



SEPTEMBER 2020

Commercial Processing Example: *Wholesale/Distribution/Warehouse* (Short Version with detailed inclusive Hazard Analysis approach)

Example: This is a Special Training Model for illustrative purposes only. The SHA models are based on recommendations in the most current version of FDA's *Fish and Fishery Products Hazards and Controls Guidance* available on the FDA website. This model was produced by the National Seafood HACCP Alliance (SHA) strictly as an example for training and does not represent a specific requirement or recommendation from FDA. Keep in mind that this model may not apply to all situations.

Narrative¹

Product Market Names: FINFISH: (fresh, not previously frozen or thawed) - Bass, Bluefish, Cod, Flounder, Hake, Mackerel, Mahi-mahi, Monkfish, Pollock, Tuna, Atlantic Salmon, Swordfish, Weakfish and Whiting; MOLLUSCAN SHELLFISH: Clams and Oysters (live shellstock), and Scallops (fresh shucked meats); and, CRUSTACEANS: Shrimp (frozen).

Receive – A variety of seafood species in different product forms are received from various suppliers to the ABC Wholesale Company.

- **FISH** are received from primary processors sourcing from vessel harvests and aquaculture farms. Farmed fish include Atlantic salmon. No fish are purchased directly from fishermen or aquaculture farms except for some wild harvested hake and whiting, which are occasionally purchased directly from local fishermen in spring and fall. The fish arrive fresh (not previously frozen), packaged in iced containers on refrigerated trucks.
- **CLAMS** and **OYSTERS** are received from primary processors that have pre-chilled the live shellstock below 50°F/10°C before initial shipment. The clams and oysters are sold refrigerated as live products. The clams and oysters are not subject to special post-harvest processing methods to retain raw product characteristics or exposed to glass containers.
- **SCALLOPS** are received as fresh shucked meats with no attached viscera. They arrive iced in pre-labeled containers ready for distribution (no ROP packaging).
- **SHRIMP** can be farm-raised or wild-harvested products purchased from primary processors which freeze packaged units containing 5-pound frozen blocks that are pre-labeled for product content (i.e., 'Shrimp' and 'sodium bisulfite' as an ingredient).

No products are received or shipped in a reduced oxygen packaging (ROP).

Refrigerated Storage – All fishery products are offloaded and immediately placed into a refrigerated storage cooler, maintained at an ambient temperature of 40°F or less.

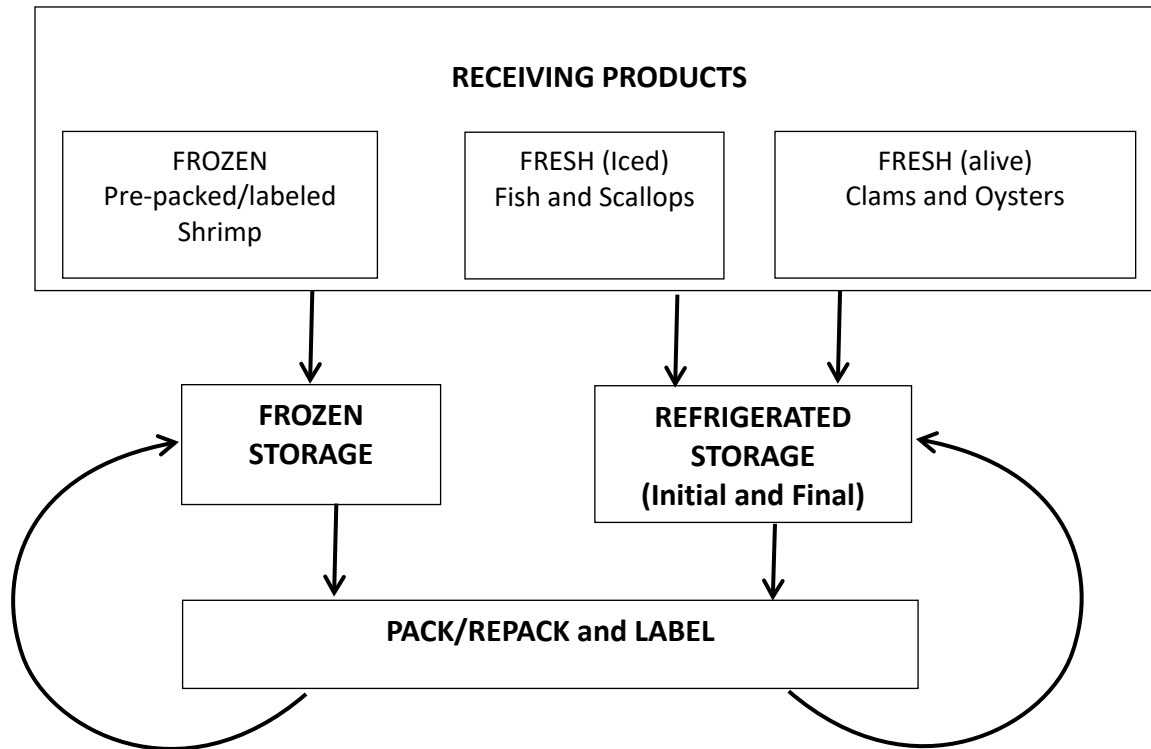
Frozen Storage – The frozen blocks of shrimp are stored in a freezer at 0°F or less.

Pack/Repack and Label – For each customer order, refrigerated products are selected, removed from cooler storage and packed into master boxes/containers, completely surrounded by ice. The master cases/containers are each marked to indicate the fishery product contents. The maximum time out of refrigerated conditions for assembling customer orders is 30 minutes. Orders for frozen shrimp are assembled for transport on freezer trucks. Frozen shrimp blocks have been previously labeled by the primary processor. Customer orders are either loaded onto delivery trucks or placed back into the same storage units used for initial refrigeration or frozen storage. ABC Wholesale Company maintains a current reshippers license for molluscan shellstock¹.

Intended Use: All products are distributed with intentions to be consumed cooked except the raw clams and oysters. There is no prior knowledge that the other products will be consumed raw.

¹Molluscan shellfish product handling, storage and labeling are consistent with recommendations in the *FDA Hazards and Controls Guidance* which include reference to specific requirements outlined in laws and regulations of States that participate in the National Shellfish Sanitation Program (NSSP; <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>)

ABC Wholesale Company Process Flow Diagram



PRODUCT DESCRIPTION: Wholesale/Distribution/Warehouse Facilities

Example: For Illustrative Purposes Only. Models are based in current guidance contained in FDA’s *Fish and Fishery Products Hazards and Controls Guidance*. Keep in mind that this model does not apply to all situations.

Description	Company: ABC Wholesale Company, Anywhere, USA																					
	Where Product Is Purchased			How Product Is Received				How Product Is Stored				How Product Is Shipped				How Product is Packaged		How Product Will Be Consumed			Intended Consumer	
Fish or Shellfish Species	From Fisherman	From Fish Farm	From Processor	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Air Packed	Reduced Oxygen/ Vacuum Packed	Raw to be cooked	Raw Ready-to-Eat	Cooked Ready-to-Eat	General Public	At Risk Population
Common Name: Striped Bass or Rockfish Market Name: Bass Scientific Name: <i>Morone spp.</i>			√		√				√					√				√			√	
Common Name: Bluefish Market Name: Bluefish Scientific Name: <i>Pomatomus saltatrix</i>			√		√				√					√				√			√	
Common Name: Atlantic Cod Market Name: Cod Scientific Name: <i>Gadus spp.</i>			√		√				√					√				√			√	
Common Name: Fluke or Summer Flounder Market Name: Flounder Scientific Name: <i>Paralichthys dentatus</i>			√		√				√					√				√			√	
Common Name: Red Hake Market Name: Hake Scientific Name: <i>Urophycis spp.</i>	√				√				√					√				√			√	
Common Name: Atlantic Mackerel Market Name: Mackerel Scientific Name: <i>Scomber scombrus</i>			√		√				√					√				√			√	
Common Name: Mahi-mahi or Dolphinfish Market Name: Mahi-mahi Scientific Name: <i>Coryphaena spp.</i>			√		√				√					√				√			√	
Common Name: Monkfish or Goosefish Market Name: Monkfish Scientific Name: <i>Lophius spp.</i>			√		√				√					√				√			√	

Fish or Shellfish Species	Where Product Is Purchased			How Product Is Received				How Product Is Stored				How Product Is Shipped				How Product is Packaged		How Product Will Be Consumed			Intended Consumer	
	From Fisherman	From Fish Farm	From Processor	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Air Packed	Reduced Oxygen/ Vacuum Packed	Raw to be cooked	Raw Ready-to-Eat	Cooked Ready-to-Eat	General Public	At Risk Population
Common Name: Atlantic Pollock Market Name: Pollock Scientific Name: <i>Pollachius spp.</i>			√		√				√				√			√		√			√	
Common Name: Yellowfin Tuna Market Name: Tuna Scientific Name: <i>Thunnus albacares</i>			√		√				√				√			√		√			√	
Common Name: Atlantic Atlantic Salmon Market Name: Atlantic Salmon Scientific Name: <i>Salmo salar</i>			√		√				√				√			√		√			√	
Common Name: Swordfish Market Name: Swordfish Scientific Name: <i>Xiphias gladius</i>			√		√				√				√			√		√			√	
Common Name: Weakfish or Sea Trout Market Name: Weakfish Scientific Name: <i>Cynoscion spp.</i>			√		√				√				√			√		√			√	
Common Name: Silver Hake or Whiting Market Name: Whiting Scientific Name: <i>Merluccius spp.</i>	√				√				√				√			√		√			√	
Common Name: Northern Clam or Quahog Market Name: Clam Scientific Name: <i>Mercenaria spp.</i>			√	√				√				√				√			√		√	
Common Name: Eastern Oyster Market Name: Oyster Scientific Name: <i>Crassostrea spp.</i>			√	√				√				√				√			√		√	
Common Name: Sea Scallop Market Name: Scallop Scientific Name: <i>Placopecten magellanicus</i>			√		√				√				√			√		√			√	
Common Name: White Shrimp Market Name: Shrimp Scientific Name: <i>Penaeus spp.</i>			√			√				√				√		√		√			√	

POTENTIAL FOOD SAFETY HAZARDS – All potential food safety hazards based on the product description and processing flow diagram associated with this product and process are identified using Tables 3-2 (species-related), 3-3 (species-related) and 3-4 (process-related) in *the FDA Hazards and Controls Guidance* (4th ed., 2020). Processors should be aware that additional guidance may be periodically posted on FDA seafood HACCP websites, and additional hazards not covered by this guidance may be relevant to certain products under certain circumstances.

For all products in the PRODUCT DESCRIPTION, the FDA recommendations indicate 12 potential hazards that are species- or process-related. **SPECIAL NOTE:** Initially two of these hazards have been excluded from further consideration in the Hazard Analysis because they are NOT INVOLVED with the particular species, products forms or processing operations. Each of the remaining 10 potential hazards must be addressed in the Hazard Analysis.

Potential Species Related Hazards

1. Pathogens from Harvest Area (presence; species –related, FDA Guidance Chapter 4)
2. Parasites (species-related, FDA Guidance Chapter 5)
3. Scombrototoxin (histamine) formation; species –related, FDA Guidance Chapter 7)
4. Natural Toxins (species –related, FDA Guidance Chapter 6)
5. Environmental Chemicals (species –related, FDA Guidance Chapter 9)
6. Aquaculture Drugs (species–related, FDA Guidance Chapter 11)

Potential Process Related Hazards

7. Pathogenic bacteria growth – temperature abuse (process-related, chapter 12)
8. **Please note:** Pathogenic Bacteria Survival through processes designed to retain raw product characteristics (process-related, FDA Guidance Chapter 17) is not applicable to this distributor and is excluded from Hazard Analysis as these processes are not used.
9. Food Allergens – (process-related, chapter 19)
10. Food Additives (use of sulfites to control melanosis; process-related, chapter 19)
11. Metal Inclusion (process-related, chapter 20)
12. **Please note:** Glass Inclusion (process-related, chapter 21) is not applicable to this distributor/warehouse and was excluded from Hazard Analysis as glass packaging is not used.

SANITATION CONTROL PROCEDURES (SCP) are monitored throughout all processing steps; SCP records documenting monitoring and corrections are maintained.

Grouping Finished Products by Pertinent Potential Species-Related and Process-Related Hazards (Reference FDA Guide, current edition)

Products are grouped by (common) market name per FDA’s Fish and Fishery Products Hazards and Controls Guidance (current edition). Please note: when meeting labeling requirements, please refer to the FDA’s Seafood List for Acceptable Market Names.

Potential Species-Related Hazards							Potential Process-Related Hazards			
No Species Hazards	Pathogens (presence) CHP 4	Parasites CHP 5	Natural Toxins CHP 6	(Scombrototoxin (histamine) formation) CHP 7	Environmental Chemicals CHP 9	Aquaculture Drugs CHP 11	Pathogenic Bacteria Growth-Temperature Abuse CHP 12	Allergens CHP 19	Food ¹ Additives CHP 19	Metal Inclusion CHP 20
Hake Swordfish Whiting	Clams Oysters Scallops	Cod Flounder Mackerel Monkfish Pollock Atlantic Salmon Weakfish	Clams Oysters Scallops	Bluefish Mackerel Mahi-mahi Tuna	Bass Bluefish Flounder Atlantic Salmon Clams Oysters Scallops Farm-raised Shrimp	Atlantic Salmon Farm-raised Shrimp	All products that are likely to be consumed without prior cooking: Clams Oysters	All finfish species and Shrimp (crustacean)	Shrimp	All Finished Products: Hake Swordfish Whiting Bass Bluefish Cod Flounder Mackerel Monkfish Pollock Atlantic Salmon Weakfish Clams Oysters Scallops

¹ No food additives are introduced by the distributor. Sulfiting agents are known to be present in the shrimp sourced from suppliers; sulfiting agents are used to prevent melanosis (black spot) in shrimp. There is no historical use of sulfiting agents in species other than the shrimp.

Hazard Analysis Approach for Grouping Finished Products by Shared Potential Hazards

One method used to determine significant hazards for processors handling many different finished products, is to begin by determining whether any of the species and/or process related hazards are significant for those finished products to which these potential hazards apply.

Potential Species and Process Related Hazard Groups	Market Names from Product Grouping Worksheet	Is the Hazard Significant? Yes/No	Justify your Decision	Identify Control Measures	Describe HACCP Plan CCP and Controls
Pathogens (presence from the Harvest Area) CHP 4	Clams and Oysters	Yes	Likely to occur: in the absence of control, raw mollusks that are not from approved harvest waters may contain pathogens likely to cause adverse health impacts as some products are consumed raw.	Source controls: adherence to State and Federal shellfish tagging Procedures.	Yes –Shellfish Source at the Receiving Step CCP (FDA Guide Chapter 4-Control Strategy Example 1).
	Scallops (shucked meats)	No	Scallop meats have been removed from the viscera and the meats are to be cooked prior to consumption – not likely to occur and not likely to cause illness.	----	
Parasites CHP 5	Cod, Flounder, Mackerel, Monkfish, Pollock, Weakfish	No	Products intended to be cooked before consumption; there is no knowledge that the products will be eaten raw, ready-to-eat.	----	----
	Atlantic Salmon	No	Not likely to occur; farmed fish are fed pelletized feed and fish are intended to be cooked prior to consumption by consumer.	----	----
Natural Toxins CHP 6	Clams and Oysters	Yes	Raw mollusk that are not from approved harvest waters may contain natural toxins and the products are consumed raw	Source controls: adherence to State and Federal shellfish tagging Procedures.	Yes –Shellfish Source Controls at the Receiving Step CCP (FDA Guide Chapter 6-Control Strategy Example 1).
	Scallops (shucked meats)	No	Shucked scallop meats (adductor muscle removed from viscera) are not likely to contain natural toxins	----	----
Environmental Chemicals	Clams and Oysters	Yes	Raw mollusk that are not from approved harvest waters may contain environmental chemicals and the products are consumed raw	Check all shellfish containers to ensure that all products are properly tagged and identified for certified dealers and approved harvest through distribution	Yes –Shellfish Source Controls at the Receiving Step CCP (FDA Guide Chapter 9-Control Strategy Example 7).

Potential Species and Process Related Hazard Groups	Market Names from Product Grouping Worksheet	Is the Hazard Significant? Yes/No	Justify your Decision	Identify Control Measures	Describe HACCP Plan CCP and Controls
	Bass, Bluefish, Flounder	No	Wild harvested finfish are not purchased directly from fishermen or fish farmers. Hazard is controlled by primary processor	----	----
	Farm-raised shrimp and Atlantic salmon.	No	Farm raised finfish (salmon) and shrimp are not purchased directly from fishermen or fish farmers. Hazard is controlled by primary processor	----	----
	Scallops (meats)	No	Scallops included shucked meats with no attached viscera (See Table 3-3, footnote ^{√2}) are not likely to be affected. Not likely to occur.	----	----
Scombrototoxin (histamine) formation	Bluefish Mackerel, Mahi-mahi, Tuna	Yes	Scombrototoxin (histamine) formation could occur in absence of time and temperature controls (in transit) and could occur in the absence of temperature controls at steps where product remains for a sufficient amount of time.	Temperature and time control procedures 1) during product transit prior to receiving and wholesale storage, 2) during product storage (SPECIAL NOTE: The wholesale product handling steps outside of refrigeration do not allow exposure time for likely pathogenic bacterial growth)	Receiving Step CCP (FDA Guide, CHP 7, Control Strategy Example 4) Refrigerated Storage CCP (FDA Guide, CHP 7, Control Strategy Example 5)
Aquaculture Drugs	Atlantic Salmon Shrimp	No	Farm-raised products are NOT purchased directly from aquaculture production or farming operations. Associated hazards are the responsibility of the primary processor.	---	---

Potential Species and Process Related Hazard Groups	Market Names from Product Grouping Worksheet	Is the Hazard significant? Yes/No	Justify your decision	Identify Control Measures	Describe HACCP Plan CCP and Controls
Pathogenic bacteria growth-temperature abuse (CHP 12)	Clams and Oysters	Yes	Pathogenic bacteria could grow in absence of time and temperature controls; product likely to be consumed raw	Temperature and/or Time Control Procedures 1) during product transit prior to receiving and wholesale storage, and 2) during storage. (SPECIAL NOTE: The wholesale product handling steps outside of refrigeration do not allow exposure time for likely pathogenic bacterial growth)	Receiving is a CCP; Reference FDA Guide, CHP 12, Control Strategy Example 1-Transit Controls. Refrigerated Storage is a CCP – Reference FDA Guide, CHP 12, Control Strategy Example 2
	All finfish, Shrimp and Scallops (shucked meats)	No	All fish, shrimp and scallop meats are intended to be cooked prior to consumption and there is no prior knowledge they will be consumed raw	—	—
Undeclared Allergens	All finfish species	Yes*	Finfish are one of the 8 major food allergens in the U.S.; in the absence of labeling controls, may adversely impact consumer health.	Fish must be properly labeled to identify the fish in the primary and/or master container. *Please Note: if box-in, box-out operation, and no re-packing is performed, this hazard is not significant as the allergen is already declared by the prior processor.	Finished Product Labeling Step CCP – Reference: FDA Guide, CHP 19, Control Strategy 8.
	Shrimp	Yes*	Shrimp (Crustaceans) are one of the 8 major food allergens in the U.S.; in the absence of labeling controls, may adversely impact consumer health.	Shrimp must be properly labeled to identify the fish in the primary and/or master container. *Please Note: if box-in, box-out operation, and no re-packing is performed, this hazard is not significant as the allergen is already declared by the prior processor.	Finished Product Labeling Step CCP – Reference: FDA Guide, CHP 19, Control Strategy 8.
Undeclared Allergens (continued)	Mollusks (oysters, clams, scallops)	No	Mollusks are not part of the 8 Major Food Allergens	—	—
Food Additives	All finfish (wild harvested)	No	High-risk additives not sourced, not introduced and no historical prevalence.	—	—

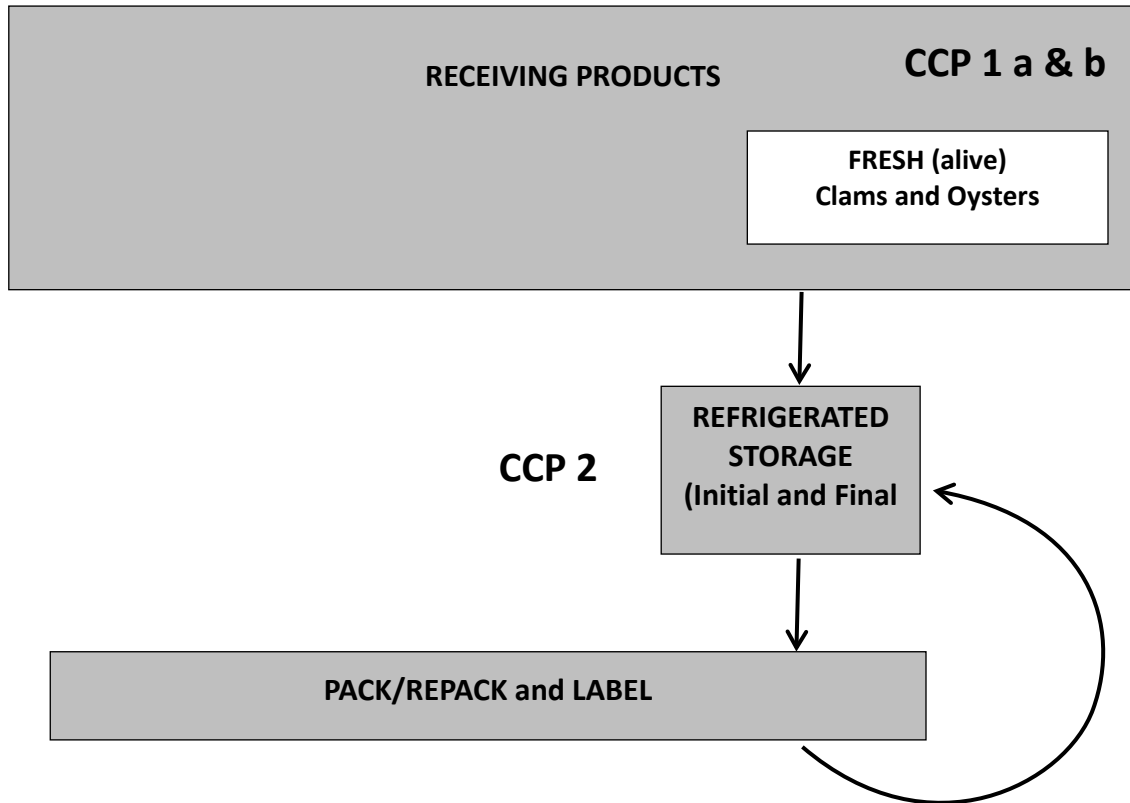
Potential Species and Process Related Hazard Groups	Market Names from Product Grouping Worksheet	Is the Hazard significant? Yes/No	Justify your decision	Identify Control Measures	Describe HACCP Plan CCP and Controls
	Farm raised salmon	No	High-risk additives not sourced, not introduced and no historical prevalence.	—	—
	Oysters, clams	No	High-risk additives not sourced, not introduced and no historical prevalence in live or shucked product.	—	—
	Farm-raised Shrimp	No	While present, this is a box-in, box-out operation; bags of shrimp are labeled with ingredients statement declaring sulfiting agent presence.	—	—
Metal Inclusion	All finished products.	No	It is reasonably unlikely that the seafood products will be exposed to metal fragments from broken blades, packing methods or other metal sources during primary processing and further wholesale handling. No likely source.	—	—

Summary of Significant Hazards, CCP Locations and FDA Guide Control Strategy Example Reference

Significant Hazards Identified in Wholesale Operations	Finished Products	CCP Strategy, FDA Guide Reference Chapter, Control Strategy Example Number.
Pathogens (presence)	Clams and Oysters	Receiving Step CCP (FDA Guide Chapter 4-Control Strategy Example 1; FDA Guide Chapter 6, Control Strategy Example 1 and FDA Guide Chapter 9, Control Strategy Example 7).
Natural Toxins		
Environmental Chemicals		
Pathogenic Bacteria Growth-Temperature Abuse	Clams and Oysters	Receiving is a CCP ; Reference FDA Guide, CHP 12, Control Strategy Example 1-Transit Controls. Refrigerated Storage is a CCP – Reference FDA Guide, CHP 12, Control Strategy Example 2
Scombrototoxin (histamine) formation	Bluefish Mackerel, Mahi-mahi, Tuna	Receiving Step CCP (FDA Guide, CHP 7, Control Strategy Example 4) Refrigerated Storage CCP (FDA Guide, CHP 7, Control Strategy Example 5)
Allergens	All finfish and shrimp	Finished Product Labeling Step CCP – Reference: FDA Guide, CHP 19, Control Strategy 8.

Wholesale/Distribution/Warehouse Facilities Process Flow Chart - *Live Clams and Oysters*

Shaded steps are Critical Control Points



****All refrigerated storage occurs in the same cooler***

Important Instructor and Participant Note: The following HACCP Plan form was developed using the *FDA Fish and Fishery Products Hazards and Controls Guidance* 4th edition (2011). Processors that operate in States participating in the Interstate Shellfish Sanitation Conference (ISSC) would also need to develop HACCP plans that comply with State regulations as outlined by the ISSC/National Shellfish Sanitation Program Model Ordinance.

HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Secondary processor for: Live clams and oysters</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed under refrigeration (live, chilled)</i>
	Intended Use & Consumer <i>Raw ready-to-eat product, to be consumed by the general public.</i>

Critical Control Point (CCP)	CCP 1a. Receiving Products		
Significant Hazard(s)	Pathogens from the harvest area	Environmental Chemicals	Natural Toxins
Critical Limits for each Control Measure	<p>CL (A) All shellstock containers must bear a tag that discloses:</p> <ul style="list-style-type: none"> Date and place of harvest (State and Site) Type and quantity of shellfish Shellfish authority harvester identification number, or if not assigned, harvester name or name/registration number of vessel. <p>AND</p> <p>CL (B) All finished product shellstock intended for raw consumption must bear a tag that instructs retailers to inform their customers that consuming raw or undercooked shellfish may increase the risk of foodborne illness, especially for individuals with certain medical conditions</p>		
Monitoring	What	(A) Presence of required Information contained on tags for incoming shellstock (B) Presence of consumer advisory statement	
	How	(A) (B) Visually	
	When	(A) Each container (B) Three containers randomly selected from every lot of shucked molluscan shellfish	
	Who	Receiving manager or designee.	
Corrective Action	<p>Restore control over the product:</p> <p>(A) If required tags, bill of lading or similar papers are not observed with the product, THEN Reject any shellfish containers that are not properly tagged</p> <p>(B) If consumer advisory statement is not present, reject or relabel.</p> <p>AND</p> <p>Restore control over the operation:</p> <p>(A) If an absence of requisite information; then, discontinue use of the supplier until evidence is obtained that harvesting, tagging, and/or label manufacturing practices have changed OR</p> <p>(B) If an absence of consumer advisory statement, then modify labeling practices</p>		
Verification	<p>Review monitoring and corrective actions records associated within a week to the day that the records were made. (Teaching point: recommend daily reviews).</p> <p>At least annually, check with state shellfish agency or FDA Shellfish Shippers List to verify that dealers are certified. (Teaching point: this is a best practice.)</p>		
Records	Daily Shellfish Receiving Log; Annual Dealer Verification Log and Corrective Actions		

HACCP Plan Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Live clams and oysters</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed under refrigeration (live, chilled)</i>
	Intended Use & Consumer <i>Raw ready-to-eat product, to be consumed by the general public.</i>

Critical Control Point (CCP)	CCP 1b. Receiving Products
Significant Hazard(s)	Pathogenic bacteria growth – temperature abuse
Critical Limits for Each Control Measure Alternative Reference: ISSC/NSSP Model Ordinance	Transportation records show product was loaded on a prechilled truck and ambient truck temperature was held ≤45°F/7.2°C during transit.
Monitoring	What Ambient temperature of truck maintained during transit.
	How Use of a continuous temperature-recording device for ambient truck temperature.
	When Each Lot Received
	Who Visual check of the continuous temperature recording device performed by Dock Receiving Manager
Corrective Action	If ambient truck temperature exceeded 45°F during transit, THEN measure the product temperature and assure product in question is placed in proper refrigeration, and evaluate total time and temperature exposure to determine product acceptance; or reject the lot. Regain control by discontinuing shipments from involved dealers and trucks until the problem can be identified, discussed and resolved.
Verification	<ol style="list-style-type: none"> 1. Suppliers (Dealers and/or Trucking operations) will conduct accuracy checks for the temperature-indicating devices (e.g., a thermometer) before placing in service. This can include periodic and/or prior factory calibrations. 2. At point of product receiving, check the accuracy of the temperature recording device used on the transit vehicle. 3. Record daily accuracy checks and annual calibration checks for all thermometers used for measuring the ambient refrigeration condition about products at receiving. 4. Perform records review of monitoring, corrective actions and verification records within one week to the day that the record was made.
Records	Receiving log containing all monitoring and verification documentation, Corrective Action Records, Thermometer Accuracy/Calibration Log

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Live clams and oysters</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed under refrigeration (live, chilled)</i>
	Intended Use & Consumer <i>Raw ready-to-eat product, to be consumed by the general public.</i>

Critical Control Point (CCP)	CCP 2. Refrigerated Storage (Initial and Final)
Significant Hazard(s)	Pathogenic bacteria growth – temperature abuse
Critical Limits for each Control Measure	Cooler Temperature not to exceed 40°F.
Monitoring	What The ambient air temperature of the cooler
	How Use of a continuous temperature-recording device
	When Continuous monitoring by the device itself, with a visual check of the recorded data at the beginning and end of each day.
	Who Cooler Manager
Corrective Action	<p>IF cooler temperature exceeds 40°F/4.4°C, THEN move shellstock to another cooler. Chill and hold the affected product until an evaluation of the total time and temperature exposure is performed. If safe; release into production. If time out of temperature exceeds safe harbor, destroy shellstock.</p> <p>AND Regain control by determining and fixing the refrigeration problem before further storage of shellstock in the malfunctioning unit.</p>
Verification	<p>Check accuracy check of continuous recording thermometer at initial use</p> <p>Perform daily accuracy checks of temperature indicating device prior to start-up.</p> <p>Calibrate cooler thermometer once per year</p> <p>Review Daily Cooler Log Monitoring, Corrective Action and Verification records within one week to the day that the record was made.</p>
Records	<p>Daily Cooler Log and Corrective Actions</p> <p>Thermometer Accuracy/Calibration Log</p>

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Live clams and oysters</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed under refrigeration (live, chilled)</i>
	Intended Use & Consumer <i>Raw ready-to-eat product, to be consumed by the general public.</i>

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for Each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
CCP 1a Receiving	Pathogens from the harvest area	CL (A) All shellstock containers must bear a tag that discloses:	(A) Presence of required information contained on tags for incoming shellstock (B) Presence of consumer advisory statement	(A) Visually	(A) Each container (B) Three containers randomly selected from every lot of shucked molluscan shellfish	Receiving manager or designee.	Restore control over the product: (A) If required tags, bill of lading or similar papers are not observed with the product, THEN Reject any shellfish containers that are not properly tagged (B) If consumer advisory statement is not present, reject or relabel. AND Restore control over the operation: (A) If an absence of requisite information; then, discontinue use of the supplier until evidence is obtained that harvesting, tagging, and/or label manufacturing practices have changed OR	Review monitoring and corrective actions records associated within a week to the day that the records were made. (Teaching point: recommend daily reviews). At least annually, check with state shellfish agency or FDA Shellfish Shippers List to verify that dealers are certified. (Teaching point: this is a best practice.)	Daily Shellfish Receiving Log; Annual Dealer Verification Log and Corrective Actions
	Environmental Chemicals	(a) Date and place of harvest (State and Site) (b) Type and quantity of shellfish		(B) Visually					
	Natural Toxins	(c) Shellfish authority harvester identification number, or if not assigned, harvester name or name/registration number of vessel. AND CL (B) All finished product shellstock intended for raw							

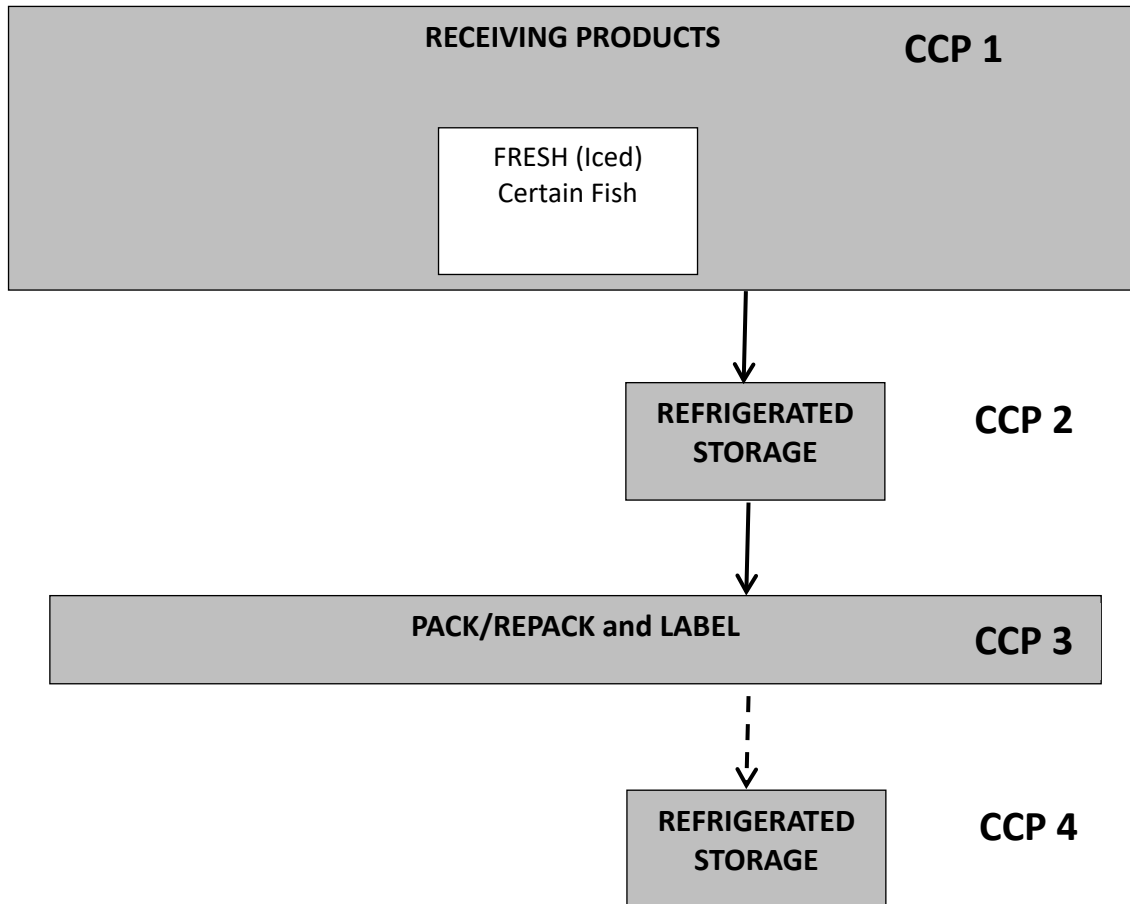
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for Each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
		consumption must bear a tag that instructs retailers to inform their customers that consuming raw or under-cooked shellfish may increase the risk of foodborne illness, especially for individuals with certain medical conditions					(B) If an absence of consumer advisory statement, then modify labeling practices		
CCP 1b Receiving	Pathogenic bacteria growth – temperature abuse	Transportation records show product was loaded on a pre-chilled truck and ambient temperature was held ≤45°F/7.2°C during transit.	Ambient temperature of truck maintained during transit	Use of a continuous temperature-recording device for ambient truck temperature	Each Lot Received	Visual check of the continuous temperature recording device performed by Dock Receiving Manager	<p>If ambient truck temperature exceeded 45°F during transit, THEN measure the product temperature and assure product in question is placed in proper refrigeration, and evaluate total time and temperature exposure to determine product acceptance; or reject the lot.</p> <p>Regain control by discontinuing shipments from involved dealers and trucks until the problem can be identified, discussed and resolved.</p>	<p>Suppliers (Dealers and/or Trucking operations) will conduct accuracy checks for the temperature-indicating devices (e.g., a thermometer) before placing in service. This can include periodic and/or prior factory calibrations.</p> <p>At point of product receiving, check the accuracy of the temperature recording device used on the transit vehicle.</p> <p>Record daily accuracy checks and annual calibration checks for all thermometers used for measuring the ambient refrigeration condition</p>	Receiving log containing all monitoring and verification documentation, Corrective Action Records, Thermometer Accuracy/Calibration Log

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for Each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
								about products at receiving. Perform records review of monitoring, corrective actions and verification records within one week to the day that the record was made.	
CCP 2 Refrigerated Storage (Initial and Final)	Pathogenic bacteria growth – temperature abuse	Cooler Temperature not to exceed 40°F.	The ambient air temperature of the cooler	Use of a continuous temperature-recording device	Continuous monitoring by the device itself, with a visual check of the recorded data at the beginning and end of each day.	Cooler Manager	IF cooler temperature exceeds 40°F/4.4°C, THEN move shellstock to another cooler. Chill and hold the affected product until an evaluation of the total time and temperature exposure is performed. If safe; release into production. If time out of temperature exceeds safe harbor, destroy shellstock. AND Regain control by determining and fixing the refrigeration problem before further storage of shellstock in the malfunctioning unit.	Check accuracy check of continuous recording thermometer at initial use Perform daily accuracy checks of temperature indicating device prior to start-up. Calibrate cooler thermometer once per year Review Daily Cooler Log Monitoring, Corrective Action and Verification records within one week to the day that the record was made.	Daily Cooler Log and Corrective Actions Thermometer Accuracy/Calibration Log

Signature	Date:
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Wholesale/Distribution/Warehouse Facilities Process Flow Chart – *Scombrototoxin Formers*

Shaded steps are Critical Control Points



All refrigerated storage occurs in the same cooler



The dashed arrow represents product assembled for specific customer orders that can be held temporarily (less than two days) before delivery to the customer.

HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Certain fish, including potential scombrotoxic fish (Bluefish, Mackerel, Mahi-mahi and Tuna/large)</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed packed in ice under refrigeration in oxygen permeable containers</i>
	Intended Use & Consumer <i>Raw fish that will be cooked before it is eaten, to be consumed by the general public.</i>

Critical Control Point (CCP)	CCP 1. Receiving
Significant Hazard(s)	Scombrotoxin (histamine) formation
Critical Limits for each Control Measure	All fish products received are properly surrounded with ice in refrigeration.
Monitoring	What Proper icing of fish.
	How Observe and record proper icing conditions for representative number of containers per respective lots.
	When Each scombrotoxic forming lot received.
	Who Receiving manager or team member.
Corrective Action	<p>IF: icing is not adequate, THEN: place product in question in proper icing and/or refrigeration and evaluate the product temperature and exposure time without proper icing to determine product acceptance; or reject the product.</p> <p>AND</p> <p>To regain control: Discontinue use of supplier until evidence is obtained that transportation practices have changed.</p>
Verification	<ol style="list-style-type: none"> 1. Conduct daily accuracy checks for thermometers used to measure product temperatures. Same thermometers should be calibrated annually. 2. Review procedures for assessing proper icing for incoming truck deliveries. 3. Perform records review of monitoring, corrective actions and verification records within one week to the day that the record was made.
Records	Daily Receiving Log; Corrective Actions and thermometer calibration and accuracy records

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Certain fish, including potential scombrototoxic fish (Bluefish, Mackerel, Mahi-mahi and Tuna/large)</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed packed in ice under refrigeration in oxygen permeable containers</i>
	Intended Use & Consumer <i>Raw fish that will be cooked before it is eaten, to be consumed by the general public.</i>

Critical Control Point (CCP)	CCP 2 and 4. Refrigerated Storage (Initial and final)
Significant Hazard(s)	Scombrototoxin (histamine) formation
Critical Limits for each Control Measure	The product is held at a cooler temperature of 40°F (4.4°C) or below.
Monitoring	What Temperature of the Cooler
	How Cooler temperature will be measured using a continuous temperature-recording device
	When Continuous monitoring during storage is accomplished by the device itself, with a visual check of the recorded data at beginning and end of day.
	Who Refrigerated storage manager or team member.
Corrective Action	<p>Chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations.</p> <p>OR Chill and hold the affected product until histamine analysis is performed on a minimum of 60 fish collected from throughout each affected lot. Destroy the lot or divert it to a non-food use if any fish is found with histamine greater than or equal to 50 ppm. OR Destroy the product; OR Divert the product to a non-food use.</p> <p>AND Move some or all of the product in the malfunctioning cooler to another cooler; AND Address the root cause: Make repairs or adjustments to the malfunctioning cooler;</p>
Verification	<p>Check accuracy check of continuous recording thermometer at initial use</p> <p>Perform daily accuracy checks of temperature indicating device.</p> <p>Calibrate cooler thermometer once per year</p> <p>Review Daily Cooler Log Monitoring, Corrective Action and Verification records within one week to the day that the record was made.</p>
Records	Cooler Log, Corrective Actions record, Verification Logs (Calibration and Accuracy Checks)

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description Certain fish , including potential scombrototoxic fish <i>(Bluefish, Mackerel, Mahi-mahi and Tuna/large)</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed packed in ice under refrigeration in oxygen permeable containers</i>
	Intended Use & Consumer <i>Raw fish that will be cooked before it is eaten, to be consumed by the general public.</i>

Critical Control Point (CCP)	CCP 3. Pack / Repack / Label
Significant Hazard(s)	Food Allergens
Critical Limits for each Control Measure	All finished product labeling must accurately list any major food allergens by their Acceptable Market Name.
Monitoring	What Labels on finished product containers
	How Visual examination of labels on finished product container or package.
	When A representative number of packages from each lot will be defined based on lot size examined over production period.
	Who Packing supervisor
Corrective Action	<p>IF the container does not declare the allergen by its acceptable market name, THEN relabel the container and other paperwork (e.g., invoice) as necessary with Acceptable Market Name.</p> <p>Regain control by identifying, recording and modifying labeling procedures to avoid future recurrence. Retrain involved staff.</p>
Verification	Monitoring and corrective actions records will be reviewed within one week to the day that the records were made.
Records	Packing Log report and Corrective Actions records

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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description CERTAIN FISH , including potential scombrototoxic fish (<i>Bluefish, Mackerel, Mahi-mahi and Tuna/large</i>)
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed packed in ice under refrigeration in oxygen permeable containers</i>
	Intended Use & Consumer <i>Raw fish that will be cooked before it is eaten, to be consumed by the general public.</i>

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Receiving	Scombrototoxin (histamine) formation	All fish products received are properly surrounded with ice in refrigeration.	Proper icing of fish	Observe and record proper icing conditions for representative number of containers per respective lots.	Each scombrototoxic forming lot received.	Receiving manager or team member.	<p>IF: icing is not adequate; THEN: place product in question in proper icing and/or refrigeration and evaluate the product temperature and exposure time without proper icing to determine product acceptance; or reject the product.</p> <p>AND</p> <p>To regain control: Discontinue use of supplier until evidence is obtained that transportation practices have changed.</p>	<p>Conduct daily accuracy checks for thermometers used to measure product temperatures. Same thermometers should be calibrated annually.</p> <p>Review procedures for assessing proper icing for incoming truck deliveries.</p> <p>Perform records review of monitoring, corrective actions and verification records within one week to the day that the record was made.</p>	Daily Receiving Log; Corrective Actions and thermometer calibration and accuracy records

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Refrigerated Storage (Initial and final)	Scombrototoxin (histamine) formation	The product is held at a cooler temperature of 40°F (4.4°C) or below.	Temperature of the Cooler	Cooler temperature will be measured using a continuous temperature-recording device	Continuous monitoring during storage is accomplished by the device itself, with a visual check of the recorded data at beginning and end of day.	Refrigerated storage manager or team member.	<p>Chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations.</p> <p>OR Chill and hold the affected product until histamine analysis is performed on a minimum of 60 fish collected from throughout each affected lot. Destroy the lot or divert it to a non-food use if any fish is found with histamine greater than or equal to 50 ppm. OR Destroy the product; OR Divert the product to a non-food use.</p> <p>AND</p> <p>Move some or all of the product in the malfunctioning cooler to another cooler; AND Address the root cause: Make repairs or adjustments to the malfunctioning cooler</p>	<p>Check accuracy check of continuous recording thermometer at initial use.</p> <p>Perform daily accuracy checks of temperature indicating device.</p> <p>Calibrate cooler thermometer once per year.</p> <p>Review Daily Cooler Log Monitoring, Corrective Action and Verification records within one week to the day that the record was made.</p>	Cooler Log, Corrective Actions record, Verification Logs (Calibration and Accuracy Checks)

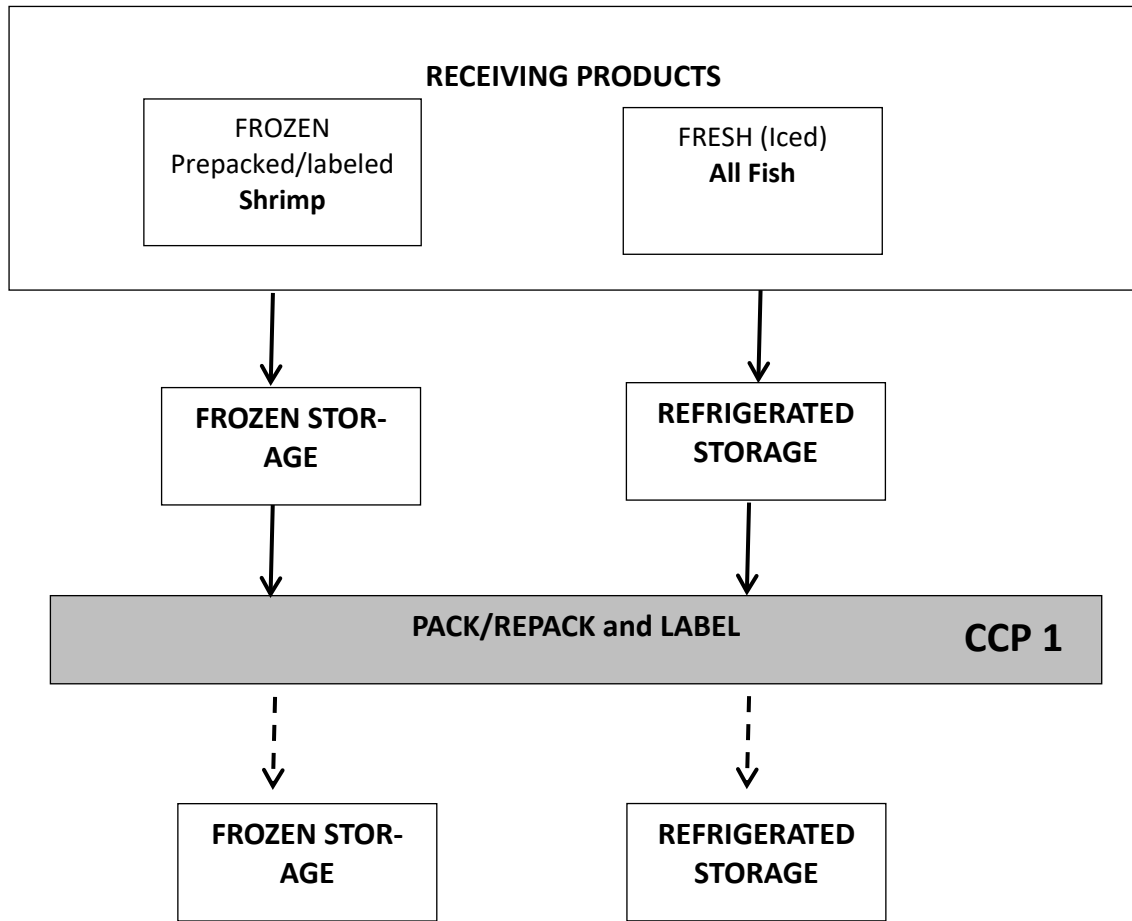
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Pack/Re-pack/Label	Food allergens	All finished product labeling must accurately list any major food allergens by their Acceptable Market Name.	Labels on finished product containers	Visual examination of labels on finished product container or package.	A representative number of packages from each lot will be defined based on lot size examined over production period.	Packing supervisor	<p>IF the container does not declare the allergen by its acceptable market name, THEN relabel the container and other paperwork (e.g., invoice) as necessary with Acceptable Market Name.</p> <p>Regain control by identifying, recording and modifying labeling procedures to avoid future recurrence. Retrain involved staff.</p>	Monitoring and corrective actions records will be reviewed within one week to the day that the records were made.	Packing Log report and Corrective Actions records

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Wholesale/Distribution/Warehouse Facilities Process Flow Chart –

All Finfish (Non-Scombrotxin Forming) and shrimp

Shaded steps are Critical Control Points



****All refrigerated storage occurs in the same cooler***

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 The dashed arrow represents product assembled for specific customer orders that can be held temporarily (less than two days) before delivery to the customer.

HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Finished Product Description: <i>All finfish (non-scombrototoxin forming) and shrimp</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed packed in ice under refrigeration in oxygen permeable containers</i>
	Intended Use & Consumer <i>Raw fish that will be cooked before it is eaten, to be consumed by the general public.</i>

Critical Control Point (CCP)	CCP 1. Pack / Repack and Label
Significant Hazard(s)	Food Allergens
Critical Limits for each Control Measure	All finished product labeling must accurately list any major food allergens by their Acceptable Market Name.
Monitoring	What Labels on finished product containers
	How Visual examination of labels on finished product container or package.
	When A representative number of packages from each lot will be defined based on lot size examined over production period.
	Who Packing supervisor
Corrective Action	<p>IF the container does not contain the market name, THEN label the container and invoice as necessary for correct identification.</p> <p>Regain control by identifying, recording and correcting the cause for the problem. Retrain involved staff.</p>
Verification	<p>Review Packing Log and Corrective Actions once per week</p> <p>Train packing room workers to correctly identify all products with appropriate labels</p>
Records	Packing Log and Corrective Actions

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>All finfish (non-scombrototoxin forming) and shrimp</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Stored and distributed packed in ice under refrigeration in oxygen permeable containers</i>
	Intended Use & Consumer <i>Raw fish that will be cooked before it is eaten, to be consumed by the general public.</i>

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Pack / Re-pack and Label	Food Allergens	All finished product labeling must accurately list any major food allergens by their Acceptable Market Name.	Labels on finished product containers	Visual examination of labels on finished product container or package.	A representative number of packages from each lot will be defined based on lot size examined over production period.	Packing supervisor	<p>IF the container does not contain the market name,</p> <p>THEN label the container and invoice as necessary for correct identification.</p> <p>Regain control by identifying, recording and correcting the cause for the problem. Retrain involved staff.</p>	<p>Review Packing Log and Corrective Actions once per week</p> <p>Train packing room workers to correctly identify all products with appropriate labels</p>	Packing Log and Corrective Actions

Signature:	Date:
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