



Hazard Analysis and Critical Control Point:
Model Safety Plans for
Small Seafood Dealers, Packers and Processors

North

Carolina

Sea Grant

College

Program

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Hazard Analysis and Critical Control Point: **Model Safety Plans for Small Seafood Dealers, Packers & Processors**

Introduction

Hazard Analysis and Critical Control Point (HACCP) monitoring has become a widely accepted tool that food handlers and manufacturers use to control potential health risks in our food supply. To ensure the safety of fish and fishery products, the U.S. Food and Drug Administration (FDA) issued its seafood HACCP regulation in 1995 and gave the industry two years to comply. All domestic seafood processing firms have had to meet those standards since Dec. 18, 1997.

The safety of our food is now a significant concern to both the public and regulators. Disease-causing bacteria have resulted in a number of severe food-borne illnesses and even deaths, and unsafe food has received a great deal of media attention. Food manufacturers now must assume greater responsibility for protecting consumer confidence in the wholesomeness of food by guaranteeing its safety.

HACCP was pioneered in the early 1960s to reduce food safety hazards. These hazards can be bacterial, chemical or physical contaminants in food that cause severe illness, injury or death if they are not prevented, eliminated or reduced to an acceptable level. Traditionally, processors tested random samples of a product to detect quality or safety problems. But as food-borne illnesses began attracting widespread attention, processors realized that it was time-consuming and inefficient to search for problems after food had been made. They found it was better to control the introduction of a hazard to food as it was being handled or processed. HACCP gives processors an advantage by focusing attention on the production line where food hazards are likely to occur and where processors can catch a safety problem before it reaches the customer.

The FDA expects five kinds of seafood dealers and processors to develop a food safety or HACCP plan:

- dealers who sell shrimp dipped in sulfites;
- dealers who sell histamine-producing fish such as mackerel, tuna or mahi-mahi;
- dealers who receive or ship shellfish out of state;
- cooked crab processors;
- smoked fish processors.

You can prepare a HACCP plan by following seven steps.

1. Conduct a hazard analysis. Walk through your plant and draw a flowchart or diagram of the production operation. Start with the delivery of your fish or fishery products and list all of the processing steps involved in manufacturing or packaging your products for retail or wholesale distribution. Once you can see your production processes outlined on paper, it will be easier to decide where your business is vulnerable to food safety hazards. To do a hazard analysis, transfer each processing step outlined on your flowchart to column 1 on a Hazard Analysis Worksheet (refer to blank form on page 65). Column 2 of this worksheet asks you to decide which of the three food safety hazards — biological, chemical or physical — your fish or fishery products are most at risk for at each step in production. If you are unsure what kinds of hazards you should be concerned about, consult the reference materials in this booklet. You can also seek advice from your state and federal health inspectors or your local Sea Grant or extension seafood specialist.

2. Establish critical control points (CCPs). Your hazard analysis will help you determine where in your operation you can control a food safety hazard. Anywhere you have answered “yes” in column 6 on your Hazard Analysis worksheet is a CCP that you will have to monitor in your HACCP plan. Transfer those processing steps that you determined are CCPs in your operation from your Hazard Analysis worksheet to column 1 on a HACCP Plan Form (refer to blank form on page 66). In column 2 of this form, write the biological, chemical or physical hazard that you can control by preventing, eliminating or reducing a hazard to an acceptable level. For example, you can prevent disease-causing bacteria or pathogens from growing on finfish through refrigeration. You can eliminate these same bacteria from crabmeat through pasteurization. And you can reduce to an acceptable level the bacteria in shellfish by harvesting oysters, clams and mussels only from state-approved waters.

3. Set critical limits. In column 3 of your HACCP Plan Form, establish boundaries that cannot be violated if your products are to be safely processed or handled. For example, the critical limit for holding histamine-producing fish such as tuna or mackerel is 50 F, according to the FDA. That means you cannot store your tuna or mackerel at temperatures higher than 50 F, or histamine will form in the meat. Histamine can be deadly to people who are allergic to it. To be certain that your fish never reaches or exceeds that temperature, you would set your cooler no higher than 50 F. That is your critical limit.

4. Devise monitoring procedures. In columns 4, 5, 6 and 7 of your HACCP Plan form, decide how you will control your hazards and meet your critical limits. Choose physical or chemical tests that give fast results to tell whether you are meeting your critical limits. For instance, you can check the temperature of your histamine-prone fish by checking the temperature of your cooler. Better yet, you can check the temperature of the meat with a dial thermometer. And you can check for the presence of sulfites on your shrimp with a quick chemical test. Sulfites produce color changes when certain dyes are applied to shrimp meat. These changes let you know within minutes if your product has been sulfite-treated to hold its natural color.

5. Establish corrective actions. Give your employees detailed instructions on how to bring a production process under control when your monitoring procedures show that you have exceeded your critical limits. For instance, you would instruct your employees to reject any shipment of live oysters that were untagged, harvested from closed areas or received from an unlicensed harvester. If the thermometer on your cooler began to rise above 50 F, you would want your employees to readjust the thermostat to bring the temperature below 50 F and/or pack your histamine-prone fish in ice to keep it cold.

6. Develop verification steps. Establish procedures that indicate whether your HACCP plan can control hazards and your employees are following the plan's rules. For example, if you record daily temperatures in the cooler where you hold your histamine-prone fish before shipping, you would regularly review those records for two reasons. First, you want to make sure that your employees are actually recording the cooler temperatures. Second, you want to know that your cooler is continuously operating at or below 50 F. If the cooler stopped working, you would want to see that your employees took the appropriate corrective action to keep the temperature of your fish below 50 F.

7. Build a record-keeping system. Keep records to document that your HACCP plan is working properly. These do not have to be complicated. For instance, you could keep a daily temperature log on your histamine-prone fish at receiving and during refrigerated storage. And you must keep the harvest tags on file for every shipment of live oysters and clams that you received at your dock. Examples of the different kinds of records that you could use for your HACCP system are shown in this booklet.

How to Use These Models

The models in this booklet illustrate how a HACCP plan can address seafood safety hazards in the five kinds of businesses expected to have plans. There is no standard, one-plan-fits-any-business HACCP program for the seafood industry. The FDA has given every processor the freedom, within general guidelines, to design a safety plan that best meets his or her needs. Because no two businesses handle seafood exactly the same way, no two HACCP plans will be alike, even among companies that process an identical commodity such as pasteurized crabmeat.

You are strongly encouraged not to copy any one of these plans and adopt it as your own. These illustrations are offered only to help you understand the HACCP concept. *Be aware that the monitoring procedures and corrective actions you commit to paper will be binding. State and federal regulators will expect you to maintain records on all of your critical control points as specified by monitoring procedures in your HACCP plan.* Think carefully through your business's safety hazards and decide how best to monitor and control them. To learn more about designing a HACCP plan, request a copy of *A Self-Guide to HACCP Inspection for Small Seafood Dealers, Packers and Processors*. Send \$2 for shipping and handling to North Carolina Sea Grant, North Carolina State University, Box 8605, Raleigh, NC 27695-8605 or call 919/515-9101. Or contact the NC State University Seafood Laboratory, P.O. Box 1137, Morehead City, NC 28557 or call 252/726-7341.

Good Manufacturing Practices

The HACCP system rests on a strong general hygiene program that prevents food from becoming contaminated through unsanitary plant conditions or handling practices. In fact, a HACCP plan cannot work without one. Sanitation standard operating procedures (SSOPs) broadly address many elements of plant and employee hygiene as food is manufactured. They describe in step-by-step detail how to handle food in a sanitary way and keep your plant clean every day. The FDA regulation requires seafood processors to establish SSOPs, even if their company isn't required to develop a HACCP plan, because a well-designed SSOP program is a valuable tool for preventing food hazards.

In some situations, you may use SSOPs to reduce the number of critical control points (CCPs) in your HACCP plan. But this in no way minimizes the importance of a particular hazard. It is often better to prevent problems by controlling a food hazard through a combination of SSOPs and CCPs. For instance, plant sanitation, employee hygiene and strict handling procedures are just as important in controlling disease-causing bacteria in cooked seafood as the actual cooking and refrigeration that you might identify as CCPs in your HACCP plan.

When SSOPs are in force, HACCP will be more effective because the plan can focus on hazards associated with processing or a particular seafood and *not* on the cleanliness of the plant. If you include sanitation controls as part of your HACCP plan, they become CCPs, so you would have to maintain additional records on critical limits, corrective actions and verification that you otherwise would not have to keep.

The regulation requires you to regularly monitor and maintain records showing you comply with eight key points.

1. Verify through your city or the county health department that the water you use to make ice and process seafood is sanitary or has been treated to make it safe to use with food.
2. Document before each day's production that employees clean and sanitize the surfaces of cleaning tables, equipment or utensils that come in contact with food.
3. If you heat-process any seafood such as blue crab, document that you prevent cross-contamination between raw and cooked products. Even if you do not heat-treat seafood, you must show that you have put procedures in place to prevent your seafood from contacting any unsanitary equipment, utensils or packaging.
4. Show that you put hand-washing and sanitizing stations in your processing areas and that you maintain them regularly. Toilets must meet state health regulations.
5. Demonstrate that employees handle and store seafood away from chemical, physical or bacterial contaminants such as sanitizers, condensate, or dirty utensils or equipment.
6. Indicate that you properly label and use cleansers and pesticides, storing them away from food-processing areas.
7. Establish a policy that keeps any employee with an illness, infected wound or open sore from handling seafood in your plant unless the condition has healed or the person has been treated by a physician.
8. Document that you use a pest-control program in your plant.

You can develop a SSOP checklist to document that you comply with these sanitation requirements daily, weekly or monthly. An example of a SSOP program is included on pages 60-62.

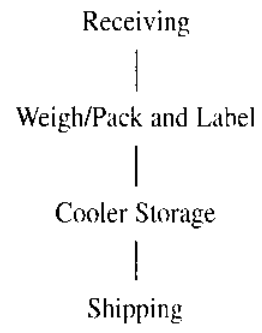
References

The following materials can help you develop a HACCP system for your business.

- *HACCP: Hazard Analysis and Critical Control Point Training Curriculum*; Third edition, 1998. National Seafood HACCP Alliance, North Carolina Sea Grant, Raleigh, NC. UNC-SG-98-07.
- *Fish and Fisheries Products Hazards and Controls Guide*; Second edition, January 1998. 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.
- *Hazard Analysis and Critical Control Point: A Self-Guide to HACCP Inspection for Small Seafood Dealers, Packers and Processors*; March 1998. North Carolina Fishery Resource Grant Program. North Carolina Sea Grant, Raleigh, NC. Project No. 97ST-2.
- *Federal Register*, Vol. 60, No. 242, Monday, Dec. 18, 1995, Rules and Regulations, pages 65197- 65202.

Fresh Shrimp

Fresh Shrimp Process Flowchart



Hazard Analysis Worksheet for Fresh Shrimp

Firm Name: ABC Shrimp Co. Product Description: Fresh head-on shrimp

Firm Address: Anywhere, USA Method of Storage and Distribution: Pack and distribute on ice in 50-pound boxes

Date: _____ Intended Use and Consumer: Cooked by the general public prior to consumption

Signature: _____

(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)
Receiving	BIOLOGICAL	Yes	Raw seafood is a natural source of pathogens.	Proper cooking will destroy pathogens prior to consumption.	No
	CHEMICAL	Yes	Sulfites can cause allergic reactions in sensitive people.	Reject shrimp containing sulfites.	Yes
	PHYSICAL	No			
Weigh/Pack and Label	BIOLOGICAL	Yes	Temperature abuse can cause pathogen growth.	Proper cooking will destroy pathogens prior to consumption.	No
	CHEMICAL	No			
	PHYSICAL	No			
Cooler Storage	BIOLOGICAL	Yes	Temperature abuse can cause pathogen growth.	Proper cooking will destroy pathogens prior to consumption.	No
	CHEMICAL	No			
	PHYSICAL	No			
Shipping	BIOLOGICAL	Yes	Temperature abuse can cause pathogen growth.	Proper cooking will destroy pathogens prior to consumption.	No
	CHEMICAL	No			
	PHYSICAL	No			

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

HACCP Plan Form for Fresh Shrimp

Firm Name: ABC Shrimp Co. Product Description: Fresh head-on shrimp

Firm Address: Anywhere, USA Method of Storage and Distribution: Pack and distribute on ice in 50-pound boxes

Date: _____ Intended Use and Consumer: Cooked by the general public prior to consumption

Signature: _____

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring			(5)	(6)	(7)	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency						
Receiving	Sulfiting agents	Presence of residual sulfite on edible portion of shrimp	Use of sulfiting agent	Letter from harvester guaranteeing no use of sulfite dip	Purchase shrimp from approved vessel owners only	Receiving supervisor		<ul style="list-style-type: none"> • Do not accept any shrimp that has been dipped in sulfites. 	<ul style="list-style-type: none"> • Preseason qualification list • Daily record review • Quarterly test for presence of sulfite 	<ul style="list-style-type: none"> • Receiving records 	
<p>Approved vessel: shrimp harvest vessel with letter declaring no sulfite use on file in office</p> <p>Unapproved vessel: shrimp harvest vessel with no letter of declaration</p>											

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

Harvest Vessel HACCP Training

Letter of Guarantee for use of sulfites

ABC Shrimp Co., Anywhere, USA

1.	All product should be handled in a manner to prevent any type of contamination (dirty ice, dirty storage bin or containers, fuel, lubricants, used brine solution, etc.).
2.	Any ice bin or freezer used to store products should be cleaned and sanitized regularly.
3.	The deck and fish baskets used to store products should be cleaned between trips. All baskets should be color coded for use with food products only.
4.	Dockside and off-loading practices include: a) no trash in baskets, b) no trash left on dock and c) no unauthorized persons on dock.
5.	Sodium bisulfite declaration for this harvest vessel. <input type="checkbox"/> YES (Allowed) <input type="checkbox"/> NO (Not allowed)
6.	Other instructions given:

This HACCP-related information was discussed with vessel operators and crews off-loading products at ABC Shrimp Co.

Vessel Name: _____

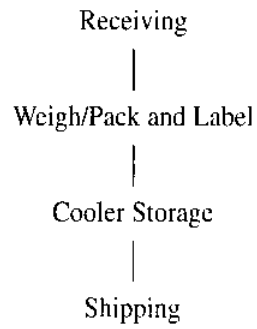
Captain: _____ Date Reviewed: _____

Trainer: _____ Date Reviewed: _____

Ideas and Notes

Fresh Shrimp Containing Sulfites

Fresh Shrimp Containing Sulfites Process Flowchart



Hazard Analysis Worksheet for Fresh Shrimp Containing Sulfites

Firm Name: <u>ABC Shrimp Co.</u>	Product Description: <u>Fresh head-on shrimp</u>
Firm Address: <u>Anywhere, USA</u>	Method of Storage and Distribution: <u>Pack and distribute on ice in</u>
Date: _____	<u>50-pound boxes</u>
Signature: _____	Intended Use and Consumer: <u>Cooked by the general public prior to</u>
	<u>consumption</u>

(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)
Receiving	BIOLOGICAL	Yes	Raw seafood is a natural source of pathogens.	Proper cooking will destroy pathogens prior to consumption.	No
	CHEMICAL	Yes	Sulfites can cause allergic reactions in sensitive people.	Segregate and label products containing sulfites.	No
	PHYSICAL	No			
Weigh/Pack and Label	BIOLOGICAL	Yes	Temperature abuse can cause pathogen growth.	Proper cooking will destroy pathogens prior to consumption.	No
	CHEMICAL	Yes	Sulfites can cause allergic reactions in sensitive people.	Ensure use of accurate labels.	Yes
	PHYSICAL	No			
Cooler Storage	BIOLOGICAL	Yes	Temperature abuse can cause pathogen growth.	Proper cooking will destroy pathogens prior to consumption.	No
	CHEMICAL	No			
	PHYSICAL	No			
Shipping	BIOLOGICAL	Yes	Temperature abuse can cause pathogen growth.	Proper cooking will destroy pathogens prior to consumption.	No
	CHEMICAL	No			
	PHYSICAL	No			

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

HACCP Plan Form for Fresh Shrimp Containing Sulfites

Firm Name: <u>ABC Shrimp Co.</u>	Product Description: <u>Fresh head-on shrimp</u>				(1)		
Firm Address: <u>Anywhere, USA</u>	Method of Storage and Distribution: <u>Pack and distribute on ice in 50-pound boxes</u>				(2)		
Date: _____ Signature: _____	Intended Use and Consumer: <u>Cooked by the general public prior to consumption</u>				(3)		
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring		Corrective Action(s)	Verification	Records
			How	Frequency			
Weight/Pack and Label	Allergic-type reaction from undeclared sulfiting agent	Declare on package all product containing residual sulfiting agent.	Visual observation	Every lot of shrimp containing sulfites that is repackaged	Packing supervisor	• If this product is mislabeled, then appropriately label. • Daily record review • Random sulfite testing of repackaged product to ensure proper labeling	• Pack room inspection sheet • Supplier declarations that their product was sulfite-treated

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

Ideas and Notes

Shucked Oysters

Shucked Oysters Process Flowchart

Receiving Live Oysters



Dry Cooler Storage



Shucking



Washing/Draining



Packing



Shucked Oyster Storage

Hazard Analysis Worksheet for Shucked Oysters

Firm Name: <u>ABC Oyster Co.</u>	Product Description: <u>Shucked oysters in plastic 1-gallon containers</u>
Firm Address: <u>Anywhere, USA</u>	Method of Storage and Distribution: <u>Shipped on ice and refrigerated;</u>
	<u>stored at retail under refrigeration</u>
Signature: _____	Intended Use and Consumer: <u>Raw and/or cooked prior to consumption</u>
Date: _____	

(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)
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
	CHEMICAL • Chemical contamination • Natural toxins	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
	PHYSICAL • None	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
Shellstock Cooler Storage	BIOLOGICAL • Bacterial pathogen growth CHEMICAL • None PHYSICAL • None	Yes	Pathogens may increase in number if oysters are not properly cooled during storage.	Maintain coolers at temperatures below 45 F.	Yes
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.		

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

Hazard Analysis Worksheet for Shucked Oysters

(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)
Washing/Draining	BIOLOGICAL • Bacterial pathogen growth CHEMICAL • None PHYSICAL • None	Yes	Excessive time at washing/drainage 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 Controls Guide*.

HACCP Plan Form for Shucked Oysters

Firm Name: ABC Oyster Co. Product Description: Shucked oysters in plastic 1-gallon containers

Firm Address: Anywhere, USA Method of Storage and Distribution: Shipped on ice and refrigerated; stored at retail under refrigeration

Signature: _____ Intended Use and Consumer: Raw and/or cooked prior to consumption

Date: _____

(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)	Verification	Records	
			What	How	Frequency				Who
Receiving Live Oysters	Pathogens	<ul style="list-style-type: none"> • Must have properly tagged containers • Must be licensed harvester • No oysters from closed areas 	<ul style="list-style-type: none"> • Harvester tag • Harvester license 	Visual check	<ul style="list-style-type: none"> • Every container • Every delivery 	Quality-control person	<ul style="list-style-type: none"> • Daily record review 	<ul style="list-style-type: none"> • Reject if untagged, improperly tagged, from closed areas or from unlicensed harvester. 	<ul style="list-style-type: none"> • Receiving record
	Chemical contamination	<ul style="list-style-type: none"> • Must have properly tagged containers • Must be licensed harvester • No oysters from closed areas 	<ul style="list-style-type: none"> • Harvester tag • Harvester license 	Visual check	Every container	Quality-control person	<ul style="list-style-type: none"> • Daily record review 	<ul style="list-style-type: none"> • Reject if untagged, improperly tagged, from closed areas or from unlicensed harvester. 	<ul style="list-style-type: none"> • Receiving record
	Natural toxins	<ul style="list-style-type: none"> • Must have properly tagged containers • Must be licensed harvester • No oysters from closed areas 	<ul style="list-style-type: none"> • Harvester tag • Harvester license 	Visual check	Every container	Quality-control person	<ul style="list-style-type: none"> • Daily record review 	<ul style="list-style-type: none"> • Reject if untagged, improperly tagged, from closed areas or from unlicensed harvester. 	<ul style="list-style-type: none"> • Receiving record

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

HACCP Plan Form for Shucked Oysters

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measure	(4) Monitoring			(7) Who	(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency				
Shellstock Cooler Storage	Bacterial pathogen growth	Coolers not to exceed 45 F for more than two hours	Cooler temperature	Visual check of continuous thermometer or record twice daily	Visual check of continuous thermometer two times a day	Quality-control person	<ul style="list-style-type: none"> Adjust cooler temperature. Hold and evaluate product based on total time of exposure to abusive temperatures. 	<ul style="list-style-type: none"> Daily record review Thermometer calibration weekly 	<ul style="list-style-type: none"> Cooler temperature record Recorder chart
Shucked Oyster Storage	Bacterial pathogen growth	<ul style="list-style-type: none"> Cooler temperature not to 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 	<ul style="list-style-type: none"> Cooler temperature Time from dry storage cooler to shucked oyster storage 	<ul style="list-style-type: none"> Visual checks of continuous thermometer or record twice daily Check progress of marked product 	<ul style="list-style-type: none"> Visual check of continuous thermometer every two hours during operation Marked product checked twice daily (a.m. and p.m.) 	Quality-control person	<ul style="list-style-type: none"> Adjust cooler temperature. Hold and evaluate based on time and exposure by competent authority. Ice product and/or return to shellstock in cooler; hold and evaluate based on time of exposure. 	<ul style="list-style-type: none"> Daily record review Weekly thermometer calibration Weekly recorder calibration 	<ul style="list-style-type: none"> Cooler temperature record Product time of exposure log

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

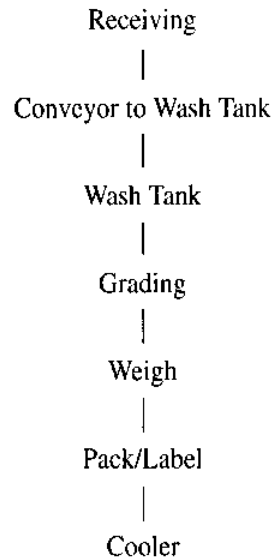
HACCP Record Form for Shucked Oysters

*Cooler temperatures must not exceed 45 F for more than two hours.
Record cooler temperatures twice daily during operations. Keep records for one year.*

Cooler Critical Control Point				
Month/Week	Time of Day	Sufficient Ice on Product (Yes/No)	Cooler 1 (F)	Cooler 2 (F)
Sun.	a.m.			
	p.m.			
Mon.	a.m.			
	p.m.			
Tues.	a.m.			
	p.m.			
Wed.	a.m.			
	p.m.			
Thur.	a.m.			
	p.m.			
Fri.	a.m.			
	p.m.			
Sat.	a.m.			
	p.m.			
Compiled by: _____ Reviewed by: _____ Date Reviewed: _____				

Histamine-Prone Finfish

Histamine-Prone Finfish Process Flowchart



Potential Species-Related Hazards: Histamine-Prone Finfish

amberjack	Spanish mackerel
bluefish	mahi-mahi (dolphin)
jack or blue runner	shad
jack crevalle	tuna
king mackerel	wahoo

Hazard Analysis Worksheet for Histamine-Prone Finfish

Firm Name: ABC Fish Co. Product Description: Histamine-prone fish

Firm Address: Anywhere, USA Method of Storage and Distribution: Pack (unprocessed) in ice; hold and distribute refrigerated

Date: _____ Intended Use and Consumer: Cooked by the general public prior to consumption

Signature: _____

(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)
Receiving	BIOLOGICAL • Bacterial pathogens CHEMICAL • Histamine formation PHYSICAL • None	Yes Yes	Potential pathogens may be present. Histamine formation may occur due to temperature abuse.	Proper cooking will destroy pathogens. Proper temperature control from harvest through distribution will prevent histamine formation.	No Yes
Conveyor	BIOLOGICAL • None CHEMICAL • Lubricants may be present PHYSICAL • None	No Yes	Chemicals used for lubrication may contact fish.	Follow established sanitation standard operating procedures (SSOPs).	No
Wash Tank	BIOLOGICAL • Bacterial pathogens CHEMICAL • Histamine formation PHYSICAL • None	Yes Yes	Potential pathogens may be present and grow. Histamine formation can occur.	Follow established SSOPs. Maintain ice in wash tank for temperature control.	No No

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

Hazard Analysis Worksheet for Histamine-Prone Finfish

(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)
Grading	BIOLOGICAL • Bacterial pathogens	Yes	Pathogens could be introduced and allowed to grow.	Follow established SSOPs.	No
	CHEMICAL • Histamine formation	Yes	Temperature abuse can cause pathogen growth.	Maintain ice on product.	No
	PHYSICAL • None	No			
Weigh	BIOLOGICAL • None	No	Introduction of bacterial pathogens is not likely to occur.	Follow established GMPs and SSOPs.	No
	CHEMICAL • None	No			
	PHYSICAL • None	No			
Pack/Label	BIOLOGICAL • None	No	Introduction of bacterial pathogens is not likely to occur.	Follow established GMPs and SSOPs.	No
	CHEMICAL • None	No			
	PHYSICAL • None	No			
Cooler	BIOLOGICAL • Bacterial pathogens	Yes	Temperature abuse can cause pathogen growth.	Proper cooking will destroy pathogens.	No
	CHEMICAL • Histamine formation	Yes	Temperature abuse may lead to histamine formation.	Maintain ice on product while in refrigerated storage.	Yes
	PHYSICAL • None	No			

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

HACCP Plan Form for Histamine-Prone Finfish

Firm Name: ABC Fish Co. Product Description: Histamine-prone fish

Firm Address: Anywhere, USA Method of Storage and Distribution: Pack in ice, hold and distribute refrigerated

Date: _____ Intended Use and Consumer: Cooked by the general public prior to consumption

Signature: _____

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) (5) (6) (7) Monitoring			(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency			
Receiving	Histamine formation	All fish must be accompanied by vessel record showing (1) cooling began as soon as possible after landing and (2) method of cooling to 50 F or below within six hours or 40 F within 18 hours of death.	Harvest vessel records	Review record. Check temperature of fish carcass at dock with dial thermometer.	Check every lot received.	Receiving supervisor	<ul style="list-style-type: none"> • Reject lot or shipment if no harvest records are provided or temperature of fish exceeds 50 F. 	<ul style="list-style-type: none"> • Review monitoring, corrective action and verification records weekly. • Harvester's records • Dockside temperature measurements
Cooler	Histamine formation	Maintain fish on ice and keep refrigerated at 40 F or less.	Check for ice on fish and check cooler temperature.	Check visually.	Check twice daily.	Dockmaster	<ul style="list-style-type: none"> • Ice fish when necessary and check the refrigeration unit. 	<ul style="list-style-type: none"> • Review monitoring, corrective action and verification records weekly. • Cooler record and ice check list

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

HACCP Record Form for Histamine-Prone Finfish

*Fish must be received at 50 F or below and maintained at 40 F or below in the cooler and at shipping.
Record cooler temperatures twice daily during operations. Keep records for one year.*

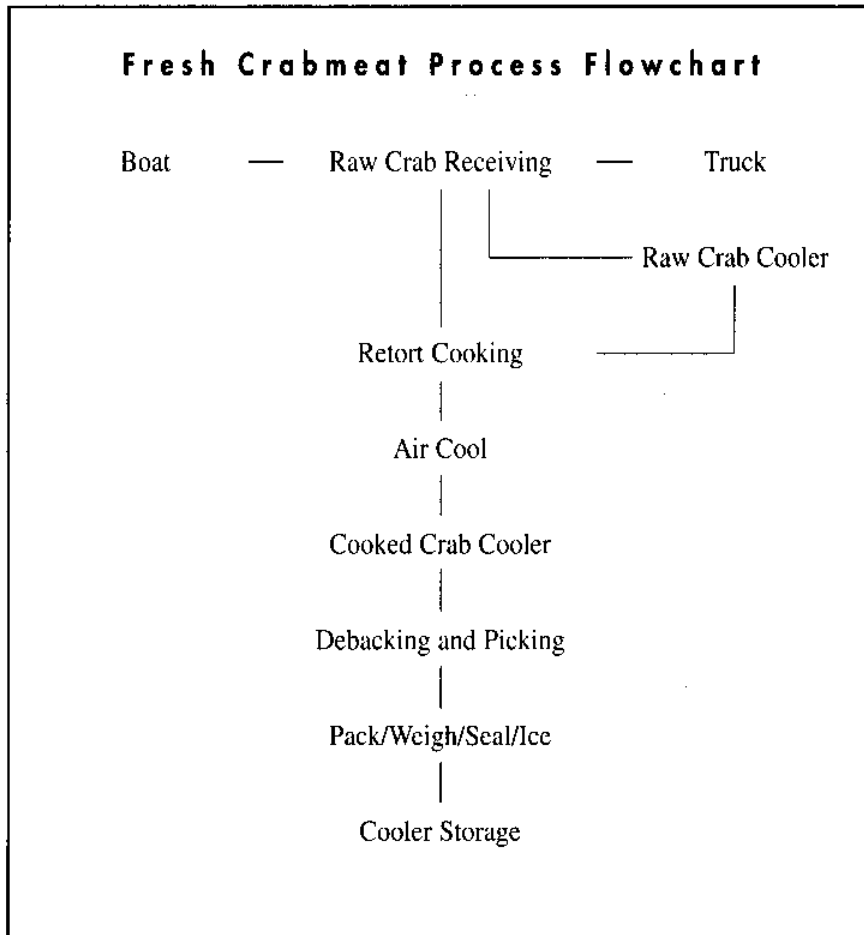
Cooler Critical Control Point				
Month/Week	Time of Day	Sufficient Ice on Product (Yes/No)	Cooler 1 (F)	Cooler 2 (F)
Sun.	a.m.			
	p.m.			
Mon.	a.m.			
	p.m.			
Tues.	a.m.			
	p.m.			
Wed.	a.m.			
	p.m.			
Thur.	a.m.			
	p.m.			
Fri.	a.m.			
	p.m.			
Sat.	a.m.			
	p.m.			
Compiled by: _____ Reviewed by: _____ Date Reviewed: _____				

Corrective Action Form for Histamine-Prone Finfish

Firm Name: _____ Product Description: _____	
Firm Address: _____	
Problem or Discrepancy	Solution or Corrective Action
Date: _____ Completed by: _____	
Date: _____ Completed by: _____	
Date: _____ Completed by: _____	
Date: _____ Completed by: _____	
Date: _____ Completed by: _____	
Date: _____ Completed by: _____	
Date: _____ Completed by: _____	
Date: _____ Completed by: _____	
Date: _____ Completed by: _____	
Date: _____ Completed by: _____	
Reviewed by: _____ Date Reviewed: _____	

Ideas and Notes

Fresh Crabmeat



Hazard Analysis Worksheet for Fresh Crabmeat

Firm Name: ABC Crab Co. Product Description: Crabmeat

Firm Address: Anywhere, USA Method of Storage and Distribution: Refrigerated storage and distribution

Date: _____ Intended Use and Consumer: General public, restaurants and retail stores

Signature: _____

(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)
Receive/Inspect/Weigh/Cull	BIOLOGICAL • Bacterial pathogens CHEMICAL • Environmental contaminants PHYSICAL • None	Yes No	Raw crabs can be a reservoir for bacterial pathogens. No history of problems with blue crabs.	Cooking eliminates pathogens.	No
Raw Crab Cooler	BIOLOGICAL • Bacterial pathogens CHEMICAL • None PHYSICAL • None	Yes No	Raw crabs can be a reservoir for bacterial pathogens.	Cooking eliminates pathogens.	No
Retort Cooking	BIOLOGICAL • Bacterial pathogen survival CHEMICAL • Boiler chemicals PHYSICAL • None	Yes No	Improper cooking will not kill or inactivate human pathogens. Controlled by SSOP	Control cooking time and temperature. Controlled by SSOP	Yes
Air Cool Room	BIOLOGICAL • Bacterial contamination • Bacterial pathogen growth CHEMICAL • None PHYSICAL • None	No No	Controlled by SSOP Bacterial growth is controlled by hot crab temperature and short holding time.	Controlled by SSOP	No

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

Hazard Analysis Worksheet for Fresh Crabmeat

(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)
Cooked Crab Cooler	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial contamination • Bacterial pathogen growth <p>CHEMICAL</p> <ul style="list-style-type: none"> • None <p>PHYSICAL</p> <ul style="list-style-type: none"> • None 	<p>No</p> <p>No</p>	<p>Controlled by SSOP</p> <p>It is unlikely that time/temperature abuse could occur. The meat in the crab is sterile.</p>	<p>Controlled by SSOP</p>	<p>No</p>
Debacking and Picking	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial contamination • Bacterial pathogen growth <p>CHEMICAL</p> <ul style="list-style-type: none"> • None <p>PHYSICAL</p> <ul style="list-style-type: none"> • Shell 	<p>No</p> <p>Yes</p> <p>No</p>	<p>Controlled by SSOP</p> <p>Excessive time at unrefrigerated temperature will promote pathogen growth.</p> <p>This quality defect is not likely to result in the food being unsafe for human consumption.</p>	<p>Control the cumulative time the product is unrefrigerated after removal from cooler to icing picked product. The CCP is at the weigh, pack and label step because that is where the monitoring is most effective and where product is iced.</p>	<p>No</p>
Pack/Weigh/Seal/Ice	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial contamination • Bacterial pathogen growth <p>CHEMICAL</p> <ul style="list-style-type: none"> • None <p>PHYSICAL</p> <ul style="list-style-type: none"> • None 	<p>No</p> <p>Yes</p>	<p>Controlled by SSOP</p> <p>Excessive time at unrefrigerated temperature will promote pathogen growth.</p>	<p>Control the cumulative time the product is unrefrigerated after removal from cooler to icing the picked product.</p>	<p>Yes</p>

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

Hazard Analysis Worksheet for Fresh Crabmeat

(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)
Cooler Storage	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogen growth <p>CHEMICAL</p> <ul style="list-style-type: none"> • None <p>PHYSICAL</p> <ul style="list-style-type: none"> • None 	Yes	Storage at high temperatures will allow growth of bacterial pathogens.	Proper refrigeration	Yes

HACCP Plan Form for Fresh Crabmeat

Firm Name: ABC Fish Co. Product Description: Crabmeat

Firm Address: Anywhere, USA Method of Storage and Distribution: Ice and refrigerated storage and distribution

Date: _____ Intended Use and Consumer: Ready to eat: retail and institutional

Signature: _____

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) (5) (6) (7) Monitoring			(8) Corrective Action(s)	(9) Verification	(10) Records	
			What	How	Frequency				Who
Retort Cooking	Bacterial pathogen survival	Minimum eight minutes at 240 F	Cook time and temperature	<ul style="list-style-type: none"> • Temperature recorder • Clock timer 	Each cook/retort load	Cook operator	<ul style="list-style-type: none"> • Stop process and recook 	<ul style="list-style-type: none"> • Daily record reviewed by quality-control supervisor • Weekly check of recorder charts and comparison with mercury-in-glass (MIG) thermometer • Monthly thermometer calibration • Process validation study of time/temperature and final product internal temperature on file 	<ul style="list-style-type: none"> • Retort log • Recording charts

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

HACCP Plan Form for Fresh Crabmeat

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measure	(4)		(5) Monitoring		(6)		(7) Who	(8) Corrective Action(s)	(9) Verification	(10) Records
			What		How	Frequency						
Pack/Weight/ Seal/Ice	Bacterial pathogen growth	From cooler to icing of picked meat, exposure of cooked crab not to exceed four hours.	Time of product exposure to unrefrigerated conditions		<ul style="list-style-type: none"> Visual observation of marked containers Monitor selected lots by recording the time that the containers of crab are removed from the cooler until the picked meat product is iced. 	Approximately every three hours during processing	Production supervisor	<ul style="list-style-type: none"> Crabmeat not refrigerated or packed and iced within four hours is pasteurized or frozen AND held for microbiological evaluation. 	<ul style="list-style-type: none"> Review of monitoring and production records Study of data to validate critical limit (on file) 	Production record		
Cooler Storage	Bacterial pathogen growth	<ul style="list-style-type: none"> Cooler temperature not to exceed 40 F for more than four hours in a 24-hour period Cooler temperature not to exceed 50 F 	Temperature of cooler	Check cooler thermometer	Two times a day	Cooler operator	<ul style="list-style-type: none"> Readjust cooler temperature Repair refrigeration if needed Re-ice product Hold and evaluate product based on time and temperature of exposure Destroy unacceptable product 	<ul style="list-style-type: none"> Supervisor review records daily Weekly check of cooler thermometer using an MIG thermometer Readjustment of thermometer or replacement if necessary Annual MIG thermometer calibration 	Cooler temperature log			

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

Fresh Crabmeat Cooler Storage Record

Cooler temperatures must not exceed 40 F for more than four hours in a 24-hour period.

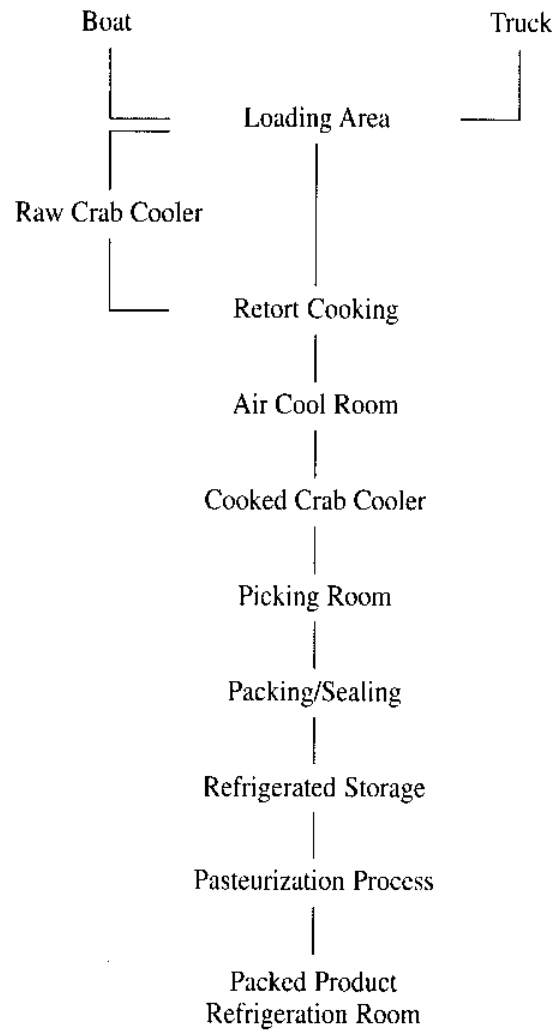
Record cooler temperatures twice daily during operations. Keep records for one year.

Cooler Critical Control Point				
Month/Week	Time of Day	Sufficient Ice on Product (Yes/No)	Cooler 1 (F)	Cooler 2 (F)
Sun.	a.m.			
	p.m.			
Mon.	a.m.			
	p.m.			
Tues.	a.m.			
	p.m.			
Wed.	a.m.			
	p.m.			
Thur.	a.m.			
	p.m.			
Fri.	a.m.			
	p.m.			
Sat.	a.m.			
	p.m.			
Compiled by: _____ Reviewed by: _____ Date Reviewed: _____				

Ideas and Notes

Pasteurized Crabmeat

Pasteurized Crabmeat Process Flowchart



Hazard Analysis Worksheet for Pasteurized Crabmeat

Firm Name: ABC Crab Co. Product Description: Pasteurized crabmeat in hermetically sealed steel cans

Firm Address: Anywhere, USA Method of Storage and Distribution: Refrigerated

Date: _____ Intended Use and Consumer: Ready to eat without further processing

Signature: _____

(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)
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 Cooking	BIOLOGICAL • Pathogen survival CHEMICAL • Boiler chemicals PHYSICAL • None	Yes No No	Improper cooking will not kill or inactivate human pathogens. SSOP	Pasteurization eliminates pathogens.	No
<i>If this product was sold as fresh crabmeat, then the retort process may be a critical control point.</i>					
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.		No

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

Hazard Analysis Worksheet for Pasteurized Crabmeat

(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)
Cooked Crab Cooler	BIOLOGICAL • Bacterial pathogen growth CHEMICAL • None PHYSICAL • None	Yes	Time/temperature abuse could allow pathogen growth.	Pasteurization will eliminate the pathogens.	No
Picking Room	BIOLOGICAL • Bacterial pathogen growth • <i>Staphylococcus aureus</i> • Bacterial pathogen recontamination CHEMICAL • None PHYSICAL • Shell	Yes No No No	Excessive time in processing room will promote pathogen growth. Although humans are natural reservoirs, using USDA's pathogen modeling program, it was determined that the temperature abuse conditions necessary for growth of <i>S. aureus</i> to levels sufficient for toxin production were not reasonably likely to occur. SSOP Hazard analysis indicates that this inherent defect is not reasonably likely to result in the food being unsafe for consumption.	Pasteurization will eliminate the pathogens.	No
Packing/Sealing	BIOLOGICAL • Bacterial pathogen recontamination through can seams • Bacterial pathogen growth • <i>Staphylococcus aureus</i> CHEMICAL • None PHYSICAL • None	Yes Yes No	Defective seams may allow entry of <i>Clostridium botulinum</i> type E. Excessive time in processing room will promote pathogen growth. Although humans are natural reservoirs, using USDA's pathogen modeling program, it was determined that the temperature abuse conditions necessary for growth of <i>S. aureus</i> to levels sufficient for toxin production were not reasonably likely to occur.	Proper can seams Pasteurization will eliminate the pathogens.	Yes No

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

Hazard Analysis Worksheet for Pasteurized Crabmeat

(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)
Refrigerated Storage	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogen growth <p>CHEMICAL</p> <ul style="list-style-type: none"> • None <p>PHYSICAL</p> <ul style="list-style-type: none"> • None 	Yes	Time/temperature abuse could allow pathogen growth.	Pasteurization eliminates the pathogens.	No
Pasteurization	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Pathogen survival <p>CHEMICAL</p> <ul style="list-style-type: none"> • None <p>PHYSICAL</p> <ul style="list-style-type: none"> • None 	<p>Yes</p> <p>No</p> <p>No</p>	Pathogens will survive an improper thermal process.	Apply proper thermal process.	Yes
Packed Product Refrigeration Room	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogens <p>CHEMICAL</p> <ul style="list-style-type: none"> • None <p>PHYSICAL</p> <ul style="list-style-type: none"> • None 	Yes	Human pathogens (<i>Clostridium botulinum</i> , Type A) could grow if product is temperature-abused.	Proper refrigeration will reduce chances for bacterial growth.	Yes

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

HACCP Plan Form for Pasteurized Crabmeat

Firm Name: ABC Crab Co. Product Description: Pasteurized crabmeat in hermetically sealed steel cans

Firm Address: Anystate, USA Method of Storage and Distribution: Refrigerated

Date: _____ Intended Use and Consumer: Ready to eat without further processing

Signature: _____

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring			(5) Who	(6) Corrective Action(s)	(7) Verification	(8) Records
			What	How	Frequency				
Packing/Sealing	Bacterial pathogen recontamination through can seams	Container seams meet manufacturer's specifications.	Can seams	<ul style="list-style-type: none"> Can-seam tear-down evaluation Visual seam examination 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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.	Water-bath temperature and time of pasteurization	Recording thermometer	Each batch	Quality-control person	Recook, reject product or hold for evaluation.	<ul style="list-style-type: none"> Daily record review Process validation (on file) Calibration of temperature recorder to MIG thermometer daily and annual calibration of MIG thermometer 	Recorder chart Calibration records
Refrigerated Storage	Bacterial pathogen growth in packed product	50 F maximum in cooler	Temperatures of cooler Ice on product	Recording thermometer and visual check	Continuous with visual checks every four hours during operation	Quality-control person	<ul style="list-style-type: none"> Hold and evaluate based on time and temperature of exposure. Adjust cooler. 	<ul style="list-style-type: none"> Daily record review Calibration of temperature recorder with MIG thermometer weekly 	<ul style="list-style-type: none"> Recorder charts Cooler temperature record

Models may not be fully consistent with guidance contained in FDA's *Fish and Fishery Products Hazards and Controls Guide*.
Page 1 of 1

Pasteurized Crabmeat Can Seam Evaluation Form

401 x 301 Tinplate, Aluminum Ends

Company: ABC Crab Co. Person Responsible: Packing room supervisor
 Address: Anywhere, USA
 Complete: At start-up and after adjustments. Visual check, every batch.
 Critical Limit: Thickness .060 ± .002; overlap .045 or longer; tightness 80-100%; visual acceptable
 Corrective Action: Adjust seamer; repack affected product and, if not yet pasteurized, pasteurize. If already pasteurized, mark basket, move to refrigeration and contact manager. Complete Notice of Unusual Occurrence and Corrective Action.

Date: _____ Code: _____ Overlap + CH + BH + .012 - L

Measurements	Time	Time	Time	Time	Time	Time	Operator's Initials
<i>Visual (Acc./Rej.)</i>							
<i>Thickness .060 ± .002</i>							
<i>Length .125 max.</i>							
<i>Body-hook .080 ± .008</i>							
<i>Cover-hook .080 ± .008</i>							
<i>Overlap .045 minimum</i>							
<i>Tightness 80-100%</i>							
<i>Pressure/ vacuum</i>							

Comments: _____

Review twice weekly Reviewed by: _____ Date: _____

Notice of Unusual Occurrence and Corrective Action

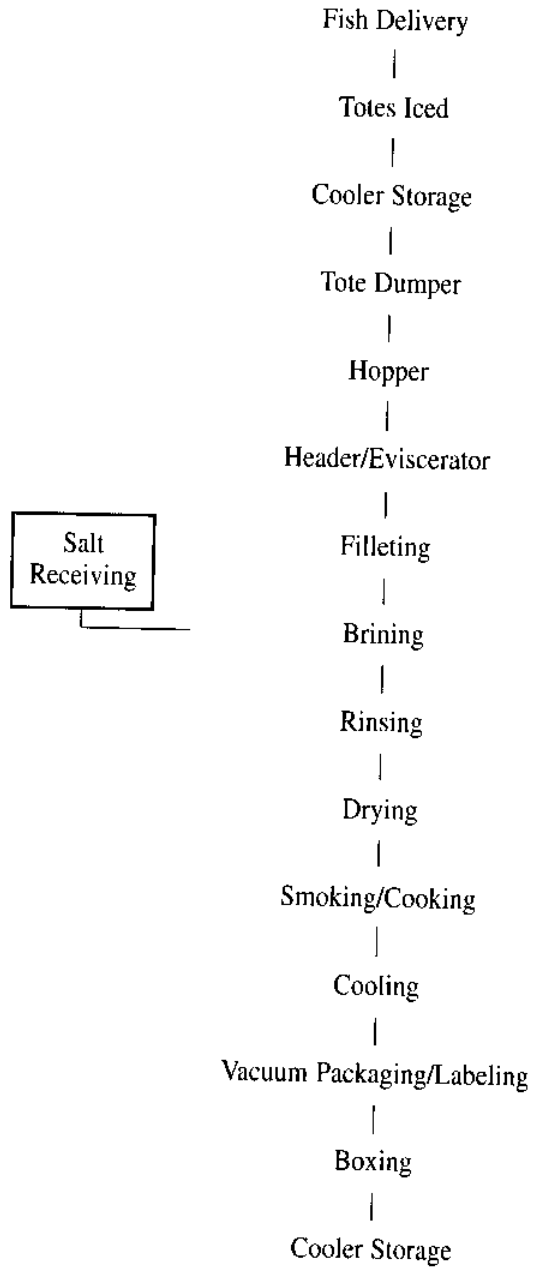
(Not covered by other form)

Time: _____	Date: _____
• Operation or Processing Step:	_____ _____ _____ _____ _____
• Description of Problem:	_____ _____ _____ _____ _____ _____
• Corrective Action Taken:	_____ _____ _____ _____ _____
• Cross-Referenced Forms or Documents:	_____
Name: _____	Date: _____
Review twice weekly	Reviewed by: _____ Date: _____

Ideas and Notes

Hot Smoked Salmon

Hot Smoked Salmon Processing Flow Chart



Hazard Analysis Worksheet for Hot Smoked Salmon

(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	Yes	Raw seafood can be a natural source for pathogens.	Hazard is controlled at the smoking/cooking step.	No
	• Parasites CHEMICAL None PHYSICAL None	Yes	Parasites occur in wild-caught fish.	Hazard is controlled at the brining and smoking/cooking step.	No
Totes feed	BIOLOGICAL • Bacterial pathogen growth • Bacterial pathogen contamination CHEMICAL None PHYSICAL None	No No	Period of time at this location is short. SSOP	SSOP	No
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 brining and 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	SSOP	No

Firm Name: <u>ABC Smoked Salmon Co.</u>	Product Description: <u>Smoked salmon</u>
Firm Address: <u>Anywhere, USA</u>	Method of Storage and Distribution: <u>Refrigeration</u>
Signature: _____	Intended Use and Consumer: <u>Ready to eat without further processing</u>
Date: _____	_____

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

Hazard Analysis Worksheet for Hot Smoked Salmon

(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 • Bacterial pathogen contamination CHEMICAL None PHYSICAL None	No No	Period of time at this location is short. SSOP	SSOP	No
Header/Eviscerator	BIOLOGICAL Bacterial pathogens including <i>C. botulinum</i> CHEMICAL None PHYSICAL Metal Fragments	Yes No	Raw seafood can be a natural source of pathogens. 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.	Hazard is controlled at the brining and cooking step, which is based on a high initial load of <i>C. botulinum</i> .	No
Filleting	BIOLOGICAL Bacterial pathogens CHEMICAL None PHYSICAL None	No	SSOP	SSOP	No
Salt Receiving	BIOLOGICAL None CHEMICAL None PHYSICAL None				No
Brining	BIOLOGICAL • <i>C. botulinum</i> growth and toxin production in finished product • Other bacterial pathogens CHEMICAL None PHYSICAL None	Yes	Salt content in the flesh in combination with the smoke and heat treatment is necessary to control growth.	Proper brining	Yes
		Yes	Salt content in the flesh is insufficient to inhibit growth.	Hazard is controlled at the smoking/cooking step.	No

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

Hazard Analysis Worksheet for Hot Smoked Salmon

(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	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogen • Bacterial pathogen contamination <p>CHEMICAL None</p> <p>PHYSICAL None</p>	No No	<p>Period of time at this location is short.</p> <p>SSOP</p>	SSOP	No
Drying	<p>BIOLOGICAL Bacterial pathogen</p> <p>CHEMICAL None</p> <p>PHYSICAL None</p>	Yes No	<p>Salt content in the flesh is insufficient to inhibit growth.</p>	Hazard is controlled at the smoking/cooking step.	No
Smoking/cooking	<p>BIOLOGICAL Bacterial pathogen survival</p> <p>CHEMICAL None</p> <p>PHYSICAL None</p>	Yes	Adequate cooking is necessary to inactivate the bacterial pathogens in the raw materials and introduced during processing.	Proper smoking/cooking	Yes
Cooling	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Pathogen recontamination • <i>C. bot.</i> type E growth • <i>C. bot.</i> type A growth <p>CHEMICAL None</p> <p>PHYSICAL None</p>	No No No	<p>Controlled by SSOPs.</p> <p>Combination of salt and inhibitors from smoke.</p> <p>Length of time necessary to grow is not reasonably likely to occur.</p>	SSOP	No
Vacuum Packaging/Labeling	<p>BIOLOGICAL</p> <ul style="list-style-type: none"> • Bacterial pathogens introduced during packaging/labeling • Growth of proteolytic <i>C. bot.</i> <p>CHEMICAL None</p> <p>PHYSICAL None</p>	No Yes	<p>Controlled by SSOPs.</p> <p>Severe temperature abuse can allow growth during subsequent distribution and storage.</p>	Appropriate label statement regarding importance of refrigeration	Yes

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

Hazard Analysis Worksheet for Hot Smoked Salmon

(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.		No
Cooler Storage	BIOLOGICAL Proteolytic <i>C. botulinum</i> growth CHEMICAL None PHYSICAL None	Yes	<i>C. botulinum</i> can grow if not refrigerated.	Proper refrigeration	Yes

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

HACCP Plan Form for Hot Smoked Salmon

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4) Monitoring			(7) Who	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency				
Brining	C. botulinum toxin production in the finished product	a) Minimum 24-hour soaking time b) Minimum salt content of 6% salometer at start of process c) Minimum 2:1 ratio of brine to fish (weight to weight) d) Maximum fish thickness 1 1/2 inches	a) Time in brine b) Salt content of brine c) Weight of fish and brine	a) Visual time checks b) Salometer c) • Weight of fish (scale) • Weight of brine (calibrated mark on tank)	a) Each batch before removing fish b) Each batch at start of process c) Each batch	a) Production employee b) Quality-control person c) Production employee	a) Hold longer in brine solution. b) Add salt. c) Adjust amount of fish or brine.	a) Daily record review b) Study showing brining method provides at least 3.5 percent water-phase salt c) Quarterly finished-product analysis for water phase salt	a) Processing record b) Processing record c) Processing record
<i>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.</i>									

Firm Name: ABC Smoked Salmon Co. Product Description: Smoked salmon

Firm Address: Anywhere, USA Method of Storage and Distribution: Refrigeration

Signature: _____ Intended Use and Consumer: Ready to eat without further processing

Date: _____

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

HACCP Plan Form for Hot Smoked Salmon

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Control Measures	(4)			(5) Monitoring		(7) Who	(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	How	Frequency				
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.	<ul style="list-style-type: none"> Daily record review Sally 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		
VacuumPacking Labeling	Growth of proteolytic <i>C. botulinum</i>	Presence of appropriate label statement	Product label	Visual	Pre-operational checks	Packing supervisor	Reject packages without label statement and replace with appropriate packages.	Weekly record review	Rack room log		
Cooler storage	<i>C. botulinum</i> (proteolytic) toxin production during storage	Maximum cooler temperature of 50 F.	Cooler temperature	Recorder thermometer	Record continuously; check chart twice daily.	Quality-control person	<ul style="list-style-type: none"> Readjust cooler thermostat Hold and evaluate based on time and temperature of exposure. 	<ul style="list-style-type: none"> Daily record review Weekly calibration of recording thermometer 	Cooler temperature chart		

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

Ideas and Notes

Sanitation Standard Operating Procedure

After conducting a hazard analysis, some businesses will discover that they are not required to implement a HACCP program. The FDA, however, does expect all seafood firms to maintain records on eight sanitation operations even if they are HACCP-exempt. The following illustrates a sanitation program for a small seafood dealer based on the FDA's sanitation requirements for seafood processing.

Sanitation Program Standard Operating Procedures (SSOPs)

This program outlines the sanitation standard operating procedures (SSOPs) in accordance with the FDA's HACCP regulation. The SSOPs include daily, monthly and annual procedures, plus corrective action reports.

Goal 1	Ensure that water that touches food or food-contact surfaces or is used to make ice comes from a safe sanitary source or is treated to make it safe.
	<i>Procedure:</i> The HACCP coordinator will make sure municipal water is used in unloading fish, handling in the processing area and in manufacturing ice. The firm will ask town officials to verify every year that the water is safe to use and will keep those records on file.
Goal 2	Clean food-contact surfaces and processing equipment, including equipment used to make and store ice. They should be made of easily cleaned, durable nontoxic materials.
	<i>Procedure:</i> The HACCP coordinator will ensure that all surfaces, including processing equipment, that come in contact with seafood will be made of materials approved by state health authorities and kept in a safe condition.
Goal 3	Prevent cross-contamination of products. Check monthly for inappropriate connections between potable and nonpotable water systems and observe employee handling practices daily.
	<i>Procedure:</i> The HACCP coordinator will inspect all plumbing and sewage lines throughout the facility to ensure that no modification has inadvertently created the potential for cross-contamination of potable and nonpotable water sources. Personnel will be watched daily to ensure proper handling.
Goal 4	Monitor hand washing and hand sanitizing; adequately maintain toilet facilities for employee convenience and product safety.
	<i>Procedure:</i> The HACCP coordinator or designee will monitor hand washing and sanitizing as well as toilet facilities to ensure they are kept clean and adequate.
Goal 5	Protect food and packaging materials to prevent accidental contamination.
	<i>Procedure:</i> The HACCP coordinator or designee will check coolers, freezers and dry storage areas daily for cleanliness and proper arrangement to prevent products and packaging materials from becoming contaminated with filth or foreign objects.
Goal 6	Properly label, use and store toxic compounds.
	<i>Procedure:</i> The HACCP coordinator or designee will check weekly that cleaning and sanitizing agents, including pesticides or other harmful compounds, are clearly identified and kept from processing areas.
Goal 7	Observe employee health to prevent microbial contamination of food, food-packaging materials or food-contact surfaces.
	<i>Procedure:</i> The HACCP coordinator will monitor employee health and hygiene daily and assign duties so that food, food-contact surfaces and packaging materials do not become contaminated.
Goal 8	Keep pests from the processing-plant floor and take appropriate action when necessary.
	<i>Procedure:</i> The HACCP coordinator will monitor the grounds and processing facility monthly to ensure that pests don't enter the processing plant and jeopardize product safety.

Sanitation Program Standard Operating Procedures (SSOPs) Preoperational Checklist

No.	Monitoring Record	Month	Week	Sun.	Mon.	Tues.	Wed.	Thur.	Fri.	Sat.
<i>Check box daily for compliance. Note weekly, monthly and annual checks.</i>										
1.1	Water and ice are drawn from a potable source.			Annually						
2.1	Work areas are in good order and not cluttered.									
2.2	Equipment, facilities and utensils are in good working condition.									
2.3	Food-contact surfaces are clean and properly sanitized before use.									
2.4	Utensils are cleaned and sanitized after use and properly stored.									
2.5	Coolers and freezers are clean and not cluttered. Products are properly stored.									
2.6	Thermometers and scales are calibrated, cleaned and sanitized.									
2.7	Food transport equipment is cleaned and sanitized (trucks, forklifts, hand trucks, dollies, carts and fish baskets).									
3.1	Plumbing is inspected to ensure no cross-connections in water supply.			Monthly						
3.2	Brushes, wiping cloths and containers used for cleaning and sanitizing in food-handling areas are separated and color coded.									
3.3	Dry and wet waste containers are properly removed from processing area for disposal.									
4.1	Hand-washing and sanitizing facilities are properly supplied and used.									
5.1	Food containers, packaging and dry-storage area are cleaned and sanitized.									
5.2	Food ingredients and supplies are properly labeled and stored.									
6.1	Chemicals are properly stored and labeled separately from food.			Weekly						
7.1	No person with illness or open or infected wounds is allowed in contact with food.									
7.2	All personnel wear clean clothing or uniforms, including caps.									
7.3	Only authorized personnel enter food-processing areas.									
8.1	Grounds are kept free of improperly stored equipment, litter, refuse and uncut grass and weeds.			Monthly						
8.2	No evidence of insect, pest or rodent infestation. Bait stations are used.									
8.3	Disposal area is properly maintained to avoid odor and pest problems.									
Completed by: _____				Date: _____						
Reviewed by: _____				Date: _____						

SSOP HACCP Training Program New Employee Sanitation Training

The following employee training is required as part of this company's HACCP program.

1.	Food, beverages and tobacco are allowed only in designated break areas.
2.	Eating is allowed only in break areas.
3.	Employees should notify the HACCP coordinator when they leave their workstations.
4.	Employees must wash hands before returning to the workstations.
5.	Employees must wash and sanitize hands after going to the bathroom.
6.	Employees must wash and sanitize hands and gloves after touching any exposed body parts or soiled clothing.
7.	Employees must use only gloves and equipment approved by the HACCP coordinator.
8.	Only authorized workers can touch or move waste receptacles and trash cans.
9.	Keep doors and windows to the processing area closed or screened as approved by the HACCP coordinator.
10.	Employees must wear clean clothes and boots while working.
11.	Employees are expected to bathe before reporting to work.
12.	Sick employees or employees with infected cuts, boils or wounds cannot handle food products.
13.	Additional instructions given:
<p>This information was discussed with all new employees at this company.</p> <p>Completed by: _____ Date: _____</p> <p>Reviewed by: _____ Date: _____</p>	

Illustrative HACCP Compliance Letters

Some customers may require you to show proof that you comply with HACCP. The FDA regulation does not obligate you to show your HACCP plan to customers, brokers or business associates outside your company. Here are two letters to illustrate how you might notify customers that you operate under HACCP or are exempt from compliance.

*This sample letter is for illustrative purposes only:
Processor/distributor telling a customer that the company complies with HACCP regulations.*

Date

Customer Name
Customer Address

Dear Customer:

We have received your letter of (date) providing notice of your company's policy about the Food and Drug Administration's Hazard Analysis and Critical Control Point regulation on seafood.

Please be advised that (company name) has taken steps to comply with the mandated HACCP requirements. These include HACCP training for one or more of our employees, completion of a hazard analysis, development and implementation of a HACCP plan, and implementation of sanitation standard operating procedures. We implemented our HACCP plan and sanitation records, including prerequisite Good Manufacturing Practices, on (date).

If you would like a copy of the HACCP and sanitation records relating to a specific shipment of seafood to (name of buyer), we would be happy to provide them. We consider copies of our HACCP plan proprietary and will only release this information along with a signed letter of confidentiality from the vendor.

Please contact me if you have questions.

Sincerely,

This sample letter for illustrative purposes only: Processor/distributor telling a customer that the company is exempt from HACCP regulations.

Date

Customer Name

Customer Address

Dear Customer:

We have received your letter of (date) providing notice of your company's policy concerning the Food and Drug Administration's Hazard Analysis and Critical Control Point seafood regulation. In accordance with the HACCP requirements, (company name) conducted a thorough hazard analysis directed by a HACCP-trained employee (or team or competent third party). We determined that our operation does not require a written HACCP plan.

We want to assure you that (company name) does have a sanitation operating procedure in force that complies with the HACCP regulations for Good Manufacturing Practices.

Please contact me if you have any questions.

Sincerely,

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 <hr/> Chemical <hr/> Physical				
	Biological <hr/> Chemical <hr/> Physical				
	Biological <hr/> Chemical <hr/> Physical				
	Biological <hr/> Chemical <hr/> Physical				
	Biological <hr/> Chemical <hr/> Physical				

HACCP Plan Form

Firm Name: _____ Product Description: _____

Firm Address: _____ Method of Storage and Distribution: _____

Intended Use and Consumer: _____

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

HACCP Plan Form

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

Ideas and Notes

Ideas and Notes

