SEPTEMBER 2020

Commercial Processing Example: *Wholesale/Distribution/Warehouse*

(Long 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.

Narrative[1]

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-label 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.

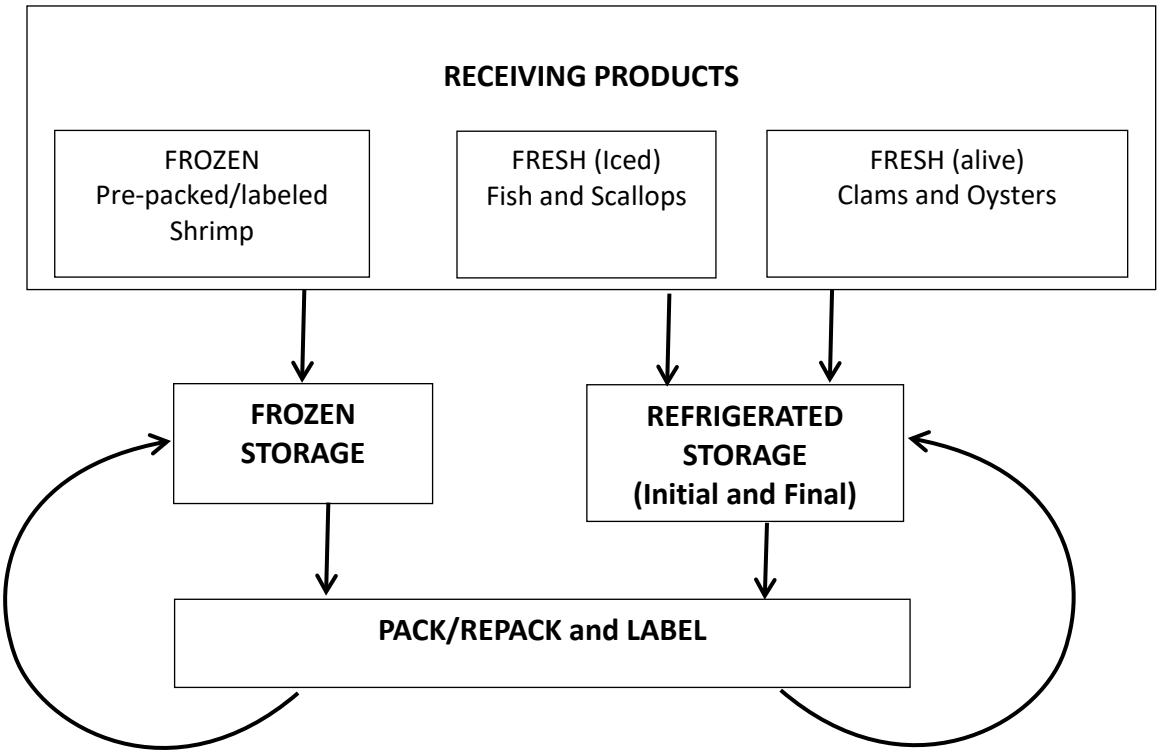
Frozen Storage –The frozen blocks of shrimp are stored in a freezer at 0°F or less.

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 shellstock[1].

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.

[1]Molluscan 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

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: Striped Bass or Rockfish **Market Name:** Bass **Scientific Name:** *Morone spp.*			√		√				√				√			√		√			√	
Common Name: Bluefish **Market Name:** Bluefish **Scientific Name:** *Pomatomus saltatrix*			√		√				√				√			√		√			√	
Common Name: Atlantic Cod **Market Name:** Cod **Scientific Name:** *Gadus spp.*			√		√				√				√			√		√			√	
Common Name: Fluke or Summer Flounder **Market Name:** Flounder **Scientific Name:** *Paralichthys dentatus*			√		√				√				√			√		√			√	
Common Name: Red Hake **Market Name:** Hake **Scientific Name:** *Urophycis spp.*	√				√				√				√			√		√			√	
Common Name: Atlantic Mackerel **Market Name:** Mackerel **Scientific Name:** *Scomber scombrus*			√		√				√				√			√		√			√	
Common Name: Mahi-mahi or Dolphinfish **Market Name:** Mahi-mahi **Scientific Name:** *Coryphaena spp.*			√		√				√				√			√		√			√	
Common Name: Monkfish or Goosefish **Market Name:** Monkfish **Scientific Name:** *Lophius spp.*			√		√				√				√			√		√			√	

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:** *Pollachius spp.*			√		√				√				√			√		√			√	
Common Name: Yellowfin Tuna **Market Name:** Tuna **Scientific Name:** *Thunnus albacares*			√		√				√				√			√		√			√	
Common Name: Atlantic Atlantic Salmon **Market Name:** Atlantic Salmon **Scientific Name:** *Salmo salar*			√		√				√				√			√		√			√	
Common Name: Swordfish **Market Name:** Swordfish **Scientific Name:** *Xiphias gladius*			√		√				√				√			√		√			√	
Common Name: Weakfish or Sea Trout **Market Name:** Weakfish **Scientific Name:** *Cynoscion spp.*			√		√				√				√			√		√			√	
Common Name: Silver Hake or Whiting **Market Name:** Whiting **Scientific Name:** *Merluccius spp.*	√				√				√				√			√		√			√	
Common Name: Northern Clam or Quahog **Market Name:** Clam **Scientific Name:** *Mercenaria spp.*			√	√				√				√				√			√		√	
Common Name: Eastern Oyster **Market Name:** Oyster **Scientific Name:** *Crassostrea spp.*			√	√				√				√				√			√		√	
Common Name: Sea Scallop **Market Name:** Scallop **Scientific Name:** *Placopecten magellanicus*			√		√				√				√			√		√			√	
Common Name: White Shrimp **Market Name:** Shrimp **Scientific Name:** *Penaeus spp.*			√			√				√				√		√		√			√	

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* (2011 edition). 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 DESRIPTION, 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. Scombrotoxin (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	(Scombrotoxin (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 impact 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.	----	----
Scombrotoxin (histamine) formation	Bluefish Mackerel, Mahi-mahi, Tuna	Yes	Scombrotoxin (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 repacking 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 repacking 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
Scombrotoxin (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.

Hazard Analysis Worksheet - *Live Clams and Oysters*

Firm Name *ABC Wholesale Company*	**Finished Product Description**: *Live clams and oysters*
Firm Location *Anywhere USA*	**Method of Storage & Distribution:** *Stored and distributed under refrigeration*
	Intended Use & Consumer: *Raw ready-to-eat product, to be consumed by the general public.*

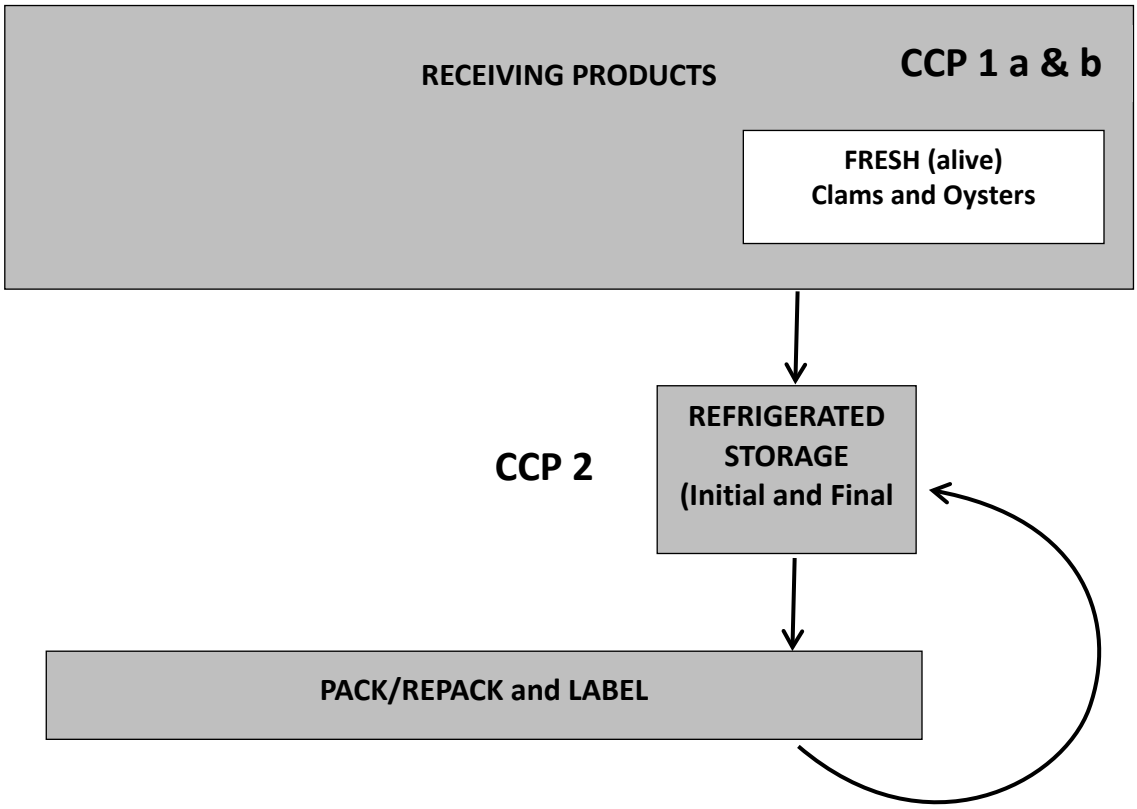
(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Receiving	Pathogens (presence) from harvest area	Yes	Pathogens could be present; product may be eaten raw; regulations require harvest tag and dealer information must accompany product through distribution	Check all product to ensure that it is properly tagged and from a certified dealer; assure tag and dealer information accompanies product distribution	Yes
	Parasites	No	Not likely to occur in oysters and clams.		
	Natural toxins	Yes	Unapproved harvest areas may have natural toxins; product may be eaten raw; regulations require harvest tag and dealer information must accompany product through distribution	Check all product to ensure that it is properly tagged and from a certified dealer; assure tag and dealer information accompanies product distribution	Yes
	Scombrotoxin (histamine) formation	No	Not likely to occur in oysters and clams.		
	Environmental chemicals	Yes	Unapproved harvest areas may have contaminants; product may be eaten raw; regulations require harvest tag and dealer information must accompany product through distribution	Check all product to ensure that it is properly tagged and from a certified dealer; assure tag and dealer information accompanies product distribution	Yes
	Aquaculture Drugs	No	Not likely to occur in these products.		
	Pathogenic bacteria growth - temperature abuse	Yes	Temp. abuse in transit could allow pathogens to grow	Shellstock loaded on pre-chilled trucks and temperature control during transit	Yes
	Allergens	No	Not likely to occur; mollusks are not part of 8 major food allergens in United States.		
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Refrigerated Storage (Initial Storage)	Pathogens (presence) from harvest area	No	Not likely to occur at this step.		
	Parasites	No	Not likely to occur in oysters and clams.		
	Natural toxins	No	Not likely to occur at this step.		
	Scombrotoxin (histamine) formation	No	Not likely to occur in oysters and clams.		
	Environmental chemicals	No	Not likely to occur at this step.		
	Aquaculture Drugs	No	Not likely to occur in these products.		
	Pathogenic bacteria growth - temperature abuse	Yes	In the absence of temperature control procedures, pathogenic bacteria growth could occur. Likely to cause adverse health consequence as the product may be raw, ready-to-eat.	Temperature control procedures during storage	Yes
	Allergens	No	Not likely to occur; mollusks are not part of 8 major food allergens in United States.		
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		
Pack/Repack/ Label	Pathogens (presence) from harvest area	No	Not likely to occur at this step.		
	Parasites	No	Not likely to occur in oysters and clams.		
	Natural toxins	No	Not likely to occur at this step.		
	Scombrotoxin (histamine) formation	No	Not likely to occur in oysters and clams.		
	Environmental chemicals	No	Not likely to occur at this step.		
	Aquaculture Drugs	No	Not likely to occur in these products.		

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
	Pathogenic bacteria growth - temperature abuse	No	Not likely to occur; insufficient time at this step.		
	Allergens	No	Not likely to occur; mollusks are not part of 8 major food allergens in United States.		
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		
Refrigerated Storage (Final Storage)	Pathogens (presence) from harvest area	No	Not likely to occur at this step.		
	Parasites	No	Not likely to occur in oysters and clams.		
	Natural toxins	No	Not likely to occur at this step.		
	Scombrotoxin (histamine) formation	No	Not likely to occur in oysters and clams.		
	Environmental chemicals	No	Not likely to occur at this step.		
	Aquaculture Drugs	No	Not likely to occur in these products.		
	Pathogenic bacteria growth - temperature abuse	Yes	In the absence of temperature control procedures, pathogenic bacteria growth could occur. Likely to cause adverse health consequence as the product may be raw, ready-to-eat.	Temperature Control Procedures	Yes
	Allergens	No	Not likely to occur; mollusks are not part of 8 major food allergens in United States.		
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		

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

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		CL (A) All shellstock containers **must bear a tag** that discloses: • 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. AND 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		
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		**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** (B) If an absence of consumer advisory statement, then modify labeling practices		
Verification		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.)		
Records		Daily Shellfish Receiving Log; Annual Dealer Verification Log and Corrective Actions		

HACCP Plan Signature:	**Date:**

HACCP Plan Form

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

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 ruck 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		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:**

HACCP Plan Form

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

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		**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.
Verification		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.
Records		Daily Cooler Log and Corrective Actions Thermometer Accuracy/Calibration Log

Signature:	**Date:**

HACCP Plan Form

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

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 Environmental Chemicals Natural Toxins	CL (A) All shellstock containers **must bear a tag** that discloses: (a) Date and place of harvest (State and Site) (b) Type and quantity of shellfish (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	(A) Presence of required Information contained on tags for incoming shellstock (B) Presence of consumer advisory statement	(A) Visually (B) Visually	(A) Each container (B) Three containers randomly selected from every lot of shucked mollusc-can 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

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 undercooked 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	If ambient truck temperature exceeded 45ºF 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.	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. At point of product receiving, check the accuracy of the temperature recording device used on the transit vehicle. Record daily accuracy checks and annual calibration checks for all thermometers used for measuring the ambient refrigeration condition	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:**

Hazard Analysis Worksheet

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

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Receiving	Pathogens (presence) from harvest area	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Parasites	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Natural toxins	No	Not likely to occur with these species of finfish		
	Scombrotoxin (histamine) formation	Yes	In the absence of time and temperature controls during transit, scombrotoxin likely to occur and cause illness as it is heat stable.	Temperature control procedures during transit	Yes
	Environmental chemicals	No	Not likely to occur with these species of finfish		
	Aquaculture Drugs	No	Not likely to occur in these products; none are farm raised.		
	Pathogenic bacteria growth - temperature abuse	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Allergens	Yes	Allergens are present; in the absence of labeling procedures, could case an adverse health consequence.	Labeling Procedures at finished product labeling step.	No
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		

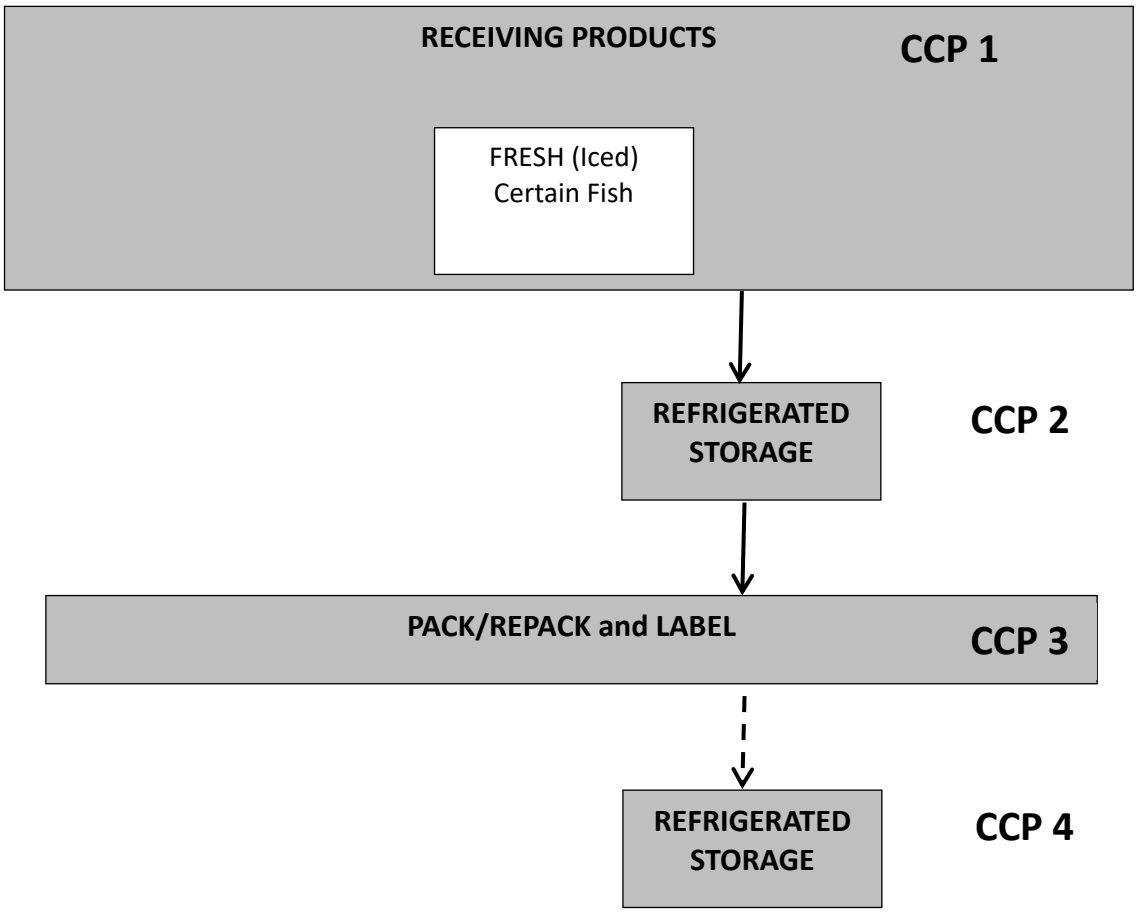
(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Refrigerated Storage	Pathogens (presence) from harvest area	No	Not likely to occur at this step or cause illness; product is intended to be cooked by consumer prior to consumption.		
	Parasites	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Natural toxins	No	Not likely to occur with these species of finfish		
	Scombrotoxin (histamine) formation	Yes	In the absence of time and temperature controls during at this step, scombrotoxin likely to occur and cause illness as it is heat stable.	Temperature control procedures during storage	Yes
	Environmental chemicals	No	Not likely to occur with these species of finfish		
	Aquaculture Drugs	No	Not likely to occur in these products; none are farm raised.		
	Pathogenic bacteria growth - temperature abuse	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Allergens	Yes	Allergens are present; in the absence of labeling procedures, could case an adverse health consequence.	Labeling Procedures at finished product labeling step.	No
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		
Pack/Repack/ Label	Pathogens (presence) from harvest area	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Parasites	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Natural toxins	No	Not likely to occur with these species of finfish		
	Scombrotoxin (histamine) formation	No	Not likely to occur; insufficient time at this step.		

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
	Environmental chemicals	No	Not likely to occur with these species of finfish		
	Aquaculture Drugs	No	Not likely to occur in these products; none are farm raised.		
	Pathogenic bacteria growth - temperature abuse	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Allergens	Yes	Allergens are present; in the absence of labeling procedures, could case an adverse health consequence.	Labeling Procedures at finished product labeling step.	Yes
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		
Refrigerated Storage (Final Storage)	Pathogens (presence) from harvest area	No	Not likely to occur at this step or cause illness; product is intended to be cooked by consumer prior to consumption.		
	Parasites	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Natural toxins	No	Not likely to occur with these species of finfish		
	Scombrotoxin (histamine) formation	Yes	In the absence of time and temperature controls during at this step, scombrotoxin likely to occur and cause illness as it is heat stable.	Temperature control procedures	Yes
	Environmental chemicals	No	Not likely to occur with these species of finfish		
	Aquaculture Drugs	No	Not likely to occur in these products; none are farm raised.		
	Pathogenic bacteria growth - temperature abuse	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
	Allergens	No	Conditions do not exist at this step to render a product undeclared.		
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		

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

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		**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. **AND** To **regain control**: Discontinue use of supplier until evidence is obtained that transportation practices have changed.
Verification		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:**

HACCP Plan Form

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

Critical Control Point (CCP)		**CCP 2 and 4. Refrigerated Storage (Initial and final)**
Significant Hazard(s)		Scombrotoxin (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		Chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations. 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. 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;
Verification		Check accuracy check of continuous recording thermometer at initial use Perform daily accuracy checks of temperature indicating device. 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.
Records		Cooler Log, Corrective Actions record, Verification Logs (Calibration and Accuracy Checks)

Signature:	**Date:**

HACCP Plan Form

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

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		**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. **Regain control** by identifying, recording and modifying labeling procedures to avoid future recurrence. Retrain involved staff.
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

Signature:	**Date:**

HACCP Plan Form

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

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Receiving	Scombrotoxin (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 scombrotoxic forming lot received.	Receiving manager or team member.	**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. **AND** To **regain control**: Discontinue use of supplier until evidence is obtained that transportation practices have changed.	Conduct daily accuracy checks for thermometers used to measure product temperatures. Same thermometers should be calibrated annually. Review procedures for assessing proper icing for incoming truck deliveries. Perform records review of monitoring, corrective actions and verification records within one week to the day that the record was made.	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)	Scombrotoxin (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.	Chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations. 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. **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	Check accuracy check of continuous recording thermometer at initial use. Perform daily accuracy checks of temperature indicating device. 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.	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/Repack/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	**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. **Regain control** by identifying, recording and modifying labeling procedures to avoid future recurrence. Retrain involved staff.	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

Signature:	**Date:**

Hazard Analysis Worksheet

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

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Receiving	Pathogens (presence) from harvest area	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Parasites	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Natural toxins	No	Not likely to occur with these species of finfish and not likely to affect the adductor muscle of scallops.		
	Scombrotoxin (histamine) formation	No	Not likely to occur in non-scombrotoxic species of fish.		
	Environmental chemicals	No	Not likely to occur with these species of finfish		
	Aquaculture Drugs	No	Not likely to occur in these products; none are farm raised.		
	Pathogenic bacteria growth - temperature abuse	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Allergens	No	Not likely to occur; Scallops are mollusks and not one of the 8 major food allergens in the United States.		
		Yes	Allergens are present; in the absence of labeling procedures, could case an adverse health consequence.	Labeling Procedures at finished product labeling step.	No
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		

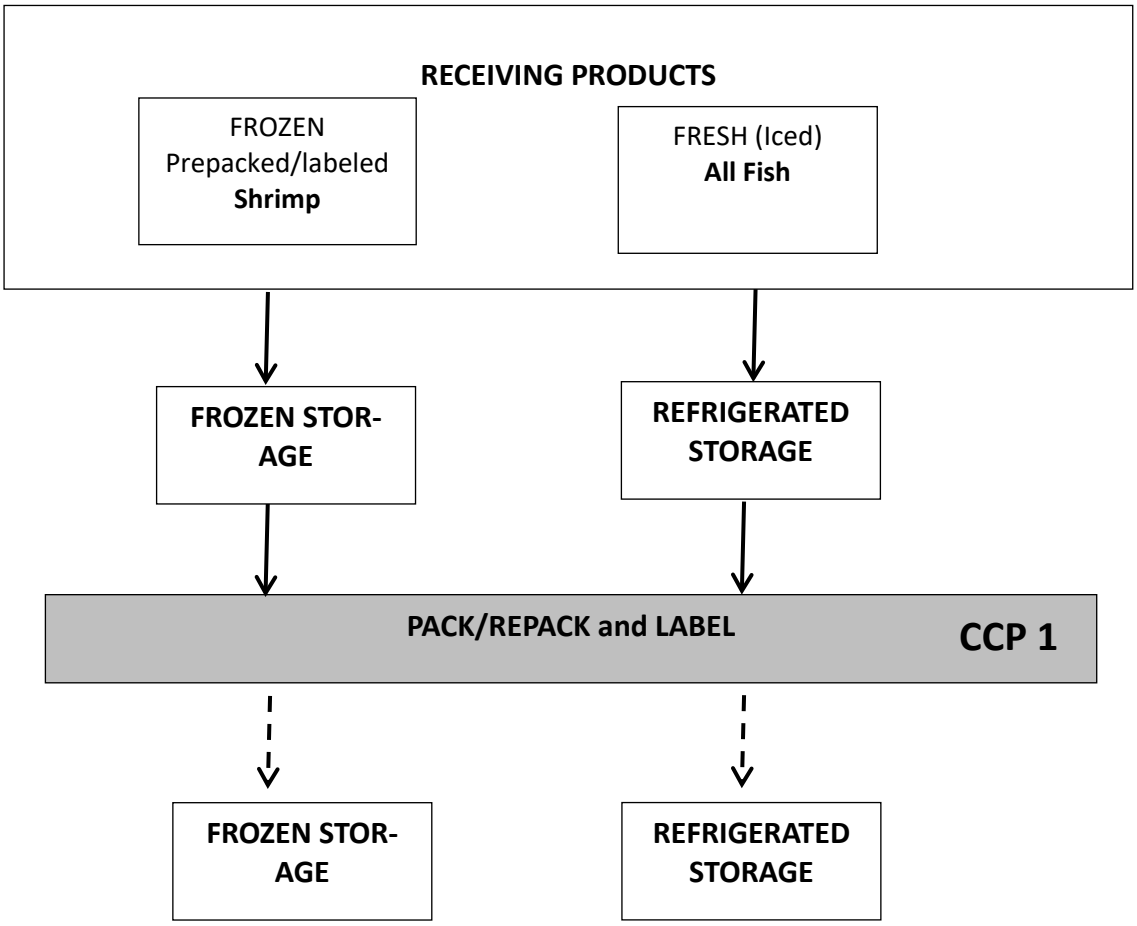
(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Refrigerated Storage	Pathogens (presence) from harvest area	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Parasites	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Natural toxins	No	Not likely to occur with these species of finfish and not likely to affect the adductor muscle of scallops.		
	Scombrotoxin (histamine) formation	No	Not likely to occur in non-scombrotoxic species of fish.		
	Environmental chemicals	No	Not likely to occur with these species of finfish		
	Aquaculture Drugs	No	Not likely to occur in these products; none are farm raised.		
	Pathogenic bacteria growth - temperature abuse	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Allergens	No	Not likely to occur; Scallops are mollusks and not one of the 8 major food allergens in the United States.		
		Yes	Allergens are present; in the absence of labeling procedures, could case an adverse health consequence.	Labeling Procedures at finished product labeling step.	No
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		
Pack/Repack/ Label	Pathogens (presence) from harvest area	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Parasites	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
	Natural toxins	No	Not likely to occur with these species of finfish and not likely to affect the adductor muscle of scallops.		
	Scombrotoxin (histamine) formation	No	Not likely to occur in non-scombrotoxic species of fish.		
	Environmental chemicals	No	Not likely to occur with these species of finfish		
	Aquaculture Drugs	No	Not likely to occur in these products; none are farm raised.		
	Pathogenic bacteria growth - temperature abuse	No	Not likely to occur; insufficient time at this step and cause illness; product is intended to be cooked by consumer prior to consumption.		
	Allergens	No	Not likely to occur; Scallops are mollusks and not one of the 8 major food allergens in the United States.		
		Yes	Allergens are present; in the absence of labeling procedures, could case an adverse health consequence.	Labeling Procedures at finished product labeling step.	No
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		
Refrigerated Storage (Final Storage)	Pathogens (presence) from harvest area	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Parasites	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Natural toxins	No	Not likely to occur with these species of finfish and not likely to affect the adductor muscle of scallops.		
	Scombrotoxin (histamine) formation	No	Not likely to occur in non-scombrotoxic species of fish.		

(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
	Environmental chemicals	No	Not likely to occur with these species of finfish		
	Aquaculture Drugs	No	Not likely to occur in these products; finfish are not farm raised. Regarding farm raised shrimp and salmon, the primary processor is responsible for this hazard, not the secondary processor.		
	Pathogenic bacteria growth - temperature abuse	No	Not likely to cause illness; product is intended to be cooked by consumer prior to consumption.		
	Allergens	No	Not likely to occur; conditions do not exist at this step to render a finished product undeclared.		
	Additives	No	Not likely to occur; none sourced, none introduced and no historical prevalence.		
	Metal inclusion	No	Not likely to occur; no likely source of metal fragments.		

Wholesale/Distribution/Warehouse Facilities
Process Flow Chart – *All Finfish (Non-Scombrotoxin Forming) and shrimp*

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

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		**IF** the container does not contain the market name, **THEN** label the container and invoice as necessary for correct identification. **Regain control** by identifying, recording and correcting the cause for the problem. Retrain involved staff.
Verification		Review Packing Log and Corrective Actions once per week Train packing room workers to correctly identify all products with appropriate labels
Records		Packing Log and Corrective Actions

Signature:	**Date:**

HACCP Plan Form

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

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Pack / Repack 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	**IF** the container does not contain the market name, **THEN** label the container and invoice as necessary for correct identification. Regain control by identifying, recording and correcting the cause for the problem. Retrain involved staff.	Review Packing Log and Corrective Actions once per week Train packing room workers to correctly identify all products with appropriate labels	Packing Log and Corrective Actions

Signature:	**Date:**