* infection may also be reduced by rapidly refrigerating oysters from the Gulf Coast during warm-weather months. Individuals in the "high risk" groups should not consume raw molluscan shellfish.

Yersinia enterocolitica

Y. enterocolitica is naturally found in soil, water and domesticated and wild animals. Yersiniosis causes diarrhea, vomiting, abdominal pain and fever, often mimicking appendicitis. Outbreaks have been associated with oysters and fish.

Hazards from *Y. enterocolitica* can be prevented by: heating seafood sufficiently to kill the bacteria, holding chilled seafoods below 40 F and preventing post-cooking cross-contamination.

- ***Viral Pathogens***

Overhead 3

Viral Pathogens:

- Hepatitis A Virus
- Norwalk Virus

Hepatitis A Virus

Viruses survive better at low temperatures and are killed at high temperatures. As a result, most outbreaks of hepatitis occur during winter and early spring. Viruses can remain alive for long periods of time in seawater and have been shown to survive over one year in marine sediments.

Both raw and steamed clams, oysters, and mussels have been implicated in outbreaks of hepatitis A. Symptoms of hepatitis A include weakness, fever and abdominal pain. As the illness progresses, the individual usually becomes jaundiced. The severity of the illness ranges from very mild (young children often experience no symptoms) to severe, requiring hospitalization. The fatality rate is low, and deaths primarily occur among the elderly and individuals with underlying diseases.

Hazards from hepatitis A can be prevented by thoroughly cooking seafood and by preventing cross-contamination of cooked seafood. But hepatitis A appears to be more resistant to heat than other viruses. A laboratory study showed that hepatitis A viruses in infected oysters were inactivated after heating at 140 F for 19 minutes. Therefore, mollusks steamed only until the shells open (a common cooking practice) are not exposed to heat long enough to inactivate hepatitis A viruses.

Norwalk Virus

Norwalk virus is considered a major cause of nonbacterial intestinal illness (gastroenteritis). Illness from Norwalk virus has been associated with eating clams (raw and steamed), oysters and cockles. Norwalk virus causes nausea, vomiting, diarrhea, abdominal cramps, and occasionally fever in humans.

Hazards from Norwalk virus can be prevented by thoroughly cooking seafood and by preventing cross-contamination of cooked seafood. Additionally, a recent outbreak has demonstrated that controlling overboard discharge of untreated sewage from shellfish harvesting vessels would reduce the incidence of illness attributable to Norwalk virus.

- ***Parasites***

Overhead 4

Parasites:

- *Anisakis simplex*
- *Pseudoterranova decipiens*
- *Diphyllobothrium latum*

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Anisakis simplex

Anisakis simplex, commonly called herring worm, is a parasitic nematode or roundworm. Its final hosts are dolphins, porpoises and sperm whales. The larval (wormlike) stage in fish and squid is usually 18 to 36 millimeters in length, 0.24 to 0.69 millimeters in width and pinkish to whitish in color.

Anisakiasis, the human illness caused by *Anisakis simplex*, is associated with eating raw fish (sushi, sashimi, lomi lomi, ceviche, sunomono, Dutch green herring, marinated fish and cold-smoked fish) or undercooked fish.

Parasites in fish are considered a hazard only in fish that the processor knows or has reason to believe will be served raw or undercooked. In other products, parasites are considered filth but not hazardous. The FDA has established three freezing processes to kill parasites. Freezing and storing at -4ºF (-20ºC) or below for 7 days (total time), or freezing at -31ºF (-35ºC) or below for 15 hours, or freezing at -31ºF (-35ºC) or below until solid and storing at -4ºF (-20ºC) or below for 24 hours is sufficient to kill parasites. FDA's Food Code recommends these freezing conditions to retailers who provide fish intended for raw consumption. Note: these conditions may not be suitable for freezing particularly large fish (e.g. thicker than six inches).

Pseudoterranova decipiens

Pseudoterranova decipiens, commonly called "codworm" or "sealworm," is another parasitic nematode or roundworm. The usual final hosts of *Pseudoterranova* are gray seals, harbor seals, sea lions and walruses. The larval stage in fish are 5 to 58 millimeters in length, 0.3 to 1.2 millimeters in width and yellowish, brownish or reddish in color.

These nematodes are related to *Anisakis simplex* and the disease associated with infections is also termed anisakiasis. These nematodes are also transmitted to humans through raw or undercooked fish. Control of *Pseudoterranova* is the same as for *Anisakis simplex.*

Diphyllobothrium latum

Diphyllobothrium latum is a cestode, or tapeworm, that parasitizes a variety of fish-eating mammals of the northern latitudes. A similar species is found in the southern latitudes and is associated with seal hosts. Cestodes have a structure that allows them to attach to the intestinal wall of their host and have segmented bodies. Cestode larvae found in fish range from a few millimeters to several centimeters in length and are white or gray in color.

Diphyllobothrium tapeworms primarily infect freshwater fish. But salmon and related fish can also carry the parasites. *Diphyllobothrium* tapeworms are usually found unencysted and coiled in musculature or encysted in viscera. These tapeworms can mature and cause disease in humans. These

cestodes are also transmitted to humans through raw or undercooked fish. Control of *Diphyllobothrium* is the same as for *Anisakis simplex*.

Chemical Hazards

• ***Marine Biotoxins***

Marine biotoxins (natural toxins) represent a significant threat to human health when humans consume fish and fishery products contaminated with them. The marine biotoxins comprise many distinct compounds, all produced by species of naturally occurring marine algae. The algae are at the bottom of the marine food chain. Consequently, the biotoxins produced by some algae are collected and concentrated through levels of the food chain (e.g., mollusks, crustaceans and finfish) and ultimately are consumed by humans.

There are several recognized marine biotoxins in the United States; e.g. paralytic, neurotoxin, diarrhetic, and amnesic shellfish poisonings and ciguatera fish poisoning. Molluscan shellfish waters are classified by state shellfish-control agencies to reduce the risk that these toxins will be carried by shellfish in commercial channels. Processors should obtain molluscan shellfish only from those waters that have been approved for harvest.

Overhead 5

Marine Toxins:

- Amnesic Shellfish Poisoning (ASP)
- Diarrhetic Shellfish Poisoning (DSP)
- Neurotoxic Shellfish Poisoning (NSP)
- Paralytic Shellfish Poisoning (PSP)
- Ciguatera Fish Poisoning (CFP)
- Gempylotoxin
- Scombroid Toxin
- Tetrodotoxin

FDA has established action levels for all of the marine biotoxins except CFP. None of these toxins can be fully destroyed by normal cooking, freezing, salting, acidification or smoking processes. However, there is some evidence that PSP levels, and perhaps levels of other shellfish toxins, can be reduced to safe levels through commercial canning processes.

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Amnesic Shellfish Poisoning (ASP)

ASP has been caused by contaminated molluscan shellfish, primarily from cold water regions of North America. The shellfish become contaminated with domoic acid produced by dense growths of an algae in the genus *Pseudonitzschia*. It should be assumed that all filter-feeding mollusks are capable of accumulating domoic acid. However, the only shellfish implicated in cases of ASP have been mussels. ASP has recently been identified as a problem in the viscera of dungeness, tanner, and red rock crabs, and anchovies along the U.S. West Coast.

In the early stages of ASP, the individual usually experiences intestinal distress. Severe ASP can cause a facial grimace or chewing motion, short-term memory loss and difficulty breathing. Death can occur.

Diarrhetic Shellfish Poisoning (DSP)

DSP is caused by contaminated molluscan shellfish. There has been no documented occurrence to date in the United States. However, instances have been documented in Japan, Southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada. Filter-feeding mollusks can accumulate toxins even at algae concentrations below that necessary to discolor the water. Mussels, oysters, hard clams and soft-shell clams have been implicated in cases of DSP. Contaminated scallops have caused cases of DSP in Japan, but the likelihood of scallops causing illness in this country is reduced because roe-on scallops are not typically consumed in the United States. A number of algae species in the genus *Dinophysis* and *Prorocentrum* have been associated with DSP. These algae are responsible for the production of a number of toxins (okadaic acid and its derivatives).

The symptoms of diarrhetic shellfish poisoning are diarrhea, nausea, vomiting, moderate to severe abdominal pain and cramps, and chills. No known fatalities have occurred, and total recovery is expected within three days with or without medical assistance.

Neurotoxic Shellfish Poisoning (NSP)

Gymnodinium breve was first recognized as causing NSP in the mid 1960s. Blooms of this algae usually result in fish kills and can make shellfish toxic to humans. The blooms generally begin offshore and move inshore. *G. breve* produces three known toxins (brevetoxins).

NSP is caused by contaminated shellfish from the southeastern United States and New Zealand. Oysters and clams are the only shellfish associated with NSP illness. However, all filter-feeding mollusks are capable of accumulating neurotoxic shellfish toxins.

NSP resembles a mild case of ciguatera or PSP. Symptoms begin within three hours of consuming contaminated shellfish and include: tingling of the face that spreads to other parts of the body, cold-to-hot sensation reversal, dilation of the pupils and a feeling of inebriation. Less commonly, victims may experience: prolonged diarrhea, nausea, poor coordination and burning pain of the rectum.

Paralytic Shellfish Poisoning (PSP)

There are many species of toxic algae that cause paralytic shellfish poisoning. These include algae in the genus *Alexandrium, Pyrodinium* and *Gymnodinium*. PSP can be caused by a combination of any of 18 toxins (saxitoxins), depending on the species of algae, geographic area and type of shellfish involved.

PSP is caused by contaminated shellfish primarily from the U.S. Northeast and Northwest and imports from similar climates. All filter-feeding mollusks accumulate paralytic shellfish toxins. Mussels become highly toxic within a few hours to a few days exposure to the organism but also lose their toxin load rapidly. Clams and oysters generally do not become as toxic as mussels. They require more time to accumulate high levels of toxins and also require longer to cleanse themselves. Scallops can become extremely toxic, even during periods when blooms are not evident. However, scallops generally do not pose a PSP threat because the adductor muscle, the only part of the scallop traditionally consumed in Western society, does not accumulate toxin. PSP has recently been reported in the liver of Atlantic mackerel, American lobsters, and cold-water crabs such as dungeness, tanner, and red rock crab.

Symptoms of PSP initially involve numbness and a burning or tingling sensation of the lips and tongue that spreads to the face and fingertips. This leads to general lack of muscle coordination in the arms, legs and neck. A variety of other less commonly reported symptoms also exist. Severe cases of PSP have resulted in respiratory paralysis and death.

Ciguatera Fish Poisoning (CFP)

By eating toxic algae, certain species of tropical and subtropical fish can become toxic to humans. The algae species most often associated with CFP is *Gambierdiscus toxicus*, but others are occasionally involved. Toxic algae populations tend to fluctuate, influenced by the turbidity and nutrient content of the water. There are at least four known toxins that concentrate in the viscera, head or central nervous system of affected fish. Ciguatoxin is the principal toxin.

CFP is carried to humans by contaminated finfish from the extreme southeastern United States, Hawaii, the tropics, and subtropics worldwide (between 35N and 34S latitude). In South Florida, Bahamian and Caribbean regions, barracuda, amberjack, horseye jack, black jack, other large species of jack, king mackerel, large groupers and snappers are likely to contain ciguatoxin. Many other species of large fish-eating fish may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack and snapper are frequently ciguatoxic, and many other species, both large and small, may be suspect. Mackerel and barracuda from mid to northeastern Australian waters are frequently ciguatoxic.

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The incidence of poisonous fish is sporadic. Not all fish of the same species and caught in the same area will necessarily be toxic. A study done in Hawaii indicated that if fish in one location are toxic, other fish in the vicinity are 60 percent likely to be toxic. Both plant-eating and fish-eating fish can become toxic. Plant-eating fish become toxic by eating the toxic algae itself. Fish-eating fish become toxic by consuming toxic plant-eating fish. Large fish are more likely to be poisonous than small fish because they consume greater amounts of the toxins.

Ciguatera causes: diarrhea, abdominal pain, nausea, vomiting, abnormal or impaired skin sensations, vertigo, lack of muscle coordination, cold-to-hot sensation reversal, muscular pain and itching. Some of the symptoms may recur for as long as six months. Death occasionally results.

Currently, the principal test method is a mouse bioassay that is not suitable for commercial use. There is no validated method suitable for shipboard or dockside testing of large catches of fish. However, some such tests are being evaluated and may soon be available. In the mean-time, for those in the fish industry to avoid ciguatoxic fish, they must rely on local knowledge of safe harvest areas and avoid harvest from any officially designated areas or species.

- ***Other Marine Toxins***

Gempylotoxin

The gempylids, escolars or pelagic mackerels are a small group of fish-eating oceanic fish. Important species in this group include: *Lepidocybium flavobrunneum* (escolar — California, Peru, Hawaiian Islands, Australia, South Africa, Cuba, Aru Islands, Madeira), *Ruvettus pretiosus* (oilfish, castor oil fish, purgative fish — tropical Atlantic and Indo-Pacific oceans).

Gempylids produce an oil that has a purgative effect. The diarrhea caused by eating the oil contained in the flesh and bones of gempylid fish devel-ops rapidly and is pronounced but generally without pain or cramping. No other bad effects have been reported. There are not specific legal restrictions, but authorities advise caution that gempylid fish, including escolar, should not be imported or marketed in the United States.

Scombroid Toxin (Histamine)

Scombroid poisoning, also known as histamine poisoning, is caused by eating fish of certain species that have undergone spoilage by types of bacteria. These bacteria produce an enzyme that reacts with natural components of the fish flesh to produce histamine. Fish that have been involved in scrombroid poisonings include tuna, mahi mahi, bluefish, sardines, amberjack and mackerel. The toxin is not eliminated by cooking or canning.

Scombroid toxicity is a common illness associated with certain seafood. Illnesses are commonly reported each year. Deaths are rarely reported.

Symptoms of scombroid poisoning begin within four hours of eating contaminated fish. The most common symptoms include: a metallic, sharp or peppery taste; nausea; vomiting; abdominal cramps; diarrhea; swelling and flushing of the face; headache; dizziness; heart palpitations; hives; rapid and weak pulse; thirst; and difficulty in swallowing.

The histamine-forming bacteria usually grow rapidly only at high temperatures. At 90 F (32.2 C), unsafe levels of histamine may appear within six hours; at 70 F (21 C), 24 hours. Because wide variations occur between individual fish even under the same conditions, it is necessary to consistently remove heat rapidly from the freshly harvested fish and maintain a low temperature until the fish are prepared for consumer use. Particularly for large fish, special precautions and equipment are required for the rapid removal of heat. Periodic increases in product temperature during storage can result in more histamine being formed. Histamine may form without the usual odors of decomposition. Sensory analysis is an effective screening method that reduces the risk of accepting histamine-containing fish. Chemical analysis for histamine is also possible. A detailed knowledge of the temperature history of the product provides the best control measure.

Tetrodotoxin (puffer fish)

Puffer fish, also called fugu or blowfish, contain the potent toxin, tetrodotoxin. It is unclear whether the fish itself produces the toxin, or like ciguatera, it is introduced to the fish by eating toxic algae. There are approximately 80 species of puffer fish that are known to contain tetrodotoxin in the Pacific, Atlantic and Indian oceans. The domestic species of puffer, sometimes called sea squab, is much less poisonous than the Japanese species.

Symptoms of poisoning usually begin within 10 minutes of consuming puffer fish. The victim first experiences numbness and tingling of the mouth. This is followed by weakness, paralysis, decreased blood pressure, and quickened and weakened pulse. Death can occur within 30 minutes. Puffer fish may not be imported into the United States except under strict certification requirements and specific authorization from FDA.

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Other Chemical Hazards

Overhead 6

Other Chemical and Physical Hazards:

- Aquaculture Drugs
- Allergens
- Chemical Contaminants
- Food Additives
- Glass
- Metal Fragments

• Aquaculture Drugs

Animal drugs may be used in the raising of aquatic species: 1) to treat or prevent disease, 2) to control parasites, 3) to affect reproduction, and 4) to tranquilize. Illegal residues of drugs may occur in aquaculture species because of the use of unapproved drugs, use of drugs not in accordance with the approved labeling directions, failure to follow approved withdrawal times, or use of general purpose chemicals not labeled or approved for drug use. There are only a few approved drugs for aquatic species. However, FDA approval is required before any animal drug is used to ensure that unsafe drug residues will not occur in edible tissue when animals are treated following approved label directions. The withdrawal period is the period from the last time of drug treatment until the residuals are allowed to reduce or be eliminated in the edible portions. The withdrawal time is usually within a number of days, depending on the drug, dosage, and growth of the seafood. Producer quality-assurance programs provide information and guidance for proper use of approved compounds and record-keeping practices that can be referenced in processor HACCP plans. Processors may consider conducting on-site audits of the animal-drug controls used by their producers. If rapid screening tests are considered for use by the processor or producer to detect or monitor drug residues in aquatic species, they must be validated for their intended use. These tests should only be used as a part of a complete risk-reduction, quality-assurance program and not be used as the only monitoring tool. Presently, FDA has no data to indicate these tests will provide reliable, quantitative results for drug screening in farm-raised aquatic species.

• Allergens

Certain food and color additives can cause an allergic-type reaction (food intolerance) in consumers. Examples of such food and color additives that are used on fish and fishery products include: sulfiting agents and FD&C Yellow #5. Sulfiting agents are mostly used during on-board handling of shrimp and lobster to prevent the formation of "black spot." They are sometimes used by cooked octopus processors as an antioxidant, to retain the red color of the octopus skin. FD&C Yellow #5 is used during in-plant

processing. These food and color additives are permitted for use in foods—with certain restrictions—but their presence must be declared on the label. This label declaration is particularly important to sensitive individuals.

Certain other food and color additives are prohibited from use in food because of a determination by FDA that they present a potential risk to the public health. Examples of such food and color additives include: safrole and FD&C Red #4.

Additionally, a number of foods contain allergenic proteins that can pose a health risk to certain sensitive individuals. Foods that account for most of all food allergies include peanuts, soybeans, milk, eggs, fish, crustaceans, tree nuts and wheat. If these foods are part of, or are directly added to your fishery product, you must ensure that the product is properly labeled. However, these controls are not designed to prevent the unintentional introduction of allergenic proteins from such foods into your fishery product because of cross-contact (e.g. use of common equipment, improper production scheduling, or improper use of rework material). Unintentional introduction of allergenic proteins must be controlled through a rigorous sanitation regime, either as part of a prerequisite program or as part of HACCP itself.

- ***Chemical Contaminants***

Fish are harvested from waters that are exposed to varying amounts of environmental contaminants. Industrial chemicals, pesticides, and many toxic elements may accumulate in fish at levels that can cause public health problems. Of greatest concern are fish harvested from freshwater, estuaries, and nearshore waters rather than from the open ocean. Pesticides and herbicides used near aquaculture operations are also of concern. Federal tolerances or action levels are established for some of the most toxic and persistent contaminants. States often use limits for deciding whether to close waters for harvesting. Processors should be aware of these closures and should not purchase fish that have been harvested in closed areas. Pesticides and herbicides that may be used near aquaculture operations are also potential problems. Producer quality-assurance programs provide useful information for avoiding potential contaminants from a variety of sources, beginning with proper site selection.

- ***Food Additives***

Food and color additives are used in many fish and fishery products, including some usage by fishermen and aquaculturists. Many additives are acceptable in such products when used in conformity with GMPs and established limits. Other additives are not permitted in fish or fishery products. Before using a food additive, the processor should become familiar with the applicable legal limitations for its use. The processor should be especially aware of food additives that are known to cause allergic-type reactions or are otherwise linked to adverse health conse-

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quences if not properly used. These reactions can be severe (e.g., anaphylactic shock induced by sulfites or yellow 5 and 6 can be fatal). The use of color additives that are permitted should be carefully controlled to ensure they remain within established limits. Correct listing of food and color additives on the product label is a legal requirement.

• ***Glass***

Glass fragments can cause injury to the consumer. FDA's Health Hazard Evaluation Board has supported regulatory action against products with glass fragments of 0.3" (7 mm) to 1.0" (25 mm) in length. See FDA Compliance Policy Guide #555.425.

Glass inclusion can occur whenever processing involves the use of glass containers. Normal handling and packaging methods, especially mechanized methods, can result in breakage. Most products packed in glass containers are intended as a ready-to-eat commodity. Glass fragments originating from other sources must be addressed, where applicable, in a prerequisite sanitation program.

Physical Hazards

• ***Metal Fragments***

Metal-to-metal contact—especially in mechanical cutting and blending operations, and with equipment that has parts that can break or fall off, such as wire-mesh belts—can introduce metal fragments into products. Such fragments serve as a hazard to the consumer. This hazard can be controlled by subjecting the product to metal detection devices or by regular inspection of at-risk equipment for signs of damage.

Appendix IV: CCP Decision Tree

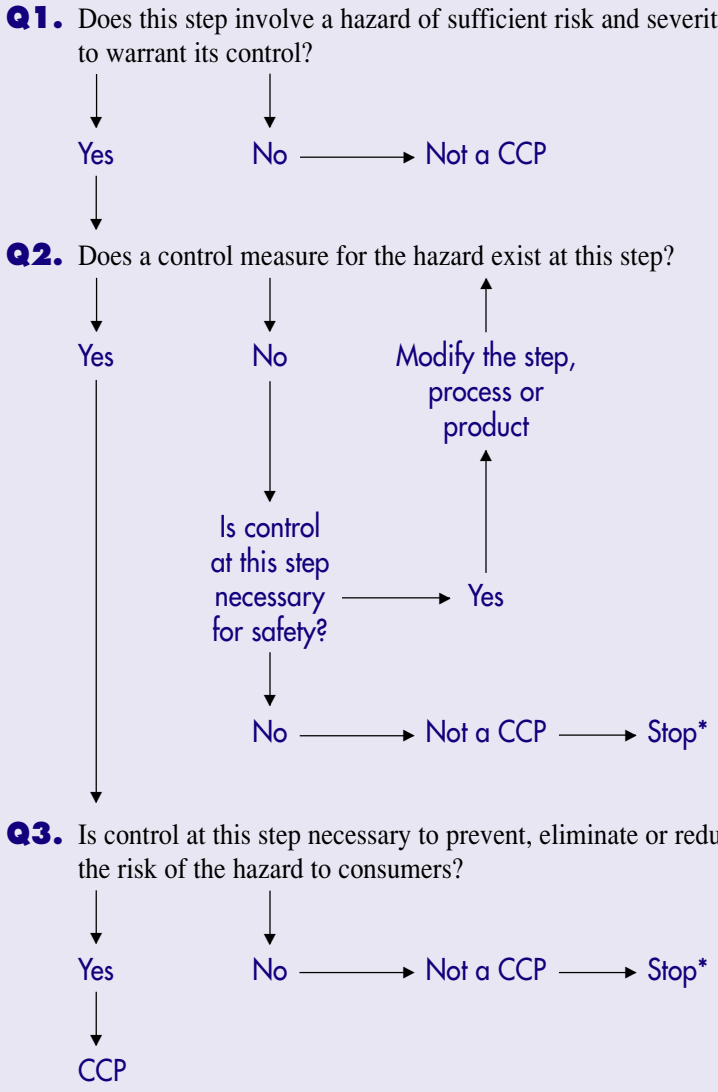
Appendix 4 - CCP Decision Tree

Notes:

Example of a CP Decision Tree

Important considerations when using the decision tree:

- The decision tree is used after the hazard analysis.
- The decision tree is used at the steps where a significant hazard has been identified.
- A subsequent step in the process may be more effective for controlling a hazard and may be the preferred CCP.
- More than one step in a process may be involved in controlling a hazard.
- More than one hazard may be controlled by a specific control measure.



** Proceed to the next step in process.*

Appendix V: **Models**

Examples For Illustrative Purposes Only
(Models may not be fully consistent with guidance contained in FDA's *Fish and Fishery Products Hazards and Control Guide*.)

Notes:

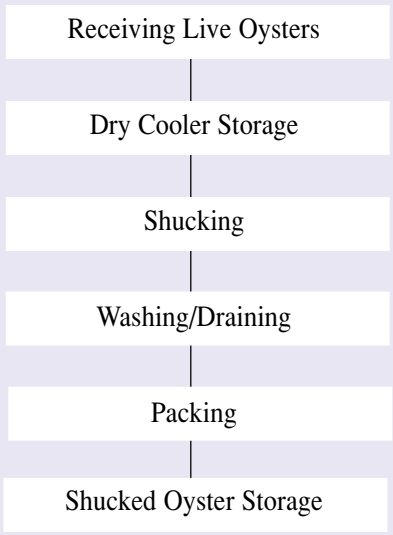
Raw Oysters: Description of the Process

Example: For Illustrative Purposes Only
(Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

Live Chesapeake Bay oysters are received from harvesters sacked and tagged. Shellstock are delivered to the processing facility within 20 hours of harvesting.

Upon delivery to the processing facility, the shellstock is refrigerated at 45 F until shucked. This is dry storage. Oysters may be kept several days before shucking. Shellstock is placed on tables for hand shucking into buckets. Buckets of shucked oyster meat are given to the packing room for washing, draining and placing into pint containers. Shucked meats are stored at 40 F.

Shucked Oyster Process Flow Chart



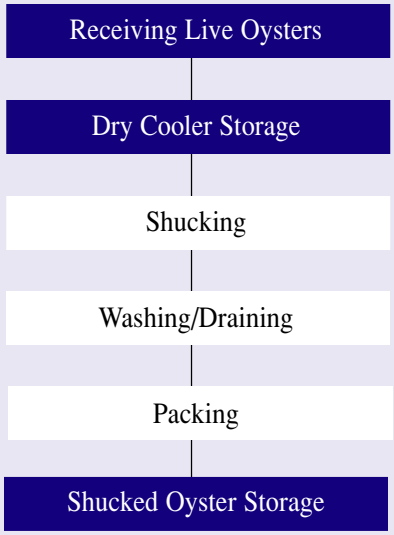
Notes:

Continued

Notes:

Shucked Oyster Process Flow Chart

Shaded step is critical control point



*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 measures can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Receiving Live Oysters	BIOLOGICAL Bacterial pathogen contamination	Yes	Oysters are assumed to be eaten raw. Oysters are easily contaminated with pathogens from harvesting waters.	• Only accept shellstock from waters open to harvest. • Require proper tagging. • Require proper harvester license.	Yes
	Baterial pathogen growth	Yes	Growth between harvest and receiving	• Limit time from harvest to receiving is less than 20 hours	Yes
	CHEMICAL Chemical contamination	Yes	Industrial pollution frequently occurs in estuarine waters. Oysters may become contaminated with these pollutants.	• Only accept shellstock from waters open to harvest. • Require proper tagging. • Require proper harvester license.	Yes
	Natural toxins	Yes	Natural toxins and organisms that produce them can be filtered and concentrated by oysters.	• Only accept shellstock from waters open to harvest. • Require proper tagging. • Require proper harvester license.	Yes
	PHYSICAL None				
Dry Cooler Storage	BIOLOGICAL Bacterial pathogen growth	Yes	Pathogens may increase in number if oysters are not properly cooled during storage.	Maintain coolers at temperatures below 45 F.	Yes
	CHEMICAL None				
	PHYSICAL None				
Shucking	BIOLOGICAL Bacterial pathogen growth	Yes	Excessive time in shucking room can promote pathogen growth.	Cumulative time of exposure is being controlled at shucked-oyster storage.	No
	CHEMICAL None				
	PHYSICAL • Bits of shell	No	Hazard analysis indicates that this inherent defect is not "reasonably likely" to result in the food being unsafe for consumption.		
	• Metal fragments	No	Not reasonably likely to occur.		

Firm Name: *ABC Oyster Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Shucked oysters in plastic pint containers*

Method of Storage and Distribution: *Shipped on ice and refrigerated; stored at retail under refrigeration.*

Intended Use and Consumer: *Raw consumption*

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step(1)	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decisions for column 3.	(5) What control measures can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Washing/Draining	BIOLOGICAL Bacterial pathogen growth CHEMICAL None PHYSICAL None	Yes	Excessive time at washing/ draining step can promote pathogen growth.	Cumulative time of exposure is being controlled at shucked-oyster storage.	No
Packing	BIOLOGICAL Bacterial pathogen growth CHEMICAL None PHYSICAL None	Yes	Excessive time at packing step can promote pathogen growth.	Cumulative time of exposure is being controlled at shucked-oyster storage.	No
Shucked Oyster Storage	BIOLOGICAL Bacterial pathogen growth CHEMICAL None PHYSICAL None	Yes	Pathogens may increase in number if oysters are not properly cooled during storage.	Maintain cooler temperature. Limit the cumulative exposure time of oysters to ambient temperatures.	Yes

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Receiving live oysters	Pathogen contamination	• Must have properly tagged containers. • Must be licensed harvester. • No oysters from closed areas.	• Harvester tag • Harvester license	• Visual check	• Every container • Every delivery	• Quality-control person	Reject if untagged, improperly tagged, from closed areas or from unlicensed harvester.	Daily record review	Receiving record
	Pathogen growth	• Harvest time less than 24 hours	• Harvest time with tag	• Visual	• Every delivery	• Quality-control person	Reject if exceed harvest time limit	Daily record review	Receiving record
	Chemical contamination	• Must have properly tagged containers. • Must be licensed harvester. • No oysters from closed areas.	• Harvester tag • Harvester license	• Visual check	• Every container	• Quality-control person	Reject if untagged, improperly tagged, from closed areas or from unlicensed harvester.	Daily record review	Receiving record
	Natural toxins	• Must have properly tagged containers. • Must be licensed harvester. • No oysters from	• Harvester tag • Harvester license	• Visual check	• Every container	• Quality-control person	Reject if untagged, improperly tagged, from closed areas or from unlicensed harvester.	Daily record review	Receiving record

Firm Name: *ABC Oyster Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Shucked oysters in plastic pint containers*

Method of Storage and Distribution: *Shipped on ice and refrigerated; stored at retail under refrigeration.*

Intended Use and Consumer: *Raw consumption*

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Dry cooler storage	Bacterial pathogen growth	closed areas. Coolers not to exceed 45 F for more than two hours.	Cooler temperature	Visual check of continuous temperature recorder	Visual check of continuous temperature recorder every two hours during operation.	Quality-control person	• Adjust cooler temperature. • Hold and evaluate product based on total time of exposure to abusive temperatures.	• Daily record review • Thermometer calibration weekly	• Cooler temperature record • Recorder chart
Shucked Oyster Storage	Bacterial pathogen growth	• Cooler temperature must not exceed 45 F for a time greater than two hours. • No more than three hours from removal of product from dry storage cooler to placement in the shucked oyster storage	• Cooler temperature recorder • Time from dry storage cooler to shucked oyster storage	• Visual checks of continuous temperature recorder • Check progress of marked product	• Visual check of continuous temperature recorder every two hours during operation • Marked product checked every two hours	Quality-control person	• Adjust cooler temperature. • Hold and evaluate based on time and exposure by competent authority. • Ice product and/or return shell-stock to cooler; hold and evaluate based on time of exposure.	• Daily record review • Weekly temperature recorder calibration	• Cooler temperature record • Marked product exposure log

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

Dried Shrimp: Description of the Process

Example: For Illustrative Purposes Only
(Models may not be fully consistent wiht guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

Shrimp received for drying are head-on, small and fresh. They are delivered on ice by fishermen. The drying process is seasonal.

Head-on shrimp are kept on ice until processed. Shrimp are washed and weighed to remove ice and damaged shrimp. Shrimp are boiled in seasoned (salt) water. The amount of salt used to season the shrimp may vary and is determined by desired flavor of the end product.

After boiling each batch of shrimp, additional salt is added to the cook water to maintain a constant concentration. Cooked shrimp are placed in forced-air drying units until the shrimp are properly dried, usually six to seven hours.

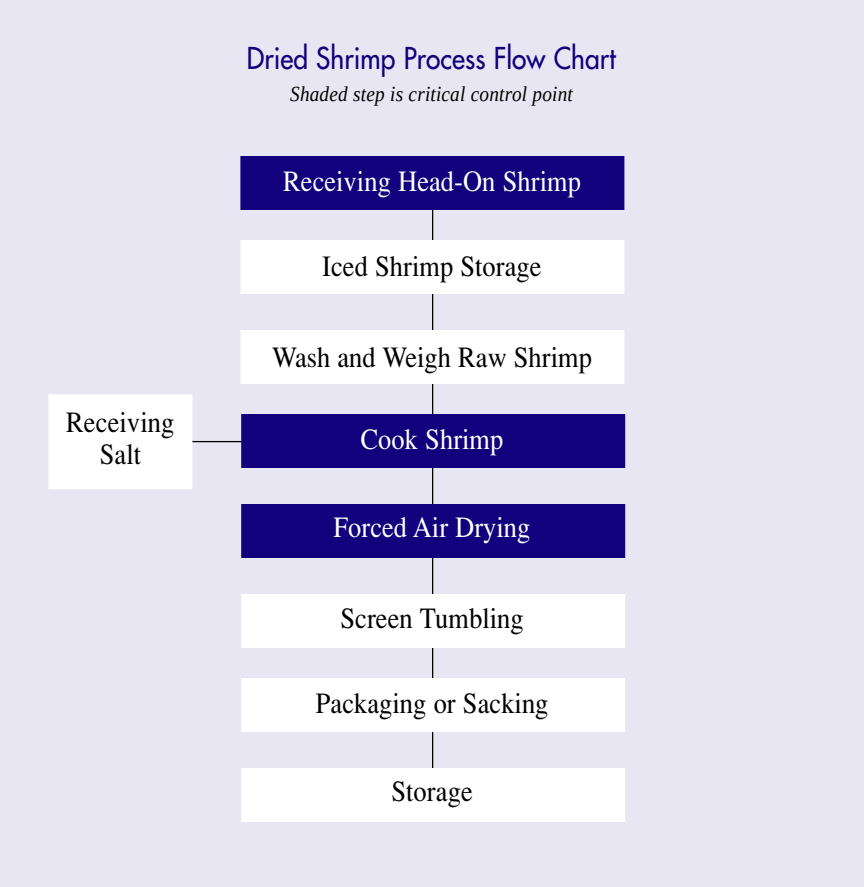
The dried shrimp are rotated in a screen drum to remove shells and heads from the dried meat. Dried shrimp tails are sacked and stored. Sulfite is not declared on the label because sulfited shrimp are not used. The shrimp may be stored under refrigeration, although this is not necessary.

Continued

Notes:

Notes:


Dried Shrimp Process Flow Chart
Receiving Head-On Shrimp
Iced Shrimp Storage
Wash and Weigh Raw Shrimp
Receiving Salt
Cook Shrimp
Forced Air Drying
Screen Tumbling
Packaging or Sacking
Storage


Dried Shrimp Process Flow Chart
Shaded step is critical control point
Receiving Head-On Shrimp
Iced Shrimp Storage
Wash and Weigh Raw Shrimp
Receiving Salt
Cook Shrimp
Forced Air Drying
Screen Tumbling
Packaging or Sacking
Storage

Notes:

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazard introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? Yes/No)	(4) Justify your decisions for column 3.	(5) What control measures can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Receiving Shrimp	BIOLOGICAL Bacterial pathogen contamination CHEMICAL Sulfiting agent PHYSICAL None	Yes Yes	Raw seafood can be natural reservoirs for pathogens. Potential for allergic-type reaction.	Cooking will destroy prior to consumption. Reject shrimp containing sulfite residuals.	No Yes
Iced Shrimp Storage	BIOLOGICAL Bacterial pathogen growth CHEMICAL None PHYSICAL None	Yes	Pathogen growth if temperature abused.	Cooking will destroy prior to consumption.	No
Receiving Salt	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Wash Raw Shrimp	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Cook Shrimp	BIOLOGICAL Pathogen survival CHEMICAL None PHYSICAL None	Yes	Improper cooking will allow survival of pathogens.	Control time/temperature during cooking.	Yes

Firm Name: *ABC Shrimp Drying Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Dried shrimp in cloth sacks*

Method of Storage and Distribution: *Dry storage, unrefrigerated*

Intended Use and Consumer: *Ready to eat without further processing*

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(1) Ingredient/processing step	(2) Identify potential hazard introduced, controlled or enhanced at this step.	(3) Are any potential food-safety hazards significant? Yes/No)	(4) Justify your decisions for column 3.	(5) What control measures can be applied to prevent the significant hazards?	(6) Is this step a critical control point? (Yes/No)
Drying	BIOLOGICAL Pathogen growth CHEMICAL None PHYSICAL None	Yes	Improperly dried shrimp will have a wet spot, allowing pathogen growth.	Reduce water activity to acceptable levels.	Yes
Tumbling	BIOLOGICAL • Pathogen recontamination • Pathogen growth CHEMICAL None PHYSICAL None	No No	Controlled by SSOP. Low water activity.		
Packing	BIOLOGICAL Pathogen recontamination Pathogen growth CHEMICAL None PHYSICAL None	No No	Controlled by SSOP. Low water activity.		
Storage	BIOLOGICAL Pathogen growth CHEMICAL None PHYSICAL None	No	Low water activity.		

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Receiving head-on shrimp	Sulfite residuals	No detectable sulfite residuals	Presence of sulfite residuals in any 3 grab samples	Rapid sulfite test	Every boat	Dockmaster	Reject if present	• Daily record review • Lab reports with official AOAC tests seasonally	Receiving record
Cook Shrimp	Survival of pathogens	Boiled at 212 F for three minutes	Water temperature and time of cook	Visual check of boiling and time check	Every batch	Cooking operator	Hold and evaluate or recook.	• Daily record review • Validation study (on file)	Cooking log
Drying	Pathogen growth	Water activity .85 or less achieved within eight hours	Water activity and drying time	Water activity meter and drying cycle timer	Every batch	Quality-control person	If .85 water activity is not achieved within eight hours, continue drying cycle and hold and evaluate by competent authority.	• Daily record review • Calibration of water activity meter	Drying record

Firm Name: *ABC Shrimp Drying Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Dried shrimp in cloth sacks*

Method of Storage and Distribution: *Dry storage, unrefrigerated*

Intended Use and Consumer: *Ready to eat without further processing*

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

Pasteurized Blue Crabmeat: Description of Process Flow

Example: For Illustrative Purposes Only
(Models may not be fully consistent wiht guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

Blue crabs are caught and transported live to processing facilities by either boat or truck. On arrival, the crabs are inspected for physical damage, chemical contamination and mortality. Those crabs that are not immediately processed are placed in a cooler (55 F to 65 F) for a maximum of 24 hours.

The crabs are cooked in a retort for 10 minutes at 250 F (15 psig). Cooked crabs are placed in an air-cool room for a maximum of two hours or until steam is not visible from the crabs. The crabs are then placed in a refrigerated room at 45 F until processed.

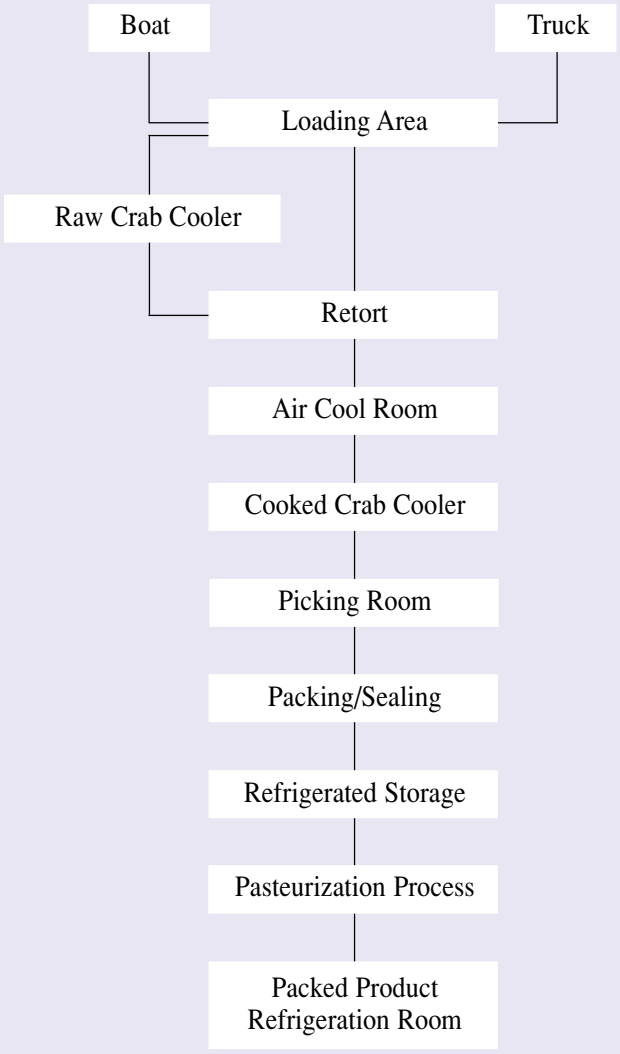
The cooled crabs are picked by hand into metal cans. In the packing rooms, cans are check-weighed and hermetically sealed on a one head seamer. The sealed containers are refrigerated. Within 48 hours of picking, meat is pasteurized. During the pasteurization process, the can of picked meat is heated in a water bath followed by cooling in ice slush. Finished product containers are stored under refrigeration.

Continued

Notes:

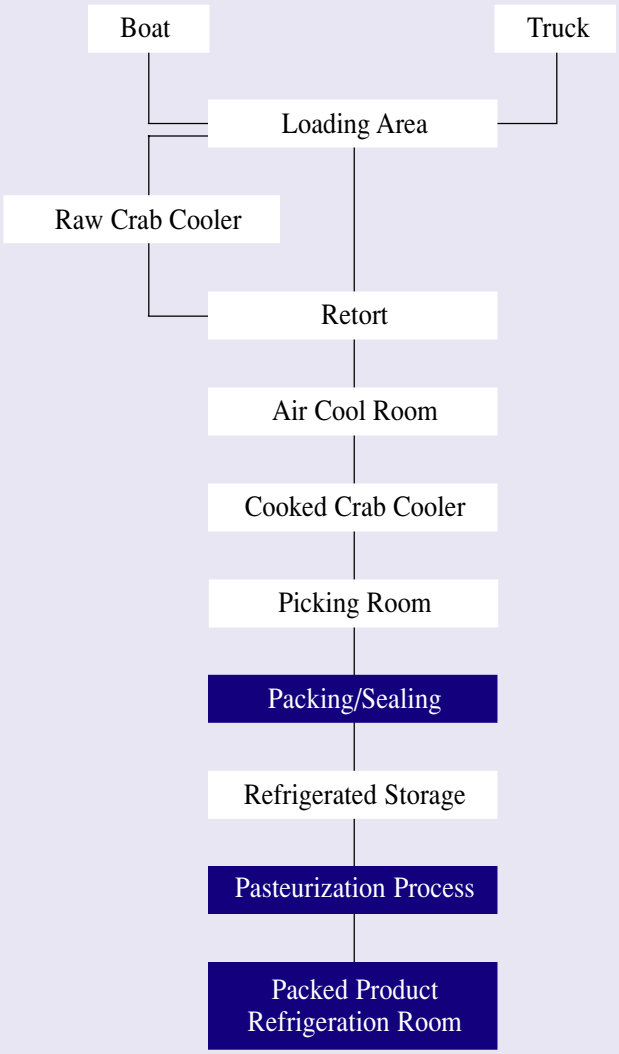
Notes:

Pasturized Blue Crabmeat Processing Flow Chart



Pasturized Blue Crabmeat Processing Flow Chart

Shaded step is Critical Control Point



Notes:

Continued

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 hazards?	(6) Is this step a critical control point? (Yes/No)
Receipt	BIOLOGICAL Bacterial pathogen contamination CHEMICAL Environmental contaminants PHYSICAL None	Yes No	Raw crabs can be a reservoir for pathogens. No history of problems with crabs in area of harvest.	Pasteurization eliminates pathogens.	No
Raw Crab Cooler	BIOLOGICAL Bacterial pathogen growth CHEMICAL None PHYSICAL None	Yes	Raw crabs contain human pathogens that can grow under refrigerated conditions.	Pasteurization eliminates pathogens.	No
Retort	BIOLOGICAL Pathogen survival CHEMICAL Boiler chemicals PHYSICAL None	Yes No No	Improper cook will not kill or inactivate human pathogens. SSOP	Pasteurization eliminates pathogens.	No
If this product was sold as fresh crabmeat, then the retort process may be a critical control point.					
Air Cool Room	BIOLOGICAL Pathogens CHEMICAL None PHYSICAL None	No	• Recontamination controlled by SSOP. • Bacterial growth controlled by hot crab temperature and short holding time.		

Firm Name: *ABC Crab Co.*

Firm Address: *Anywhere, USA*

Signature:

Date:

Product Description: *Pasteurized crabmeat in hermetically sealed steel cans*

Method of Storage and Distribution: *Refrigerated*

Intended Use and Consumer: *Ready to eat without further processing*

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 hazards?	(6) Is this step a critical control point? (Yes/No)
Cooked Crab Cooler	BIOLOGICAL Bacterial pathogen growth	Yes	Time/temperature abuse could allow pathogen growth.	Pasteurization eliminates the pathogens.	No
	CHEMICAL None				
	PHYSICAL None				
Picking Room	BIOLOGICAL • Bacterial pathogen growth	Yes	Excessive time in processing room will promote pathogen growth.	Pasteurization will eliminate the pathogens.	No
	• *Staphylococcus aureus*	No	Although humans are natural reservoirs, using USDA's pathogen modeling program, it was determined that the temperature abuse conditions necessary for growth of *S. aureus* to levels sufficient for toxin production were not reasonably likely to occur.		
	• Bacterial pathogen recontamination	No	SSOP		
	CHEMICAL None				
	PHYSICAL Shell	No	Hazard analysis indicates that this inherent defect is not "reasonably likely" to result in the food being unsafe for consumption.		
Packing/Sealing	BIOLOGICAL • Bacterial pathogen recontamination through can seams	Yes	Defective seams may allow entry of *Clostridium botulinum* type E.	Proper can seams.	Yes
	• Bacterial pathogen growth	Yes	Excessive time in processing room will promote pathogen growth.	Pasteurization will eliminate the pathogens.	No
	• *Staphylococcus aureus*	No	Although humans are natural reservoirs, using USDA's pathogen modeling program, it was determined that the temperature abuse conditions necessary for growth of *S. aureus* to levels sufficient for toxin production were not reasonably likely to occur.		
	CHEMICAL None				
	PHYSICAL None				

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 hazards?	(6) Is this step a critical control point? (Yes/No)
Refrigerated Storage	BIOLOGICAL Bacterial pathogen growth CHEMICAL None PHYSICAL None	Yes	Time/temperature abuse could allow pathogen growth.	Pasteurization eliminates the pathogens.	No
Pasteurization	BIOLOGICAL Pathogen survival CHEMICAL None PHYSICAL None	Yes No No	Pathogens will survive an improper thermal process.	Apply proper themal process.	Yes
Packed Product Refrigeration Room	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	Yes	Human pathogens (*Clostridium botulinum*, Type A) could grow if product is temperature abused.	Proper refrigeration.	Yes

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4)	(5) Monitoring	(6)	(7)	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Packing/Sealing	Bacterial pathogen recontamination through can seams	Container seams meet manufacturer's specifications	Can seams	• Can-seam tear-down evaluation • Visual seam examination	• Monitor one can at start-up when an adjustment is made to sealing machine and every four hours during operation • One can every half hour	Quality-control person	• Readjust can seaming machine. • Hold and evaluate product since previous checks.	Daily record review	Can-seam evaluation form
Pasteurization	Survival of pathogens	For 401 x 301 can, minimum water bath 188 F, time 120 minutes in bath. This cook achieves F=31, ref. 185 F, z=16 and 6D kill process	Water-bath temperature and time of pasteurization	Recording thermometer	Each batch	Quality-control person	Recook, reject product or hold for evaluation.	• Daily record review • Process validation (on file). • Calibration of temperature re-corder to MIG thermometer daily and annual calibration of MIG thermometer	Recorder chart
Refrigerated Storage	Bacterial pathogen, *C. botulimum* type A growth in packed product	50 F maximum for cooler cooler	Temperature of thermometer	Recording visual checks and visual check during operation	Continuous with person every four hours	Quality-control evaluate based temperature	• Hold and review on time and temperature of exposure. • Adjust cooler.	• Daily record • Cooler • Calibration of record recorder with MIG thermometer weekly	• Recorder charts temperature

Firm Name: *ABC Crab Co.*

Firm Address: *Anywhere, USA*

Signature:

Date:

Product Description: *Pasteurized crabmeat in hermetically sealed steel cans*

Method of Storage and Distribution: *Refrigerated*

Intended Use and Consumer: *Ready to eat without further processing*

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

Notes:

Vacuum Packed Hot Smoked Salmon, Cooked Ready-to-Eat Product: Description of Process Flow

Example: For Illustrative Purposes Only
(Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

Salmon are caught in set nets, which are positioned near the shoreline. The fish are held on ice in the round (whole, uneviscerated) until delivery to the processing plant, usually within a few hours of harvest. At the processing facility, the raw material is placed into totes, iced and placed in a cooler until needed for processing.

The totes are brought from the cooler into the processing area where they are placed onto a tote dumper that lifts the tote and dumps the product into a hopper. As needed, the hopper door is opened, and the fish flow onto a table. An employee aligns the fish toward an automatic header and eviscerator. After heading and eviscerating, the fish are transported via a conveyer belt to a table where employees fillet the fish. Employees at the end of the fillet line check for bones and inadequate evisceration, sort by size and place the fillets into a brine solution. These fish are brined for 24 hours under refrigeration to achieve the desired water-phase salt content.

After brining, the brine tanks are drained. The fillets are rinsed and placed onto racks for surface drying prior to smoking. Drying takes approximately four hours and is performed under refrigeration. After drying, the racks are rolled into the smoking/cooling unit. The fish are hot smoked for approximately six hours.

After smoking, the racks are removed from the unit and rolled into the cooler. Employees remove the smoked salmon from the racks and place them into prelabeled packages. The packages are vacuum sealed and then placed into 25-pound boxes. The boxes are palletized and stored in a cooler until distributed.

Continued

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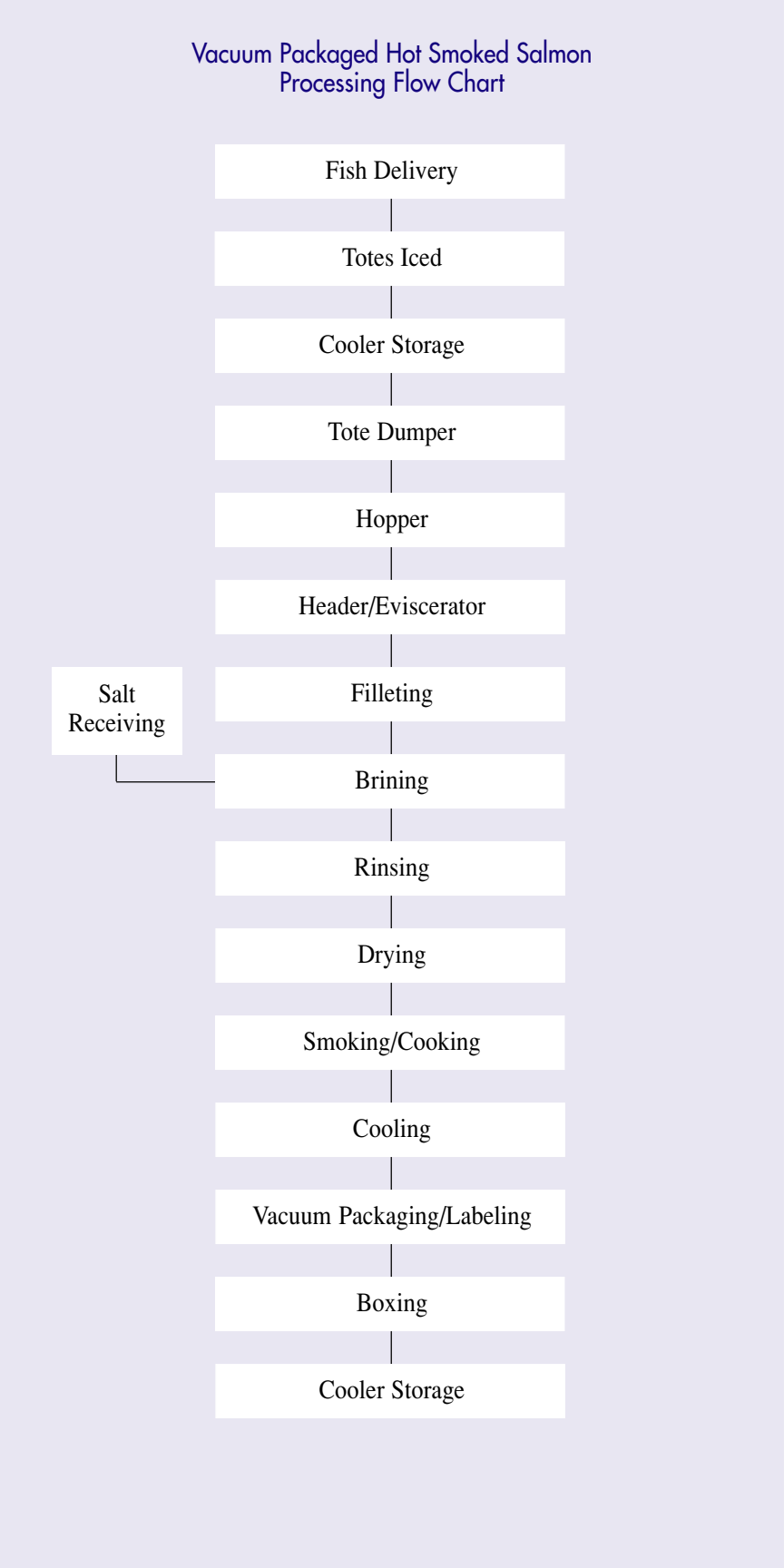
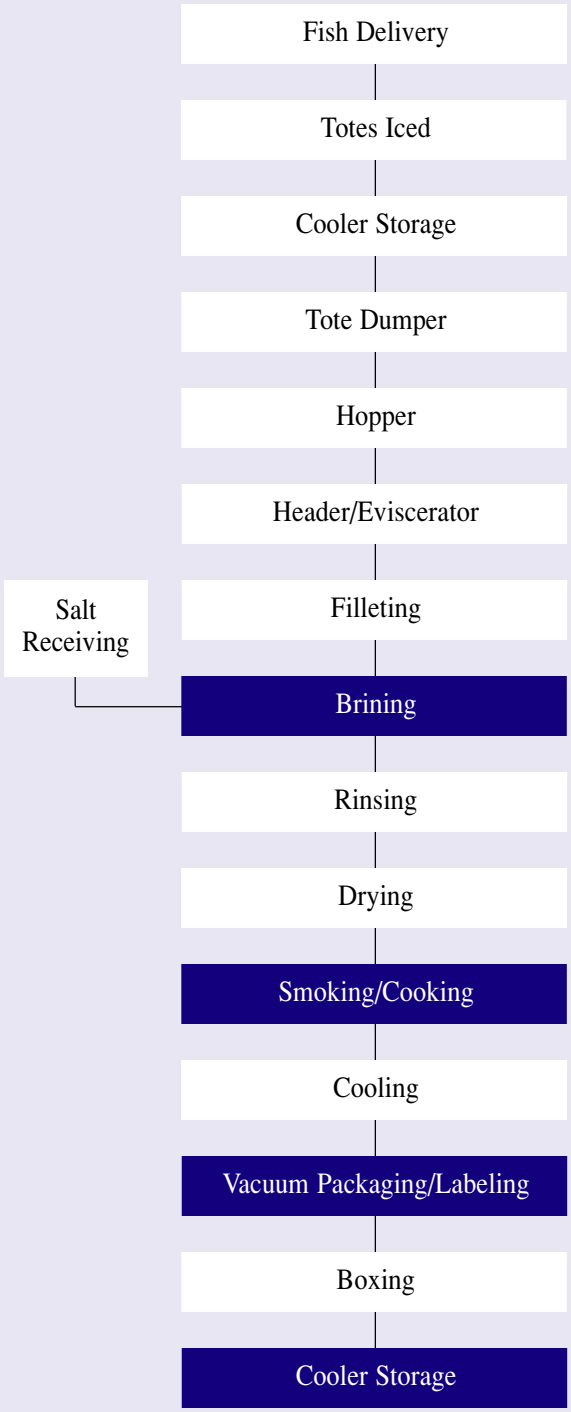

Vacuum Packaged Hot Smoked Salmon
Processing Flow Chart
Fish Delivery
Totes Iced
Cooler Storage
Tote Dumper
Hopper
Header/Eviscerator
Salt Receiving
Filleting
Brining
Rinsing
Drying
Smoking/Cooking
Cooling
Vacuum Packaging/Labeling
Boxing
Cooler Storage

Vacuum Packaged Hot Smoked Salmon Processing Flow Chart

Shaded step is Critical Control Point



Notes:

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 hazards?	(6) Is this step a critical control point? (Yes/No)
Fish Delivery	BIOLOGICAL • Bacterial pathogen contamination • Parasites CHEMICAL None PHYSICAL None	Yes Yes	Raw seafood can be natural sources for pathogens. Parasites occur in wild-caught fish.	Hazard is controlled at the smoking/cooking step. Hazard is controlled at the smoking/cooking step.	No No
Totes Iced	BIOLOGICAL • Bacterial pathogen growth • Bacterial pathogen contamination CHEMICAL None PHYSICAL None	No No	Period of time at this location is short. SSOP		
Cooler Storage	BIOLOGICAL Bacterial pathogen growth CHEMICAL None PHYSICAL None	Yes	Temperature abuse can allow the growth of pathogenic microorganisms.	Hazard is controlled at the smoking/cooking step.	No
Tote Dumper	BIOLOGICAL • Bacterial pathogen growth • Bacterial pathogen contamination CHEMICAL None PHYSICAL None	No No	Period of time at this location is short. SSOP		

Firm Name: *ABC Smoked Salmon Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Smoked salmon*

Method of Storage and Distribution: *Refrigeration*

Intended Use and Consumer: *Ready to eat without further processing*

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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)
Hopper	BIOLOGICAL • Bacterial pathogen growth	No	Period of time at this location is short.		
	• Bacterial pathogen contamination	No	SSOP		
	CHEMICAL None				
	PHYSICAL None				
Header/Eviscerator	BIOLOGICAL Bacterial pathogens including *C. botulinum*	Yes	Raw seafood can be a natural source of pathogens.	Hazard is controlled at the cooking step, which is based on a high initial load of *C. botulinum.*	No
	CHEMICAL None				
	PHYSICAL Metal Fragments	No	Subsequently brining and rinsing will remove any metal fragments; little opportunity for any metal to become embedded into the flesh of fish. No historical problem.		
Filleting	BIOLOGICAL • Bacterial pathogen growth	No	Period of time at this location is short.		
	• Bacterial pathogen contamination	No	SSOP		
	CHEMICAL None				
	PHYSICAL None				
Salt Receiving	BIOLOGICAL None				
	CHEMICAL None				
	PHYSICAL None				
Brining	BIOLOGICAL • *C. botulinum* growth and toxin production in finished product	Yes	Salt content in the flesh in combination with the smoke and heat treatment is necessary to control growth.	Proper brining.	Yes
	• Other bacterial pathogens	Yes	Salt content in the flesh is insufficient to inhibit growth.	Hazard is controlled at the smoking/cooking step.	No
	CHEMICAL None				
	PHYSICAL None				

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 hazards?	(6) Is this step a critical control point? (Yes/No)
Rinsing	BIOLOGICAL • Bacterial pathogen • Bacterial pathogen contamination CHEMICAL None PHYSICAL None	No No	Period of time at this location is short. SSOP		
Drying	BIOLOGICAL Bacterial pathogen CHEMICAL None PHYSICAL None	Yes No	Salt content in the flesh is insufficient to inhibit growth.	Hazard is controlled at the smoking/cooking step.	No
Smoking/cooking	BIOLOGICAL Bacterial pathogen survival CHEMICAL None PHYSICAL None	Yes	Adequate cook is necessary to inactivate the bacterial pathgens in the raw materials and introduced during processing.	Proper smoking/cooking .	Yes
Cooling	BIOLOGICAL • Pathogen recontamination • *C. bot.* type E growth • *C. bot.* type A growth • Growth of other pathogens CHEMICAL None PHYSICAL None	No No No No	Controlled by SSOPs. Combination of salt and inhibitors from smoke. Length of time necessary to grow is not reasonably likely to occur. Length of time necessary to grow is not reasonably likely to occur.		
Vacuum Packaging/Labeling	BIOLOGICAL • Bacterial pathogens introduced during packaging/labeling • Growth of proteolytic *C. bot.* CHEMICAL None PHYSICAL None	No Yes	Controlled by SSOPs. Severe temperature abuse can allow growth during subsequent distribution and storage.	Appropriate label statement regarding importance of refrigeration. Include time temperature integrator label or recorder	Yes

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*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 hazards?	(6) Is this step a critical control point? (Yes/No)
Boxing	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	No	Period of time at this location is short.		
Cooler Storage	BIOLOGICAL Proteolytic *C. botulinum* growth CHEMICAL None PHYSICAL None	Yes	*C. botulinum* can grow if not refrigerated.	Proper refrigeration and temperature integrator labels or recorders	Yes

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Brining	*C. botulinum* toxin production in the finished product	• Minimum 24-hour soaking time • Minimum salt content of 60° salometer at start of process • Minimum 2:1 ratio of brine to fish (weight to weight)	• Time in brine • Salt content of brine • Weight of fish and brine	• Visual time checks • Salometer • Weight of fish (scale) • Weight of brine (calibrated mark on tank)	• Each batch before removing fish • Each batch at start of process • Each batch	• Production employee • Quality-control person • Production employee	• Hold longer in brine solution. • Add salt. • Adjust amount of fish or brine.	• Daily review record • Study showing brining method provides at least 3.5 percent water phase salt • Quarterly finished product analysis for water phase salt	• Processing record • Processing record • Processing record
Explanatory Note: In many cases it will be necessary to control the drying step to achieve the desired water-phase salt content in finished product.									

Firm Name: *ABC Smoked Salmon Co.*

Firm Address: *Anywhere, USA*

Signature:

Date:

Product Description: *Smoked salmon*

Method of Storage and Distribution: *Refrigeration*

Intended Use and Consumer: *Ready to eat without further processing*

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Smoking/Cooking	Bacterial pathogen survival	• Minimum internal temperature of fish of 145 F for 30 minutes	• Fish internal temperature and time	• Thermocouple probes in the three thickest fish in the coldest part of oven	• Continuous with visual check at the end of each batch	• Smoker operator	• Recook, destroy, or hold product and evaluate.	• Daily record review • Study identifying cold spot in the smoker • Calibration of the recording device at the beginning and end of each day • Quarterly testing of water phase salt content	• Thermocouple recording chart
• Vacuum/Packing Labeling	• Growth of proteolytic *C.botulinum* in prolonged product	• Presence of appropriate label statement • Presence of time temperature integrator labels (TTI's)	• Product label • TTI's present and activated	• Visual • Visual	• Pre-operational checks • Every package	• Packing supervisor • Quality-control person	• Reject packages without label statement and replace with appropriate . packages • Hold and evaluate packages without TTI's; place and activate proper TTI's	• Weekly record review • Daily record review	• Pack room log
• Cooler storage	• Pathogen growth and potential toxin production	• Maximum cooler temperature of 40ºF > 2 hours TTI color	• Cooler temperature and exposure time • TTI color changes	• Recorder thermometer and TTI visuals daily	• Record continuously; check chart every 12 hours and TTI's.	• Quality-control person	• Readjust cooler thermostat. Hold and evaluate, based on time and temperature of exposure	• Daily record review and weekly calibration of recording thermometer	• Cooler temperature chart and pack room record

Explanatory note: TTI's would accompany the products until they are opened to atmospheric conditions that prevent *C. botulinum* growth

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

Notes:

Frozen Breaded Fish Sticks: Description of Process Flow

Notes:

Example: For Illustrative Purposes Only
(Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

The fish sticks are not fully cooked. They are packed in a PET tray with a heat-sealed plastic film lid. There is no atmosphere modification. Each package is labeled with a "use by" date, cooking instructions and the phrase, "keep frozen." The product is intended for the general public.

Imported frozen minced fish (either pollock or haddock) is received in frozen blocks via freezer truck. The blocks are transferred to frozen storage (-10 F).

Dry ingredients (batter, breading) and packaging materials are delivered to the plant by truck. Dry goods are placed in dry, cold storage.

To be processed, the fish blocks are removed from the freezer, one pallet at a time. Cases are opened and blocks unwrapped. Blocks are mechanically cut into preformed fish sticks. As sticks proceed on a conveyor belt, they are culled for uniformity and then battered and breaded, twice each. Recirculated batter is chilled to 45 F.

From the last breading application, the portions pass through a fryer containing soy bean oil for less than one minute at 400 F. This fryer sets the batter/breading but does not cook the fish.

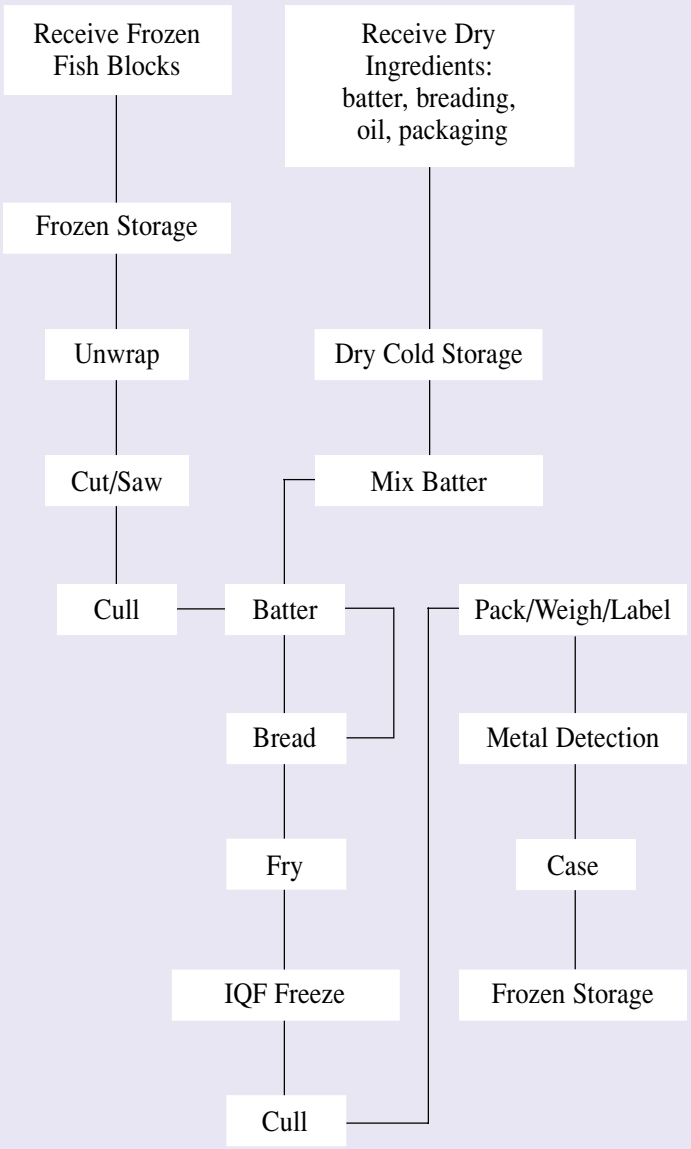
The fish sticks exit the fryer and enter a nitrogen tunnel for individual quick freezing. The nitrogen tunnel freezer is set at -120 F; the exposure time is 6 to 10 minutes.

As the fish sticks exit the freezer, they are culled for breading uniformity and packaged into either consumer packages (8 oz. or 22 oz.) or large food-service cartons (10 pounds). Then they are labeled and passed through a metal detector. Packages are cased, palletized and stored in the freezer at -10 F. Product is shipped on freezer trucks to retail or food-service distribution centers.

Continued

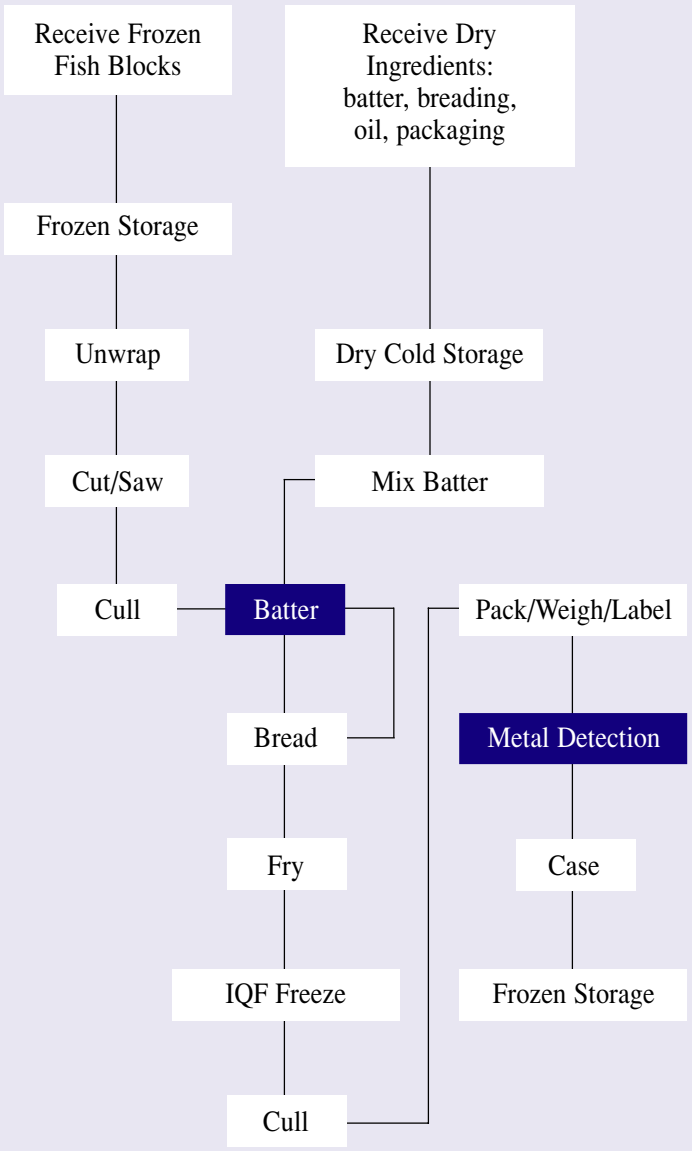
Notes:

Breaded Fish Sticks Process Flow Chart



Breaded Fish Sticks Process Flow Chart

Shaded step is Critical Control Point



Notes:

Continued

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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) Justifiy your decision for 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)
Receiving Frozen Fish Blocks	BIOLOGICAL • Pathogen contamination • Parasites CHEMICAL None PHYSICAL Bones	No No No	Product will be fully cooked by the consumer. Unlikely to be viable in frozen product. Hazard analysis indicates that this inherent defect is not "reasonably likely" to result in the food being unsafe for consumption.		
Frozen Storage	BIOLOGICAL Pathogens CHEMICAL None PHYSICAL None	No	Product is frozen so opportunity for pathogen growth is low.		
Unwrap	BIOLOGICAL • Pathogen growth • Pathogen contamination CHEMICAL None PHYSICAL None	No No	• Period of time at this step is short. • Product is frozen. SSOP		

Firm Name: *ABC Breaded Fish Stick Co.*

Firm Address: *Anywhere, USA*

Product Description: *Partially cooked, battered and breaded fish sticks*

Method of Storage and Distribution: *Frozen*

Signature: _____

Date: _____

Intended Use and Consumer: *Cook and serve*

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 harzards?	(6) Is this step a critical control point? (Yes/No)
Cut/Saw	BIOLOGICAL • Pathogen growth	No	• Period of time at this step is short. • Product is frozen.		
	• Pathogen contamination	No	SSOP		
	CHEMICAL None				
	PHYSICAL Metal fragments	Yes	Risk of contaminating the product with broken saw blades	Metal detector at later step	No
Cull	BIOLOGICAL • Pathogen growth	No	• Period of time at this step is short. • Product is frozen.		
	• Pathogen contamination	No	SSOP		
	CHEMICAL None				
	PHYSICAL None				
Receive Dry Ingredients	BIOLOGICAL Pathogen contamination	No	Possibility of pathogen contamination is remote as documented by past experience.		
	CHEMICAL None				
	PHYSICAL None				
Dry Cold Storage	BIOLOGICAL None				
	CHEMICAL None				
	PHYSICAL None				
Mix Batter	BIOLOGICAL • Pathogen growth	No	Risk is low due to short mixing time.		
	• Pathogen contamination	No	Potable water is used (SSOP)		
	CHEMICAL None				
	PHYSICAL None				

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*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 hazards?	(6) Is this step a critical control point? (Yes/No)
Batter	BIOLOGICAL • Pathogen growth	Yes	Pathogen growth (staph toxin) if batter held too long at elevated temperature.	Keep temperature low.	Yes
	• Pathogen contamination	No	SSOP		
	CHEMICAL None				
	PHYSICAL Metal fragments	Yes	Metal fragments from wire-mesh conveyers	Metal detector at later step	No
Breading Operation	BIOLOGICAL • Pathogen growth	No	Application of dry breading does not promote pathogen growth.		
	• Pathogen contamination	No	SSOP		
	CHEMICAL None				
	PHYSICAL Metal fragments	Yes	Metal fragments from wire-mesh conveyor	Metal detector at later step	No
Fryer	BIOLOGICAL None				
	CHEMICAL Rancid cooking oil	No	Potential for toxic compounds from cooking oil is remote.		
	PHYSICAL None				
IQF Freeze	BIOLOGICAL Pathogens	No	Product is frozen within minutes of frying, making pathogen growth remote.		
	CHEMICAL None				
	PHYSICAL None				
Cull	BIOLOGICAL • Pathogen growth	No	• Period of time at this step is short. • Product remains frozen.		
	• Pathogen contamination	No	SSOP		
	CHEMICAL None				
	PHYSICAL None				

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 hazards?	(6) Is this step a critical control point? (Yes/No)
Pack/Weigh/Label	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Metal Detection	BIOLOGICAL None CHEMICAL None PHYSICAL Metal fragments	Yes	Metal fragments from saw and conveyer belts	Operable metal detector/ reject mechanism	Yes
Case	BIOLOGICAL Pathogen growth CHEMICAL None PHYSICAL None	No	• Time at this step is short so pathogens unlikely to grow. • Product remains frozen.		
Frozen Storage	BIOLOGICAL Pathogen growth CHEMICAL None PHYSICAL None	No	Product is frozen so pathogen growth unlikely.		

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4) Monitoring What	(5) Monitoring How	(6) Monitoring Frequency	(7) Monitoring Who	(8) Corrective Action(s)	(9) Verification	(10) Records
Batter	Bacterial pathogens and potential pathogen growth	Batter temperature not to exceed 50 F for greater than four hours	Temperature and exposure time for batter	Check temperature in hold tank.	Every hour	Quality-control person	• If batter temperature is over 50 F for more than four hours, dump batter and reclean hold tank. Destroy or hold and evaluate product made during deviation.	• Check records daily. • Calibrate thermometer weekly.	Quality-control log
Metal Detection	Metal	No detectable metal fragments in finished products	Metal fragments	Metal detector	Continuous	Labeling operator checks hourly to ensure detector is on.	If detector is not on or fails sensitivity check, then all product since last acceptable check is held and rechecked for metal.	• Run test material with metal of appropriate size to check sensitivity daily • Supervisor reviews operator logs daily.	• Operator's log

Explanatory note: FDA's Health Hazard Evaluation Board has supported action against product with metal fragments of 0.3" (7mm) to 1.0" (25mm)

Firm Name: *ABC Breaded Fish Stick Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Partially cooked, battered and breaded fish sticks*

Method of Storage and Distribution: *Frozen*

Intended Use and Consumer: *Cook and serve*

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

Frozen Salmon Fillets for Raw Consumption

Example: For Illustrative Purposes Only
(Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

Iced, whole wild-caught salmon are received directly from the fisher. The processor sells directly to XYZ Sushi Bar for raw consumption.

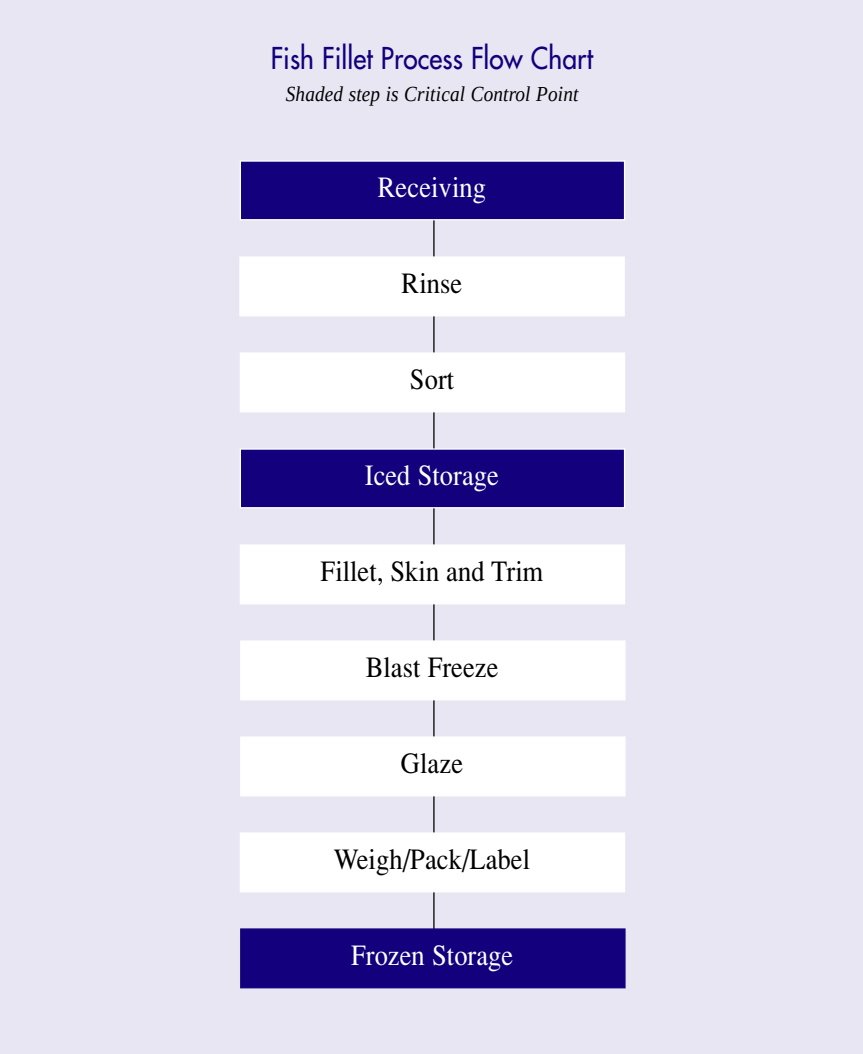
Fish are rinsed with potable water and sorted to remove ice and damaged fish. The fish are re-iced and held less than 24 hours before processing. Fish are filleted and trimmed by hand. Fillets are blast frozen, glazed with potable water, bagged and stored in the freezer. The finished product is distributed frozen.

Fish Fillet Process Flow Chart

Continued

Notes:

Notes:


Fish Fillet Process Flow Chart
Shaded step is Critical Control Point
Receiving
Rinse
Sort
Iced Storage
Fillet, Skin and Trim
Blast Freeze
Glaze
Weigh/Pack/Label
Frozen Storage

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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) Justifiy your decision for 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)
Receiving	BIOLOGICAL • Parasites	Yes	Parasites are present in the species being processed.	Freezing	No
	• Pathogens growth	Yes	Raw seafood can be natural source for pathogens. Therefore consumption of raw seafood carries some inherent risks. Risk can be reduced with thermal controls	Proper icing	Yes
	CHEMICAL Chemical contamination	No	Fish are harvested from waters where chemical contaminants are not likely to occur.		
	PHYSICAL None				
	If the processor has reasonable assurances that the product will be adequately frozen (as FDA Food Code) prior to consumption, the response in column 3 is "no" and the parasite hazard becomes a hazard to be controlled by the XYZ Sushi bar.				
Rinse	BIOLOGICAL • Bacterial pathogen growth	No	Period of time at this location is short.		
	• Bacterial pathogen contamination	No	SSOP		
	CHEMICAL None				
	PHYSICAL None				

Firm Name: *ABC Fish Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Salmon fillets, skinless*

Method of Storage and Distribution: *Frozen*

Intended Use and Consumer: *To be consumed raw*

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 harzards?	(6) Is this step a critical control point? (Yes/No)
Sort	BIOLOGICAL • Bacterial pathogen growth • Bacterial pathogen contamination CHEMICAL None PHYSICAL None	No No	Period of time at this location is short SSOP		
Iced storage	BIOLOGICAL Bacterial pathogen CHEMICAL None PHYSICAL None	Yes	Hazardous pathogen growth	Proper icing	Yes
Fillet, skin and trim	BIOLOGICAL • Bacterial pathogen growth • Bacterial pathogen contamination CHEMICAL None PHYSICAL Metal inclusion	No No No	Period of time at this location is short. SSOP No history of occurrence with hand operation		
Blast freeze	BIOLOGICAL None CHEMICAL None PHYSICAL None				
Glaze	BIOLOGICAL Pathogen contamination CHEMICAL None PHYSICAL None	No	SSOP		

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 harzards?	(6) Is this step a critical control point? (Yes/No)
Weigh/Pack/Label	BIOLOGICAL None CHEMICAL None PHYSICAL None				
If this product is sold fresh or not previously frozen, product labeling can be used for further assurance that the product will be properly frozen prior to consumption.					
Frozen storage	BIOLOGICAL Parasite survival CHEMICAL None PHYSICAL None	Yes	Parasite survival if not not properly frozen	Proper time and temperature of freezing	Yes

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Receiving	• Pathogen growth	• Proper icing	• Icing	• Visual	• Every lot	• Process supervisor	• Reject if not properly iced	• Weekly record review	• Receiving log
Iced Storage	• Pathogen growth	• Proper icing	• Icing	• Visual	• Daily	• Process supervisor	• If ice melted or inadequate, check product temperature, hold and evaluate, or consider diverting to cook use or reject	• Weekly record review	• Refrigeration storage log
Frozen storage	• Parasite survival	• Freeze to -4 F (-20 C) for 7 days	• Freezer temperature • Time in freezer	• Recording thermometer • Visual	• Continuous with one visual check per day • When removed from freezer • Every lot	• Processing supervisor • Processing supervisor	• Adjust freezer • Extend storage time	• Weekly record review • Calibrate thermometer every six months	• Temperature chart • Frozen storage log

Firm Name: *ABC Fish Co.*

Firm Address: *Anywhere, USA*

Signature:

Date:

Product Description: *Salmon fillets, skinless*

Method of Storage and Distribution: *Frozen*

Intended Use and Consumer: *To be consumed raw*

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

Fresh Tuna Loins:
Description of Process

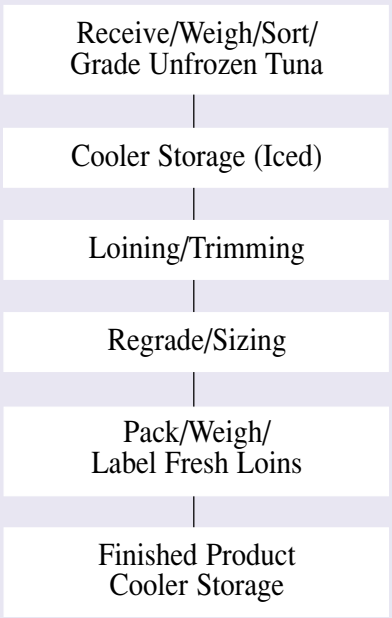
Notes:

Example: For Illustrative Purposes Only
(Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

Domestic yellowfin tuna are caught by hook-and-line day boats returning on same day catch. The fish are headed and gutted before being held in ice and packed in ice, including ice in gut cavity, on the vessel until delivery to the plant.

Upon receipt at the processing plant, the unfrozen tuna is immediately individually weighed, sorted (culled) and graded. They are iced and placed in cooler storage at 40 F, followed by loining and trimming. The loined product is regraded, sized, cello-wrapped and placed in 40- to 60-pound waxed or foam cartons with ice. It is labeled and placed in a cooler for shipment to the fresh market. The cumulative process time is less than two hours.

Fresh Tuna Loins Processing Flow Chart

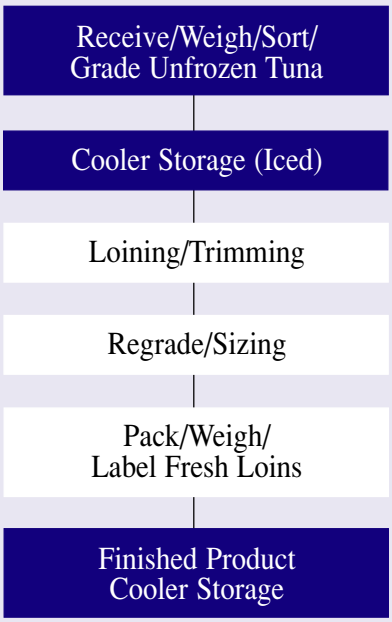


Continued

Notes:

Fresh Tuna Loins Processing Flow Chart

Shaded step is Critical Control Point



*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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) Justifiy your decision for 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)
Receive/weigh/sort/ grade unfrozen tuna	BIOLOGICAL • Bacterial pathogen contamination	No	Product is to be cooked by consumer.		
	• Parasites	No	Not likely in species		
	CHEMICAL Scombrotoxin (histamine)	Yes	Tuna subjected to time-temperature abuse can develop scombrotoxin (histamine).	Ensure proper handling of fish during harvest.	Yes
	PHYSICAL None				
Cooler storage (iced)	BIOLOGICAL • Bacterial pathogen growth	No	Product is to be cooked by consumers.		
	CHEMICAL Scombrotoxin (histamine)	Yes	Tuna subjected to time-temperature abuse can develop scombrotoxin (histamine).	Maintain adequate temperature control.	Yes
	PHYSICAL None				
Loining/trimming	BIOLOGICAL • Bacterial pathogen contamination	No	Controlled by SSOPs		
	• Bacterial pathogen growth	No	Product is to be cooked by consumer.		
	CHEMICAL Scombrotoxin (histamine)	No	Hazard is not significant due to short process time.		
	PHYSICAL None				

Note: If the cumulative processing time (from ice product cooler to final product cooler) approaches four hours, procedures should be in place at the intervening processing steps to ensure temperature control.

Firm Name: *ABC Tuna Co.*

Firm Address: *Anywhere, USA*

Signature: _____

Date: _____

Product Description: *Fresh tuna loins*

Method of Storage and Distribution: *Refrigerated*

Intended Use and Consumer: *General public will cook product before eating.*

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

(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 harzards?	(6) Is this step a critical control point? (Yes/No)
Regrade/sizing	BIOLOGICAL • Bacterial pathogen contamination	No	Controlled by SSOPs		
	• Bacterial pathogen growth	No	Product is to be cooked by consumer.		
	CHEMICAL Scombrotoxin (histamine)	No	Hazard is not significant due to short process time.		
	PHYSICAL None				
Pack/Weigh/label	BIOLOGICAL • Bacterial pathogen contamination	No	Controlled by SSOPs		
	• Bacterial pathogen growth	No	Product is to be cooked by consumer.		
	CHEMICAL Scombrotoxin (histamine)	No	Hazard is not significant due to short process time.		
	PHYSICAL None				
Finished product cooler storage	BIOLOGICAL Bacterial pathogen growth	No	Product is to be cooked by consumer.		
	CHEMICAL Scombrotoxin (histamine)	Yes	Tuna subjected to temperature abuse can develop scombrotoxin (histamine).	Proper temperature control.	Yes
	PHYSICAL None				

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Receive/weigh/sort/ grade unfrozen tuna (headed and gutted)	Scombrotoxin formation	• Internal fish temperature must not be higher than 50 F and gut cavitey properly iced.	• Internal fish temperature	• Thermometer	• Every lot (entire lot up to 12 fish)	• Dockmaster	• Reject lot or test for histamine; reject if exceeds 50 PPM.	• Calibrate thermometer weekly	• Temperature log
		• Harvest record must show fish cooled to 50 F within six hours of death.	• Time-temperature record of harvest	• Visual check of record	• Every lot	• Dockmaster	• Reject lot or test for histamine; reject if exceeds 50 PPM.	• Quarterly verification of histamine test method	• Receiver's log
		• No more than 2.5 percent of lot should exhibit decomposition.	• Harvest vessel records	• Sensory examination	• Every lot (entire lot up to 12 fish)	• Quality-control person	• Reject lot or test fish exhibiting decomposition for histamine; reject if any exceeds 50PPM.	• Daily record review	• Sensory log

Firm Name: *ABC Tuna Co.*

Firm Address: *Anywhere, USA*

Signature:

Date:

Product Description: *Fresh tuna loins*

Method of Storage and Distribution: *Refrigerated*

Intended Use and Consumer: *General public will cook product before eating.*

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Cooler storage (iced)	Scombrotoxin (histamine)	Product adequately iced	Presence of ice	Visual	Every six hours while plant is in operation	Operations manager	Add ice; check product internal temperature. If internal temperature exceeds 45 F, or above 40ºF > 4 hours, reject or conduct histamine test.	Calibrate thermo-meter weekly. Daily record review	Cooler log
Finished product cooler	Scombrotoxin (histamine)	Product adequately iced	Presence of ice	Visual	Every six hours while plant is in operation	Operations manager	Add ice; check product internal temperature. If internal temperature exceeds 45ºF, or above 40ºF > 4 hours, reject or conduct histamine test.	Calibrate thermo-meter before use. Daily record review	Cooler log

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

Wholesale/Distribution/Warehouse Facilities:
Description of Process Flow

Notes:

Example: For Illustrative Purposes Only
(Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.)

A variety of different fish species in various product forms (whole, gutted, dressed, fillets, steaks, loin, etc.) are received from various suppliers by the Metro Fish Co. Fresh fish are not purchased directly from fishers or aquaculture farms except for some red hake and whiting that are occasionally purchased directly from local fishers in the spring and fall. No shellfish are purchased directly from fishers or aquaculture farms. All fish are fresh and are delivered by refrigerated truck or in containers in which the product is thoroughly iced. Clams and oysters are received and sold as live shellstock and stored in a cooler at 45 F. Minimal time is involved in repacking these shellfish products. Shucked scallops are received in gallon containers and packed in ice. With the exception of shellstock, products are immediately moved after receipt into a refrigerated storage cooler on ice. Customer orders are packed and loaded on company-owned refrigerated trucks for delivery to customers.

Finfish species: flounder, cod, hake, pollock, monkfish, whiting, bluefish, striped bass (wild), hybrid striped bass (farm-raised), catfish (farm-raised), mackerel (northern), weakfish, tuna, mahi-mahi, swordfish and salmon (farm-raised)

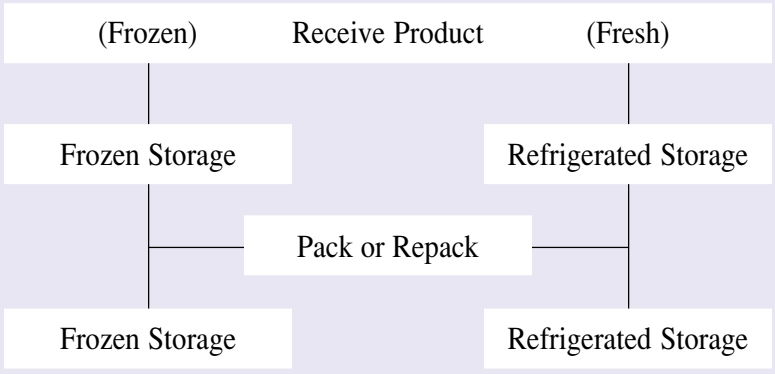
Shellfish species: clams and oysters (live shellstock), shrimp (farm-raised) and sea scallops (wild) (meats)

Intended use: All products except clams and oysters are intended to be thoroughly cooked before being eaten. Live clams and oysters may be eaten raw or partially cooked. All products are intended for sale to the general public.

Continued

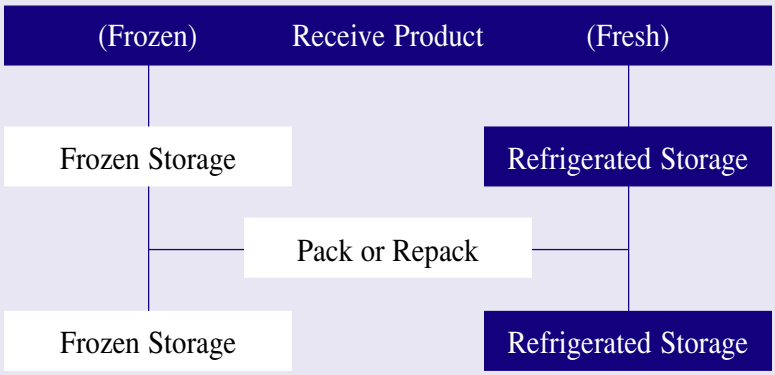
Notes:

Wholesale/Distribution/Warehouse Facilities Processing Flow Chart



Wholesale/Distribution/Sharehouse Facilities Processing Flow Chart

Shaded step is Critical Control Point



Worksheet 1 — Hazard Analysis Product Grouping

(HACCP Wholesale Seafood Teaching Example)

certian Finfish and Shellfish Species with Related Hazards

No Hazards	PRODUCT SOURCE RELATED HAZARDS*				Parasites	Histamine
	Pathogens	Toxins	Chemical Contaminants	Aquaculture Drugs		

** Product source-related hazards are generally controlled by the first buyer or processor who receives the product directly from a fisher, a vessel or an aquaculture farm.*
*** This table can be derived by starting with the FDA Hazards and Control Guide and using any supplemental information or experience the processor might have.*

Worksheet 1 — Hazard Analysis Product Grouping

(HACCP Wholesale Seafood Teaching Example)

certian Finfish and Shellfish Species with Related Hazards

No Hazards	PRODUCT SOURCE RELATED HAZARDS*				Parasites	Histamine
	Pathogens	Toxins	Chemical Contaminants	Aquaculture Drugs		
red hake weakfish whiting swordfish	clams oysters	clams oysters	salmon (f) catfish (f) bluefish striped bass (w) flounder (i) shrimp (f) clams oysters sea scallops	salmon (f) catfish (f) hybrid bass (f) shrimp (f)	salmon (f) mackerel cod pollock flounder monkfish	mackerel tuna bluefish mahi-mahi

(f)= farm-raised; (w)= wild; (i)=inshore

** Product source-related hazards are generally controlled by the first buyer or processor who receives the product directly from a fisher, a vessel or an aquaculture farm.*

*** This table can be derived by starting with the FDA Hazards and Control Guide and using any supplemental information or experience the processor might have.*

Worksheet 2 — Species-Related Hazard Analysis

Processing Step = Receiving

Hazard enhanced, introduced or controlled at this step	Fish and Shellfish Species (from Product Grouping Worksheet)	Is this hazard significant? Yes/No	Justify your decision (from column 3)	Identify control measure	Is this CCP? Yes/No
Pathogens from Harvest Area					
Natural Toxins					
Chemical Contaminants & Pesticides					
Aquaculture Drugs					
Histamine					
Parasites					

*** This table can be derived by starting with the FDA Hazards and Control Guide and using any supplemental information or experience the processor might have.*

Worksheet 2 — Species-Related Hazard Analysis

Processing Step = Receiving

Hazard enhanced, introduced or controlled at this step	Fish and Shellfish Species (from Product Grouping Worksheet)	Is this hazard significant? Yes/No	Justify your decision (from column 3)	Identify control measure	Is this CCP? Yes/No
Pathogens from Harvest Area	Group 1 — Clams and oysters	Yes	Raw shellfish is a known source of pathogenic organisms; temperature abuse during transit could lead to bacterial growth.	Check tags to ensure that all product is tagged, from certified shippers and temperature-controlled during transit.	Yes
Natural Toxins (e.g. PSP)	Group 1 — Clams and oysters	Yes	Products from unapproved waters, harvesters or shippers could contain natural toxins.	Check tags to ensure that all product is tagged and from certified shippers.	Yes
Chemical Contaminants & Pesticides	Group 1 — Clams and oysters	Yes	Products from unapproved waters, harvesters or shippers could have chemical contaminants.	Check tags to ensure that all product is tagged and from certified shippers.	Yes
	salmon, catfish, hybrid striped bass, wild striped bass, flounder, bluefish, shrimp, sea scallops	No	Not purchased directly from fishers or fish farms. Hazard is controlled by first processor.	Temperature controlled during transit.	No
Aquaculture Drugs	salmon, catfish, hybrid striped bass, shrimp	No	Not purchased directly from fishers or fish farms. Hazard is controlled by first processor.		No
Histamine	Group 2 — mackerel, tuna, bluefish mahi-mah	Yes	Could develop a histamine hazard if time-temperature abuse occurs.	Temperature controlled during transit. Not purchased directly from fishers or fish farms.	Yes
Parasites	salmon, mackerel, cod, pollock, flounder, monkfish	No	Sold to retail stores or restaurants for sale to general public who will cook them before they are eaten.		No

*** This table can be derived by starting with the FDA Hazards and Control Guide and using any supplemental information or experience the processor might have.*

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet
Group 1 — Clams and Oysters

(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) Justifiy your decision for 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)
Receiving	BIOLOGICAL • Pathogens from harvest area	Yes	Pathogen could be present in product. May be eaten raw.	Check all incoming product to ensure that it is properly tagged and from a certified dealer.	Yes
	• Pathogen growth during transit	Yes	Potential thermal abuse could elevate pathogen levels	Temperature control	Yes
	CHEMICAL • Chemical contaminants	Yes	Chemical contaminants may be present.	Check incoming product to ensure that it is properly tagged and from a certified dealer.	Yes
	• Natural toxins	Yes	Toxins may be present.	Check incoming product to ensure that it is properly tagged and from a certified dealer.	Yes
	PHYSICAL None				
Refrigerated storage	BIOLOGICAL Pathogen growth	Yes	Pathogens could grow if product is not stored properly and temperature abuse occurs.	Temperature control	Yes
	CHEMICAL Food and color additives	No	No additives used in storage		
	PHYSICAL Metal or glass	No	Not likely to occur in storage		
Pack/Repack	BIOLOGICAL • Pathogen growth	No	Time and temperature abuse is not likely to occur because of short duration of process step.		
	• Pathogen contamination	No	SSOPs		
	CHEMICAL None				
	PHYSICAL None				

Firm Name: *Metro Fish Co.*

Firm Address: *One Metropolitan Ave.*

Metropolis, USA

Signature: _____

Date: _____

Product Description: *Group 1 — Live Clams and Oysters*

Method of Storage and Distribution: *Stored and distributed under refrigeration*

Intended Use and Consumer: *May be eaten raw or partially cooked.*

Sold to the general public.

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet
Group 2 — Mackerel, Tuna, Bluefish, and Mahi-Mahi

(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) Justifiy your decision for 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)
Receiving	BIOLOGICAL • Parasites	No	Product intended to be fully cooked before being eaten.		
	• Pathogen contamination	No	Product intended to be fully cooked before being eaten.		
	CHEMICAL • Histamine	Yes	Temperature abuse could lead to histamine formation.	Proper temperature control during transit	Yes
	• Chemical contaminants	No	Hazard controlled by first receiver from fishers.		
	PHYSICAL None				
Refrigerated storage	BIOLOGICAL Pathogen growth	No	Product to be fully cooked		
	CHEMICAL Histamine	Yes	Time and temperature abuse could lead to histamine formation.	Proper icing during storage	Yes
	PHYSICAL None				
Pack/Repack	BIOLOGICAL Pathogen growth	No	Product to be fully cooked		
	CHEMICAL Histamine	No	Minimal time out of refrigeration		
	PHYSICAL None				

Firm Name: *Metro Fish Co.*

Firm Address: *One Metropolitan Ave.*
Metropolis, USA

Signature: _____

Date: _____

Product Description: *Group 2 — Mackerel, tuna, bluefish and mahi-mahi*

Method of Storage and Distribution: *Stored and distributed fresh on ice.*

Intended Use and Consumer: *Product will be fully cooked by consumer.*
Sold to the general public.

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

*Example: For Illustrative Purposes Only**

Hazard-Analysis Worksheet

Group 3 — Salmon, Catfish, Hybird, Striped Bass, Wild Striped Bass, Flounder, Bluefish, Cod, Pollock, Monkfish, Shrimp, and Sea Scallops

(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) Justifiy your decision for 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)
Receiving	BIOLOGICAL • Parasites (salmon, pollock cod, flounder, monkfish)	No	Product to be fully cooked		
	• Pathogen growth during transit	No	Product to be fully cooked		
	CHEMICAL • Aquaculture drugs (salmon, catfish, hybrid striped bass, shrimp)	No	Hazard controlled by first receiver from aquaculture farm.		
	• Chemical contamination (salmon, catfish, hybrid striped bass, wild striped bass, flounder, shrimp, sea scallops)	No	Hazard controlled by first receiver from fishers.		
	PHYSICAL None				
Refrigerated storage	BIOLOGICAL Pathogen growth	No	Product to be fully cooked		
	CHEMICAL None				
	PHYSICAL None				
Pack/Repack	BIOLOGICAL Pathogen growth	No	Minimal time lapse at this end step. Product is to be fully cooked.		
	CHEMICAL None				
	PHYSICAL None				

Firm Name: *Metro Fish Co.*

Firm Address: *One Metropolitan Ave.*
Metropolis, USA

Signature: _____

Date: _____

Product Description: *Group 3 — Salmon, catfish, hybrid striped bass, wild striped bass, flounder, cod, pollock, monkfish, red hake, whiting, weakfish, swordfish, shrimp, sea scallops.*

Method of Storage and Distribution: *Stored and distrributed fresh on ice.*

Intended Use and Consumer: *Product to be fully cooked before it is eaten. Sold to the general public.*

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form

Group 1 — Clams and Oysters

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Receiving	Pathogens and chemical contaminants, and natural toxins from harvest area.	All shellfish are properly tagged and received from certified dealers or shippers.	Visual check of shellstock tags and certification number at delivery.	Visual check at delivery of tags	Each shipment	Receiving manager	Reject all product not properly tagged or from certified dealer.	Review all records at least once a week.	Shellfish purchase log
	Pathogen growth	All product is kept less than 45 F throughout transit.	Shipping temperature recorder chart	Visual check of temperature control chart	Each shipment	Receiving manager	If product greater than 45 F, hold and contact state authority for disposition or reject.	Check dealer certified against FDA shippers' list monthly.	Shellfish purchase log
Storage	Pathogen growth	Cooler temperature not to exceed 45 F for more than four hours	Cooler temperature	Recording themometer and visual temperature checks.	Continuous temperature recorder. Visual check every four hours during operation.	Plant manager	If cooler temperature is greater than 45 F for four hours, check meat temperature. If meat temperature is > 45 F, hold and contact state authority or destroy product.	Review all records at least once a week Check and calibrate thermometers once per week.	Continuous recorder and cooler log

Firm Name: *Metro Fish Co.*

Firm Address: *One Metropolitan Ave.*

Metropolis, USA

Signature: _____

Date: _____

Product Description: *Group 1 — Live Clams and Oysters*

Method of Storage and Distribution: *Stored and distributed under refrigeration*

Intended Use and Consumer: *May be eaten raw or partially cooked. Sold to the general public.*

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

*Example: For Illustrative Purposes Only** – HACCP Plan Form
Group 2 — Mackerel, Tuna, Bluefish, and Mahi-Mahi

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4) Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who			
Receiving	Histamine	All fish are adequately iced.	Check for ice	Visual check	Each delivery	Receiving manager	Re-ice. If ice is not adequate, check internal product temperature. If temperature is greater than 45 F reject lot or test 60 fish or entire lot. Reject if any test is greater than 50 ppm histamine.	Daily record review Calibrate thermometer.	Receiving log
Storage	Histamine	Products are adequately iced and stored in the cooler	Presence of ice	Visual check	Every four hours during plant operating hours.	Plant manager	Re-ice. if ice is not present, check internal product temperature. If greater than 45 F for more than four hours, re-ice and test for histamine. Destroy lot if any sample exceeds 50 ppm histamine.	Daily record review. Calibrate thermometer.	Cooler log

Firm Name: *Metro Fish Co.*

Firm Address: *One Metropolitan Ave.*

Metropolis, USA

Signature:

Date:

Product Description: *Group 2 — Mackeral, tuna, bluefish and mahi-mahi*

Method of Storage and Distribution: *Stored and distributed fresh on ice.*

Intended Use and Consumer: *Product will be fully cooked by consumer. Sold to the general public.*

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

Notes:

Appendix VI: Current Good Manufacturing Practices (21CFR110)

Notes:

Authority: Secs. 402, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

Source: 51 FR 24475, June 19, 1986, unless otherwise noted.

Subpart A — General Provisions

§ *110.3 Definitions.*

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below.

(b) Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) Blanching except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) Critical control point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) Food means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment.

(h) Lot means the food produced during a period of time indicated by a specific code.

(i) Microorganisms means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.

(j) Pest refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) Plant means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_W). An a_W will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_W will not support the growth of undesirable microorganisms.

(o) Sanitize means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) "Shall" is used to state mandatory requirements.

(q) "Should" is used to state recommended or advisory procedures or identify recommended equipment.

(r) Water activity (a_W) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Continued

Notes:

Notes:

§ *110.5 Current good manufacturing practice.*

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ *110.10 Personnel.*

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
(2) Maintaining adequate personal cleanliness.
(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign sub stances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

Notes:

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§ 110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B — Buildings and Facilities

§ 110.20 Plant and grounds.

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:
   (i) Using protective coverings.
   (ii) Controlling areas over and around the vessels to eliminate harborages for pests.
   (iii) Checking on a regular basis for pests and pest infestation.
   (iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

Notes:

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§ *110.35 Sanitary operations.*

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) Substances used in cleaning and sanitizing; storage of toxic materials.

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.
(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.
(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.
(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ *110.37 Sanitary facilities and controls.*

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:
(1) Carry sufficient quantities of water to required locations throughout the plant.
(2) Properly convey sewage and liquid disposable waste from the plant.

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(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:
(1) Maintaining the facilities in a sanitary condition.
(2) Keeping the facilities in good repair at all times.
(3) Providing self-closing doors.
(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:
(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
(2) Effective hand-cleaning and sanitizing preparations.
(3) Sanitary towel service or suitable drying devices.
(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

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Subpart C — Equipment

§ *110.40 Equipment and utensils.*

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

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(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D — [Reserved]

Subpart E — Production and Process Controls

§ *110.80 Processes and controls.*

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) Raw materials and other ingredients.

(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

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(b) Manufacturing operations.

(1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of micro-organisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_W, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable micro organisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45%F (7.2%C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140%F (60%C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a_W that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:
- (i) Using ingredients free of contamination.
- (ii) Employing adequate heat processes where applicable.
- (iii) Using adequate time and temperature controls.
- (iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
- (v) Cooling to an adequate temperature during manufacturing.
- (vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

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(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:
  (i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
  (ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
  (iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in § 130.3(d) of this chapter.
  (iv) Providing physical protection from contamination, particularly airborne contamination.
  (v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_W for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:
  (i) Monitoring the a_W of food.
  (ii) Controlling the soluble solids-water ratio in finished food.
  (iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_W of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:
  (i) Monitoring the pH of raw materials, food in process, and finished food.
  (ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

§ 110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F — [Reserved]

Subpart G — Defect Action Levels

§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

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