



Hazard Analysis and Critical Control Point:
A Self-Guide to HACCP Inspection
for Small Seafood Dealers, Packers and Processors

North

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Program

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Hazard Analysis and Critical Control Point: **A Self-Guide to HACCP Inspection** **for Small Seafood Dealers, Packers and Processors**

Introduction

Hazard Analysis and Critical Control Point, or HACCP, is a widely accepted monitoring system used to control the risks that can be associated with food. To someone who has just started learning about HACCP, it can seem complicated and demanding. But once you understand its concepts, you'll see the program as a common-sense tool to control food-safety hazards.

And, considering the United States' rank as the world's second-largest exporter of seafood, the HACCP program will protect your economic well-being in the long run. Complying with a strong HACCP program will result in a continuous supply of safe seafood for consumers at home and abroad.

The Pillsbury Co. developed the first HACCP program in the early 1960s while studying how to supply packaged food to the U.S. space program. Pillsbury executives thought their quality-control checks were not rigorous enough to spot contamination after food was processed. They decided that the only way to know the food was safe was to prevent hazards from reaching the food while being made.

The Food and Drug Administration (FDA) used Pillsbury's HACCP program as a model for the safe seafood regulation it issued in December 1995. The FDA took this action to assure the public that seafood was safe to eat, and it gave the industry two years to comply. The regulation also gives processors and dealers a way to document that the seafood they manufacture and ship is wholesome and safe. This regulation went into effect nationwide for all domestic and foreign seafood processing firms on Dec. 18, 1997.

The FDA defines processing as "handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling and dockside loading or holding." This definition does not pertain to fishing boats, where crews head,

eviscerate or freeze fish solely for holding before they come to shore. At this time, the seafood regulation does not cover the harvest or transport of fish or the retail sale of fish and fishery products.

In North Carolina, five kinds of seafood dealers and processors must develop a HACCP program:

- Dealers who sell shrimp that has been dipped in sulfites
- Dealers who sell histamine fish such as blue fish, mackerel, tuna or mahi-mahi
- Blue crab processors
- Smoked fish processors
- Shellfish dealers who ship out of state.

Why Be Your Own Inspector?

The HACCP regulation requires every seafood processor to thoroughly review its products and operations, identify potential hazards and take preventive measures to control them. No regulator knows your operation better than you do. So it makes sense that you, the owner, should evaluate your plant, determine whether you need a written HACCP plan and then, if necessary, write a plan that best suits your production and products. And, because you write the plan, it makes even more sense for you to have the right and the responsibility to enforce it for your company. The seafood regulation gives you this flexibility because you are the expert on running your business.

Why Be Aware of Your Plant's Problem Areas?

As a business owner, you are responsible for knowing the rules that regulate your business. A hazard analysis will tell you at the very least how to improve your sanitation and hygiene practices to ensure a safer supply of seafood. Even if you find that you do not need a written HACCP plan, the sanitation requirements of the regulation will go a

long way toward improving not only the safety, but also the quality of your products.

Hazards: What Are You up Against?

HACCP plans must address three kinds of hazards that may make food unsafe to eat — biological, chemical and physical.

- **Biological hazards** include bacteria, viruses and parasites. When ingested, certain bacteria, such as salmonella, can make people ill. They can grow rapidly in the intestinal tract and often cause nausea, vomiting, diarrhea, cramping, fever and headache. This is called a food-borne infection because a person becomes sick only after consuming the bacteria.

A food-borne intoxication is caused by bacteria that produce a toxin, such as clostridium, which is responsible for botulism. The toxin, rather than the bacteria, causes the illness. In the case of clostridium, the toxin can even cause death.

Like salmonella, some viruses can cause illness when they are consumed in food. But, unlike bacteria, viruses can exist in food without growing, and they do not cause food to spoil. Viruses cannot begin growing until they are inside a person's body. An example of a viral food infection is hepatitis, which people can get from eating raw molluscan shellfish from polluted harvesting areas.

Parasites are organisms that must live on or in a person to grow. They are often embedded in the flesh of certain kinds of fish or shellfish such as amberjack or Atlantic cod. A person can be infected by eating raw fish, such as sashimi, if the meat contains a parasite. A well-known example of a parasite is the tapeworm. It attaches to the walls of the intestine and feeds on the digested food that passes by it. It can grow up to 7 feet long, and as it thrives, it will cause severe cramping, gas and diarrhea.

- **Chemical hazards** can occur naturally, or they can be intentionally or unintentionally added to food during processing. Histamine, found in fish such as tuna, mahi-mahi and mackerel, is a naturally occurring hazardous chemical that can cause a severe allergic reaction in people who are sensitive to it, such as those suffering from asthma.

Sulfite is a chemical that some harvest boat crews intentionally add to shrimp to prevent black spots. It is hazardous to people who are sensitive to

it, and they can develop breathing difficulties soon after ingesting shrimp containing sulfite.

Unintentionally added chemicals include insecticides, lubricants and equipment sanitizers, which may contaminate food if they are used or applied during food preparation.

- **Physical hazards** include broken glass or metal fragments in food. These hazards can cause serious cuts, broken teeth or bleeding that could require emergency medical treatment. Physical hazards are the most commonly reported consumer complaint because the injury occurs during or soon after eating, making the source of the hazard easy to identify.

Writing Your HACCP Plan

Preliminary Steps

If possible, a team of at least two people within the company should analyze the potential hazards of your processing operation. These employees should be directly involved with and know the company's daily routine. Ideally, at least one team member should be familiar with food-safety issues. If not, consult an expert such as a university extension or Sea Grant specialist, a health official or consultant.

Although a single person can evaluate food-safety risks and write a HACCP plan, businesses may find that the team approach is more helpful. Important points in your firm's operation can be missed or misunderstood if only one person looks for possible hazards. This is especially possible if the company hires a consultant to write its HACCP plan. Because employees better understand how the operation runs, they will be less likely to overlook key parts of it during the hazard analysis. Also, the team approach to creating a HACCP program builds employee ownership in the plan. And employee commitment to HACCP is critical for its success in your plant.

The HACCP team's first job is to write about the products the company makes or sells and to tell how products are shipped to market, who the customers are (e.g., the general public, infants, the elderly) and how consumers will use the products (e.g., eaten raw or cooked). The second step is to diagram, in simple block or symbol form, each step the business performs to manufacture and distribute its products. (See diagram in the appendix.) The HACCP team then should walk through the facility to make sure it realistically describes the operation on the production

chart. The team will use this chart as an essential blueprint for building the HACCP program.

See the appendix for a sample HACCP Plan Form and for checklists to help guide you through the process. The appendix also includes a list of additional reading material.

Conducting the Hazard Analysis

The HACCP plan should focus solely on hazards that are *reasonably likely to occur and would cause illness or injury to the consumer*. The HACCP team members must decide which hazards are significant to their business and how to control them in their operation. (See Hazard Analysis Worksheet in the appendix.)

To determine how critical a hazard is, the team can rely on a combination of personal experience, scientific literature, guidance materials such as the FDA's *Fish and Fisheries Products Hazards and Controls Guide* and the expertise of state regulatory agencies. Do not confuse quality issues with safety concerns during the hazard analysis. While spoilage, insects and hair are undesirable in food, they do not pose a significant health hazard to consumers. A good sanitation program, rather than a HACCP plan, will address these issues.

Setting Critical Control Points

Every hazard you identify during the analysis must have one or more *critical control points (CCPs)* to manage the hazard. A critical control point is any step in the production process where a biological, physical or chemical hazard *can be controlled so that food-safety risks are prevented, eliminated or reduced to acceptable levels*. If the step does not control the hazard, it cannot be a CCP.

For example, you can *prevent* disease-causing bacteria (pathogens) from growing on finfish by refrigerating the fish. You can *eliminate* these same bacteria from crabmeat through pasteurization. And you can *reduce the bacteria to an acceptable level* in shellfish by harvesting oysters, clams and mussels only from approved waters.

Sometimes a CCP can be used to control more than one hazard. For example, refrigeration can control the growth of pathogens on the surface of tuna as well as slow the formation of histamine in the meat.

Establishing Critical limits

Critical limits are the boundaries set around a CCP to ensure that seafood is produced safely. Each CCP must have critical limits. When a process strays outside these limits, you must take corrective action to return the process to compliance. As in the hazard analysis, the HACCP team may draw on personal experience, regulatory guidelines or expert opinion to set the critical limits.

Here's an example of this concept. Cooking is the *CCP* for killing potential pathogens in ready-to-eat shrimp. The *critical limit* for this CCP would be heating the shrimp to 212 F for three minutes so that the internal temperature reaches at least 145 F for three seconds.

A *deviation* occurs the moment an operation strays outside the critical limits. To prevent a deviation, set your operating limits within a CCP's critical limits. For example, keep tuna, mahi-mahi and bluefish iced and refrigerated at 35 to 40 F to minimize histamine formation in the meat. That way, the meat's temperature never comes close to the 50 F upper limit for the first receiver set by the FDA.

Monitoring

It is essential that you know your critical limits are met consistently. If they are ever out of line, a corrective action must follow quickly. Workers maintain control at a CCP by following a planned sequence of observations or measurements. You should keep a diary of events for each day's production as a record that all of your firm's products are produced in compliance with its HACCP plan.

Monitoring procedures must encompass the following issues:

- **What will you monitor?** This may mean measuring something on the production line (such as refrigeration temperatures) or on the product (such as the presence of sulfite on shrimp). It also may include observing that a preventive measure at a CCP is being performed (such as verifying that shellfish are harvested from approved waters).

- **How will you measure the critical limits?** The monitoring system must generate results rapidly so that deviations can be corrected as soon as they are detected. Physical and chemical measurements are recommended because they can be taken quickly. Examples of monitoring equipment include thermometers, clocks, scales, pH meters and chemical

analytical devices. No matter what method is chosen, it must deliver accurate results.

- **How frequently will you monitor a critical limit?**

Monitoring can be continuous or intermittent, but you *should use continuous monitoring wherever possible*. For example, you should constantly record the time and temperature of crabmeat pasteurization on a temperature-recording chart.

If continuous monitoring is impossible, keep the monitoring interval short. The frequency of non-continuous monitoring will depend on the variability of the process being monitored or the amount of a product you are willing to risk destroying if a critical limit is violated. For example, record the temperature of your holding cooler twice a day.

- **Who will monitor?** Monitors can include line workers, supervisors or quality-control workers. They should fully understand the importance of CCP monitoring and be trained to run the CCP monitoring equipment. Also, monitors should report their results accurately, and they must report any deviations immediately so corrective action can be taken and recorded.

Corrective Action

When a critical limit has been violated, you must follow procedures to bring the process under control. Isolate the product made during the deviation and determine how to handle it. It is very important to correct the process as soon as possible to prevent more of the product from being produced under these unacceptable conditions.

An example of a deviation would be when only part of a batch of crabmeat reaches its required pasteurization temperature for its required cook time. The corrective action would be to recook or destroy the entire batch of crabmeat.

When a product has been produced out of compliance, follow four steps to decide how to handle it:

1. Determine whether the product could be a safety hazard. This decision can be based on physical, chemical or bacterial tests or by consulting an expert, such as a health official, university extension or Sea Grant specialist, or a consultant.
2. If there is no hazard, the product can be released.
3. If there is a hazard, decide whether the product can be reprocessed.

4. If a potentially hazardous product cannot be safely reprocessed or reworked, it must be destroyed.

All corrective actions must be documented. A written report should include four components:

- The kind of product.
- A description of the problem in the process.
- The steps taken to correct the problem and the action taken with the product made when the problem occurred.
- The name of the person responsible for taking the corrective action. This should be someone who understands the process, the product and the company's HACCP plan and who has the authority to make decisions.

Verification

The role of verification is to show that a company's HACCP system can control food-safety hazards and that all personnel follow it. Verification involves the following:

- Validating that the HACCP plan will work. Before you implement the plan, thoroughly review all of the information used during the hazard analysis to ensure the plan is based on sound scientific principles. The HACCP team or a consultant can do this. If you find your critical limits are frequently being violated after your plan is in force, you need to revalidate your plan. You also should revalidate your HACCP plan any time you have to alter it, such as when you change your products or the way you process and distribute them. Finally, amend the HACCP plan when new information becomes available about potential hazards and the means to control them. *Remember that as your company's business changes over time, your HACCP plan will too.* The effort to improve food safety never stops, and processors have to adapt to new regulations as well.

- Calibrating the monitoring equipment. You need to calibrate the equipment to make sure monitoring results are always accurate.
- Reviewing the calibration records to make sure the monitoring equipment performs as it should over time. Record the dates and methods of calibration, as well as the test results (i.e., whether it passed or failed).
- Performing physical, chemical or bacterial tests on products to confirm that they comply with the HACCP plan. For example, a dealer might test a

sample of raw shrimp for sulfites to ensure that the boat captains who guarantee that they do not use sulfites are in fact not using them.

- Reviewing monitoring and corrective action records to make sure employees follow the HACCP plan.
- Having regulatory personnel review your HACCP plan to verify that it can control the hazards you identify and to review your records to make sure they are accurate.

Record Keeping

Maintaining records is an important part of your HACCP system. You can store these records on a computer, but it is best to keep a paper copy too, as insurance against a system failure. Keep four kinds of records:

1. The HACCP plan and all of the information you used to create it. This includes the hazard analysis and documentation used to do the analysis and to establish critical control points and critical limits. This file also should include notes or correspondence from experts who helped with your hazard analysis.
2. Monitoring records. Keep monitoring records to show the HACCP team and regulators that CCPs are under control and that the company is complying with its HACCP plan. Monitoring records also can help identify trends in production where adjustments may be needed to improve product safety.
3. Records of corrective actions. These records document how a company brought a deviation under control and how it handled the product made during the deviation.
4. Verification records. These records include any changes the team makes to the HACCP plan. You also should add the results of accuracy tests performed on the monitoring equipment and the results of plant inspections or equipment evaluation tests.

Sanitation

After completing a hazard analysis, you may find that your business does not need a HACCP plan. But the regulation does require you to maintain records showing that you comply with eight key sanitation points. (See the appendix for a checklist.)

- Document that the water you use to clean or process your seafood and to make ice is drawn from

a sanitary source or is treated to make it sanitary. For example, you may ask the city that supplies your water to write a letter verifying that the water is sanitary.

- In handling and processing seafood, use only utensils and equipment that are made of nontoxic materials and that can be cleaned with food-cleaning chemicals and sanitizers. This provision covers all storage rooms for raw and processed products as well as ice machines. Stainless steel is the best surface for equipment that touches food.
- Don't allow cross-contamination from unsanitary objects to food, food packages or anything that food comes in contact with, such as utensils, gloves, aprons and table surfaces. In addition, you must handle raw and cooked seafood separately in different parts of your plant so the raw product can't contaminate the cooked product.
- Locate hand-washing and hand-sanitizing stations in all processing areas, where good hygiene practices require employees to wash and sanitize their hands. You must maintain toilets that properly dispose of sewage in sanitary condition for all employees and require employees to wash their hands after using the toilet.
- Prevent contamination of food, food-contact surfaces and food packaging by lubricants, fuel, pesticides, sanitizers, metal fragments or other physical and chemical food hazards.
- Label any toxic chemicals that you store in your plant. Use and store them far enough away from food and food-contact surfaces so that contamination does not occur.
- Do not allow an employee with an illness, infected wound, open sore or any other problem that might contaminate food, food-contact surfaces or food packaging to work in your plant until the condition has healed or been treated by a physician.
- Do not allow insects or animals to enter any part of your food plant.

Notes

Appendix

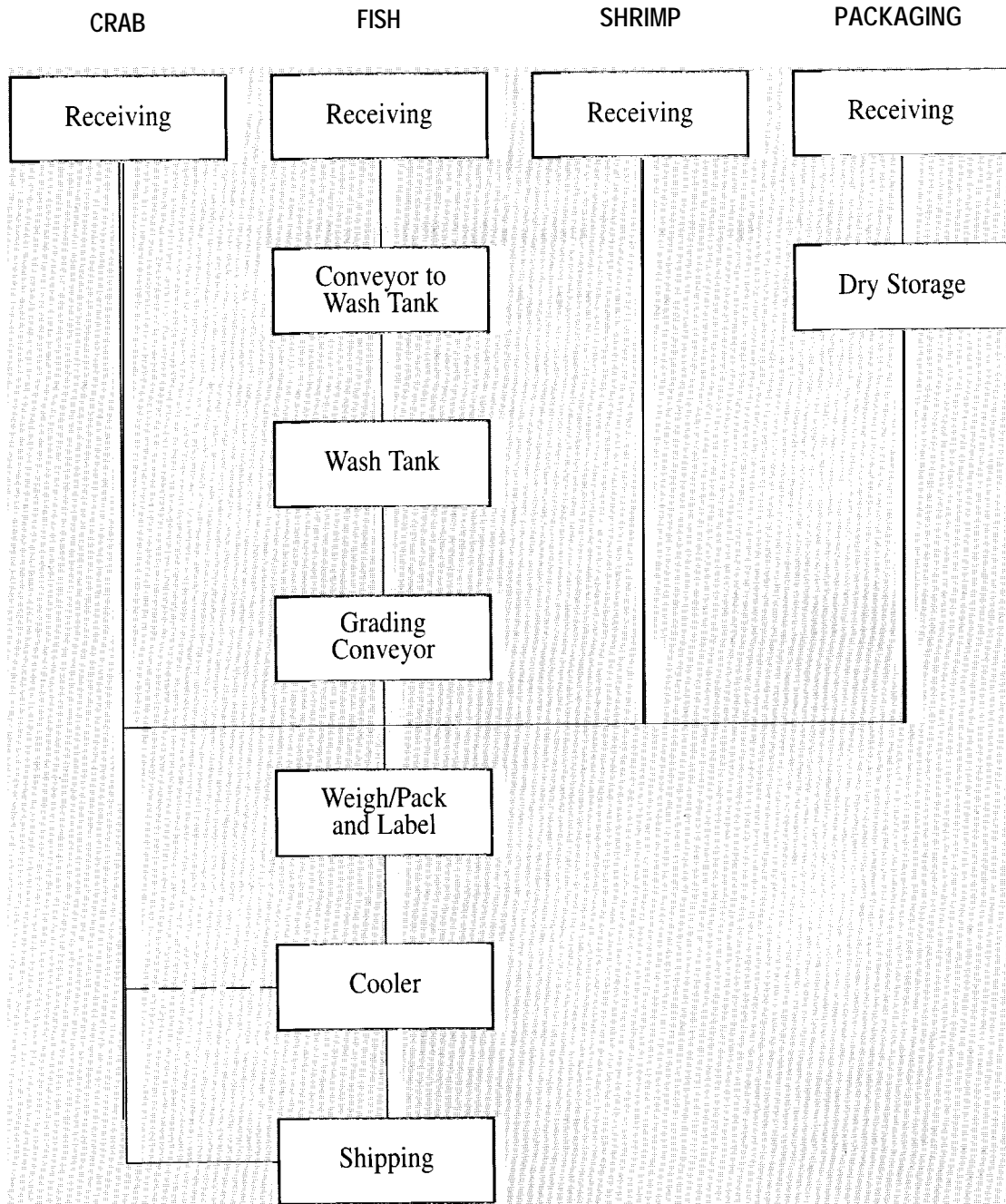
Flow Diagram

Checklists

Hazard Analysis Worksheet

HACCP Plan Form

Flow Diagram For a Small Seafood Dealer



Preliminary Steps Checklist

OK Needs
Attention

- Form a HACCP team of two to three people from within your company who are familiar with its daily routine. At least one member should be knowledgeable about food-safety issues.
- Describe the fish and shellfish products you handle (e.g., tuna, crab, shrimp), the finished product forms (e.g., fresh tuna loins, pasteurized crabmeat) and the types of packaging you use (e.g., bulk, wax-coated paperboard box, vacuum-packed plastic bag, aluminum can).
- Describe how you distribute your products (e.g., on ice, frozen, mail order with chemical refrigerant) and store them (e.g., refrigerated, frozen).
- Tell how customers will eat your products (e.g., raw or cooked) and the kind of consumer who will buy them (e.g., the general public, hospitals or nursing homes, other processors).
- Diagram the steps you take in handling and processing your products, from receipt to distribution. Walk through your plant to verify that your diagram is accurate.

Hazard Analysis Checklist

OK Needs
Attention

- From your diagram, identify the potential chemical, biological and physical hazards that could occur at each processing step. Do this for each fish and shellfish product you handle. List the hazards on a Hazard Analysis Worksheet.
- From the Hazard Analysis Worksheet, identify as critical control points only those hazards *that are reasonably likely to occur and that you can control, eliminate or reduce to an acceptable level.*
- If you find that your operation does not involve significant food-safety hazards, proceed to the sanitation section of this guide. Otherwise, continue through these checklists to create your HACCP plan.

Critical Control Points Checklist

OK Needs
Attention

- Write the name and location of your business on a HACCP Plan Form.
- Indicate the kind of products you will cover in your HACCP plan (e.g., shrimp, histamine fish, pasteurized blue crabmeat, smoked fish or shellfish going out of state). List only one category of products per HACCP form. For example, if you deal in shrimp and histamine fish, you need two separate HACCP plans.
- Tell how you expect your customers will prepare your products for eating.
- From your Hazard Analysis Worksheet, list the processing steps on your HACCP Plan Form that you have identified as critical control points.
- Identify a way to objectively measure each critical control point (e.g., harvest tag on shell stock, temperature of histamine fish, recording charts for pasteurized crab cookers).

Critical Limits Checklist

OK Needs
Attention

- Set a minimum and maximum boundary around each critical control point to establish a flexible range for managing your hazard(s) at each processing step. For example, the critical control point for holding fresh, unfrozen histamine fish is keeping the meat at or below 50 F. This is not only an FDA requirement, it is also a maximum limit. To keep histamine fish cool, yet unfrozen, maintain it between 32 and 49 F. These boundaries are your critical limits.
- Set an *operating* limit for each critical control point that falls *within* your critical limits. That way, you can adjust your process so the critical limits are never exceeded (e.g., ice and refrigerate histamine fish so the meat stays between 35 and 45 F). Do not declare these operating limits on your HACCP plan.

Monitoring Checklist

OK Needs
Attention

- Decide *what* you will observe (e.g., presence of sulfites on shrimp).
- Decide *how* you will control the hazard (e.g., require a letter of guarantee from boat captains saying they have not dipped their shrimp in sulfites).
- Determine how *often* you will control the hazard (e.g., request a letter of guarantee from every boat captain at least once per season).
- Assign the monitoring to an employee who is trained to monitor and knows how to record observations.

Corrective Action Checklist

OK Needs
Attention

- Decide on a corrective action to take when a critical limit has been exceeded or has not been met (e.g., reject shrimp from captains who do not provide a letter of guarantee saying that they have not used sulfites on their shrimp).
- Develop a procedure to ensure that an unsafe product does not reach the consumer.
- Develop a procedure to correct the problem that caused your critical limits to be violated.
- Follow the four-step procedure outlined in this guide for handling a product when a deviation occurs.
- Document your corrective actions and how you handle products produced outside your critical limits.

Record Keeping Checklist

OK Needs
Attention

- Keep a copy of the HACCP plan on file. It should include all of the information used in developing the plan, such as the Hazard Analysis Worksheets and correspondence from experts.
- Keep records that detail your monitoring procedures.
- Keep records that clearly show monitoring procedures have been followed. Be sure the records contain the actual values and observations obtained during monitoring.
- Ensure that the employee who makes the observation initials and dates the monitoring record daily.
- Keep written records that tell how you brought a deviation under control and how you handled the product made when a deviation occurred.
- Keep records that show any changes you make to your HACCP plan, the accuracy of your monitoring equipment and the results of plant inspections or equipment evaluation tests.

Verification Checklist

OK Needs
Attention

- Validate your HACCP plan to demonstrate that it can control the food-safety hazards identified and that all plant personnel follow it.
- Calibrate your monitoring equipment to verify that it is accurate.
- Review the calibration records to see that the equipment performs as it should.
- Periodically perform a measurable physical, chemical or microbiological test in your operations or on your products to confirm that they comply with the goals of your HACCP plan.
- Make sure your plant's designated HACCP coordinator reviews, signs and dates all monitoring and corrective action records.
- Keep a copy of the inspection reports from regulatory personnel that demonstrate your HACCP plan is adequate and that you comply with the food-safety regulations.

Self-Inspection Sanitation Checklist

OK Needs
Attention

- Make sure the water you use to make ice and to clean or process food is from a safe source that is protected from contamination.
- Inspect the grounds around your business to make sure that they are clear of debris, brush and weeds, which harbor insects and rodents that could infest your plant.
- See that your plumbing and sewage disposal system complies with state and federal regulations.
- Make adequate arrangements to remove solid waste and wastewater from your buildings and grounds.
- Make sure all food-contact surfaces, process equipment and utensils are made of durable materials such as stainless steel and that they are cleaned and sanitized after use.
- Place hand-washing and sanitizing stations at locations that are accessible to employees who handle food.
- Prevent cross-contamination between raw and cooked products.
- Do not allow dirty utensils, gloves, aprons, food packaging or equipment to come in contact with food.
- See that pesticides, equipment lubricants and sanitizers do not contaminate food and food-contact surfaces.
- Train your employees about personal cleanliness and good hygiene practices.
- Provide adequate supervision and training for your employees to ensure that your sanitation program is followed properly.

Hazard Analysis Worksheet

Firm Name: _____ Product Description: _____

 Firm Address: _____ Method of Storage and Distribution: _____

 _____ Intended Use and Consumer: _____

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/processing step	Identify potential hazards introduced, controlled or enhanced at this step	Are any potential food-safety hazards significant? (Yes/No)	Justify your decisions for column 3.	List measure(s) to prevent the significant hazards	Is this step a critical control point? (Yes/No)
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				

Hazard Analysis Worksheet

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/processing step	Identify potential hazards introduced, controlled or enhanced at this step(1)	Are any potential food-safety hazards significant? (Yes/No)	Justify your decisions for column 3.	List measure(s) to prevent the significant hazards	Is this step a critical control point? (Yes/No)
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				

HACCP Plan Form

Firm Name: _____

Product Description: _____

Firm Address: _____

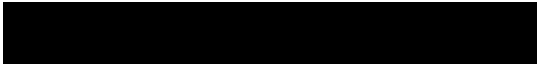
Method of Storage and Distribution: _____

Intended Use and Consumer: _____

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action(s)	Records	Verification	
			What	How	Frequency	Who				

HACCP Plan Form

(1)	(2)	(3)	(4) Monitoring				(8)	(9)	(10)
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure					Corrective Action(s)	Records	Verification
			What	How	Frequency	Who			



These additional materials can help you develop and implement your HACCP plan and sanitation program:

- *HACCP: Hazard Analysis and Critical Control Point Training Curriculum*; Second Edition 1997. National Seafood HACCP Alliance, North Carolina Sea Grant, Raleigh, NC. UNC-SG-96-02.
- *Fish and Fisheries Products Hazards and Controls Guide*; Second Edition, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Seafood. January 1998.
- *Do Your Own Plant Inspection -A Guide for Self-Inspection for the Shellfish Shipper or Processor*. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Bureau of Foods, HHS Publication No. (FDA) 91-2248, 1991.
- *HACCP Program Assistance for Small Seafood Processors and Dealers*. North Carolina Fishery Resource Grant Program. North Carolina Sea Grant, Raleigh, NC. Project No. 97ST-2, March 1998.
- *Federal Register*, Vol. 60, No. 242, Monday, Dec. 18, 1995, Rules and Regulations, pages 65197-65202.