



September 2020

Commercial Processing Example: Wholesale/Distribution of Histamine Fish

Example: This is a Special Training Model for illustrative purposes only. The SHA models are based on guidance contained in FDA's *Fish and Fishery Products Hazards and Control Guidance* (4th edition, 2020) and additional updates 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

Product Market Names – Amberjack (Yellowtail), Bluefish, Mahi-mahi, Swordfish and Yellowfin Tuna (*Thunnus albacares*)

Receive – Wild caught fish are received from various suppliers. No fish are purchased directly from fishermen. All fish are fresh (not previously frozen). All five fish species are shipped from suppliers throughout the year by refrigerated truck in containers in which the product is thoroughly iced. Weekly shipments of tuna are received from one supplier by air freight. The tuna shipped by air is surrounded by frozen gel packs in insulated containers. Bluefish and swordfish are received during times of seasonal availability from a local supplier in a non-refrigerated open-bed truck in containers that are thoroughly iced. No fish are received or shipped in reduced oxygen containers.

Store – Fresh fish are immediately moved into a refrigerated storage cooler where they are stored in containers in which the product is thoroughly iced.

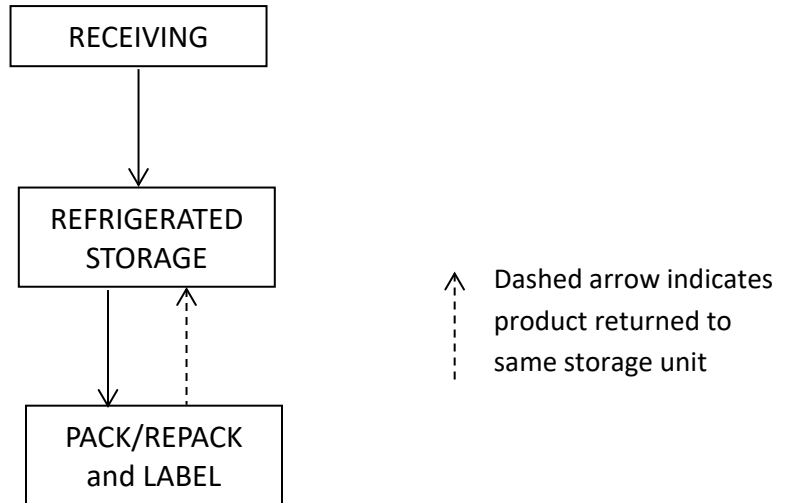
Customer orders are stored in the same storage units overnight if necessary.

Pack/Repack & Label – For each customer's order the products are removed from cooler, re-packed on ice as necessary, labeled and then loaded onto company trucks or placed back into refrigerated storage overnight for delivery the next day. The maximum time out of refrigerated conditions for this step is less than 30 minutes.

Intended Use: All fish are distributed with intentions to be consumed cooked by the consumer. There is no prior knowledge that the fish products will be consumed raw.

Wholesale/Distribution of Histamine Fish

Processing Flow Chart



****Both refrigerated storage steps occur in the same cooler***

Commercial Processing Example: Wholesale/Distribution of Histamine Fish

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

Description Company: ABC Wholesale Company																						
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	ROP*	Raw to be cooked	Raw RTE*	Cooked RTE*	General Public	At Risk Population
Common Name: Amberjack or Yellowtail Market Name: Amberjack Scientific Name: <i>Seriola lalandi</i>			√		√																	√
Common Name: Bluefish Market Name: Bluefish Scientific Name: <i>Pomatomus saltatrix</i>			√		√																	√
Common Name: Swordfish Market Name: Swordfish Scientific Name: <i>Xiphias gladius</i>			√		√																	√
Common Name: Mahi-mahi or Dolphin Market Name: Mahi-mahi Scientific Name: <i>Coryphaena spp.</i>			√		√																	√
Common Name: Yellowfin Tuna Market Name: Tuna (Large) Scientific Name: <i>Thunnus albacares</i>			√		√ + Gel Packs																	√

*ROP = Reduced Oxygen Packaging; *RTE = Ready-to Eat

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 Hazards) and 3- 4 (Process-Related Hazards) in the *FDA Hazards and Controls Guidance* (2011 edition and 2019 updates). 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.

Recommendations in the FDA Guidance indicate 2 potential Species-Related hazards and 4 potential Process-Related Hazards as listed in Tables 3-2 and 3-4. Four of these potential hazards must be addressed in the Hazard Analysis and two potential hazards are not included because they do not apply to this processor as described below.

The potential food safety hazards that must be considered in this firm's Hazard Analysis are:

Species related hazards:

1. Scombrototoxin (Histamine formation) (All 5 fish species; Species-Related Hazard, Chapter 7)

Process-related hazards:

2. Pathogenic Bacteria Growth/Temperature Abuse (All 5 fish species; Process-Related Hazard, Chapter 12 – specifically see page 214 of the Guide)
3. Undeclared Food Allergens – (All 5 fish species; Process-Related Hazard, Chapter 19)
4. Metal Inclusion (if used in packaging) – (All 5 fish species; Process-Related Hazard, Chapter 20)
5. Environmental chemicals (Species-Related Hazard for Bluefish only, Chapter 5). Because this potential hazard must be controlled by the primary processor/supplier, it is not included in the Hazard Analysis for this firm who is a secondary processor.
6. Food Intolerance Substances (Process-Related Hazards, Chapter 19) – This hazard was not included in the Hazard Analysis because these products are all fresh fish that have not been exposed to any food intolerance substances (additives) prior to delivery or during the processing steps used by this processor.

SANITATION CONTROL PROCEDURES (SCP) are monitored throughout all processing steps and the daily SCP records accompany the HACCP records.

Hazard Analysis Worksheet

Firm Name <i>ABC Wholesale Company</i>	Finished Product Description: <i>Amberjack (Yellowtail), Bluefish, Mahi-mahi, Swordfish and Yellowfin Tuna</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>

Histamine Fish: *Amberjack (Yellowtail), Bluefish, Mahi-mahi, Swordfish and Yellowfin Tuna*

(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	Scombrototoxin	Yes	Temperature abuse during shipping could cause histamine	Proper icing or temperature control during shipping	Yes
	Pathogen Growth-Temperature Abuse**	No	All products are intended to be cooked before they are consumed		
	Undeclared Food Allergens	Yes	Amberjack, Bluefish, Mackerel, Mahi-mahi and Tuna are food allergens	Each species will be labeled with the correct market name at pack/ repack & label step	No
	Metal Inclusion	No	Not likely to occur at this step; no introduction of metal fragments		
Refrigerated storage	Scombrototoxin	Yes	Histamine could form if temperature abuse occurs in storage	Histamine fish will be stored on ice in the refrigerated cooler	Yes
	Pathogen Growth-Temperature Abuse**	No	All products are intended to be cooked before they are consumed		
	Undeclared Food Allergens	Yes	Amberjack, Bluefish, Mackerel, Mahi-mahi and Tuna are food allergens	Each species will be labeled with the correct market name at pack/ repack & label step	No
	Metal Inclusion	No	Not likely to occur at this step; no introduction of metal fragments		
Pack / Repack / and Label	Scombrototoxin	No	Time-temp abuse not likely because of short time at this step		
	Pathogen Growth-Temperature Abuse**	No	All products are intended to be cooked before they are consumed		

	Undeclared Food Allergens	Yes	Amberjack, Bluefish, Mackerel, Mahi-mahi and Tuna are food allergens	Each container must be labeled with the market name of the fish species at this step	Yes
	Metal Inclusion	No	Not likely to occur at this step		
Refrigerated storage (final)	Scombrototoxin	Yes	Histamine could form if temperature abuse occurs in storage	Histamine fish will be stored on ice in the refrigerated cooler	Yes
	Pathogen Growth-Temperature Abuse**	No	All products are intended to be cooked before they are consumed		
	Undeclared Food Allergens	No	Each species was labeled with the correct market name at pack/ repack & label step		
	Metal Inclusion	No	Not likely to occur at this step; no introduction of metal fragments		

* Note - All five fish species are shipped from suppliers throughout the year by refrigerated truck in containers in which the product is thoroughly iced. Weekly shipments of tuna are received from one supplier by air freight. The tuna shipped by air is surrounded by frozen gel packs in insulated containers. Bluefish and swordfish are received during times of seasonal availability from a local supplier in a non-refrigerated (open-bed) truck in containers that are thoroughly iced.

** Pathogenic bacteria growth – temperature abuse - as FDA removed the superscript related to "All products are intended to be cooked before they are consumed" in the hazard tables, it might be a good idea to reference page 214, Ch. 12 under intended use which also references sanitation controls and GMPs as a justification as to why this is not a CCP.

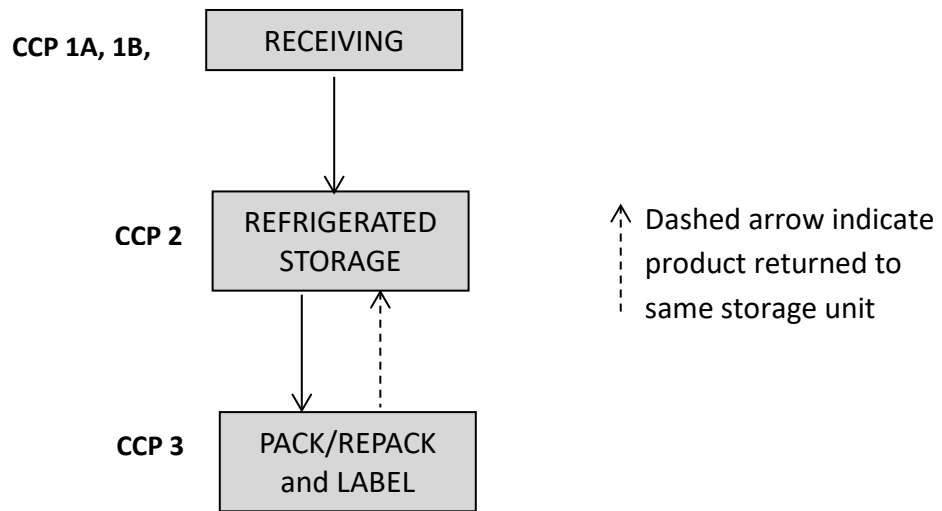
"Except as noted, it is unlikely that the intended use will affect the significance of the hazard. FDA is not aware of any HACCP controls that exist internationally for the control of pathogenic bacteria in fish and fishery products that are customarily fully cooked by the consumer or end user before consumption, other than a rigorous sanitation regime as part of a prerequisite program or as part of HACCP itself.

The Fish and Fishery Products regulation, 21 CFR 123 (called the Seafood HACCP Regulation in this guidance document) requires such a regime. The proper application of sanitation controls is essential because of the likelihood that pathogenic bacteria can be introduced into fish and fishery products through poor handling practices by the aquaculture producer, the fisherman, or the processor. FDA is interested in information regarding any HACCP controls beyond sanitation that could be necessary and practical for the control of pathogenic bacteria in fish and fishery products that are customarily fully cooked by the consumer or end-user. However, the agency makes no recommendations in this the guidance document and has no specific expectations with regard to such controls in processors' HACCP plans."

Wholesale/Distribution of Histamine Fish

Processing Flow Chart

Shaded steps are Critical Control Points



****Both refrigerated storage steps occur in the same cooler***

HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Amberjack (Yellowtail), Bluefish, Mahi-mahi, Swordfish and Yellowfin Tuna</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 1A: RECEIVING (All species delivered surrounded by ice in a refrigerated truck)
Significant Hazard(s)	Scombrototoxin
Critical Limits for each Control Measure	All products are completely surrounded with ice at the time of delivery
Monitoring	What The adequacy of ice surrounding the product at the time of delivery
	How Visual check of the adequacy of ice in a representative number of containers from throughout the shipment at delivery
	Frequency Every shipment
	Who Receiving Manager
Corrective Action	IF: containers do not have enough ice; THEN: reject product To regain control: Call supplier to let them know CL was not met and provide product delivery specifications and standards; Discontinue use of supplier until their transport procedures are corrected. Retrain involved staff.
Verification	Review Daily Receiving Log and Corrective Actions once per week. Conduct quarterly internal product temperature checks with a thermometer to verify that proper icing procedures are being used by each supplier. Check thermometer accuracy before quarterly temperature checks for proper icing. Calibrate thermometer at least once per year or according to manufacturer specifications.
Records	Daily Receiving Log; Corrective Action Reports; Thermometer Accuracy Check and Calibration Log

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Yellowfin tuna delivered by air freight using gel packs to maintain product temperature</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 1B: RECEIVING (Tuna delivered by air freight using gel packs to maintain product temperature)
Significant Hazard(s)	Scombrototoxin
Critical Limits for each Control Measure	There is an adequate quantity of frozen gel packs surrounding the fish at the time of delivery, AND The internal temperature of the fish at the time of delivery is 40°F or below
Monitoring	What The quantity and frozen status of gel packs at the time of delivery, and The internal temperature of the fish at the time of delivery
	How Visual observation of the adequacy and frozen state of the gel packs in a representative number of containers at the time of delivery, and Use a thermometer to measure the internal temperature in a representative number of fish from throughout the shipment at delivery
	Frequency Every shipment of tuna by air freight
	Who Receiving Manager
Corrective Action	IF: containers do not have enough gel packs or the gel packs are not frozen or the internal temperature of the fish in any container is above 40°F; THEN: reject product To regain control: Call supplier to let them know CL was not met and provide product delivery specifications and standards; Discontinue use of supplier until their transport procedures are corrected. Retrain involved staff.
Verification	Review Daily Receiving Log and Corrective Actions once per week. Check the accuracy of the thermometer used to measure the internal temperature of fish before each use. Calibrate this thermometer annually or according to manufacturer specifications.
Records	Daily Receiving Log; Corrective Action Records; and Thermometer Accuracy Check and Calibration Log

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Bluefish and Swordfish seasonally received from a local and delivered on an unrefrigerated truck.</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 1C: RECEIVING (Seasonal deliveries of bluefish and swordfish surrounded by ice in an unrefrigerated open-bed truck)
Significant Hazard(s)		Scombrototoxin
Critical Limits for each Control Measure		All fish are completely surrounded with ice at the time of delivery, and The internal temperature of the fish at the time of delivery is 40°F or below
Monitoring	What	The adequacy of ice surrounding the fish at the time of delivery, AND The internal temperature of the fish at the time of delivery
	How	Visual observation of the adequacy of ice in a representative number of containers from throughout the shipment at the time of delivery, AND Use a thermometer to measure the internal temperature in a representative number of fish from throughout the shipment at delivery
	Frequency	Every shipment of bluefish and mackerel received in an unrefrigerated (open-bed) truck
	Who	Receiving Manager
Corrective Action		IF: containers do not have adequate ice or the internal temperature of the fish in any container is above 40°F; THEN: reject product To regain control: Call supplier to let them know CL was not met and provide product delivery specifications and standards; Discontinue use of supplier until their transport procedures are corrected. Retrain involved staff.
Verification		Review Daily Receiving Log and Corrective Actions once per week. Check the accuracy of the thermometer used to measure the internal temperature of fish before each use. Calibrate this thermometer annually or according to manufacturer specifications.
Records		Daily Receiving Log; Corrective Action Reports; and Thermometer Accuracy Check and Calibration Log

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Amberjack (Yellowtail), Bluefish, Mahi-mahi, Swordfish and Yellowfin Tuna</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: REFRIGERATED STORAGE (INITIAL AND FINAL)
Significant Hazard(s)	Scombrototoxin
Critical Limits for each Control Measure	All products are completely surrounded with ice while stored in the cooler
Monitoring	What The adequacy of ice surrounding fish stored in the cooler
	How Visual check of representative number of containers stored throughout the cooler
	Frequency Every 4 hours during business operating hours
	Who Cooler manager
Corrective Action	<p>IF the amount of ice is not adequate; THEN: Chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations; Reject suspect and obviously abused products</p> <p>To regain control, determine and document the cause for improper icing; document the problem and corrections through further training of involved staff.</p>
Verification	Review Daily Receiving Log and Corrective Actions once per week. Conduct quarterly internal product temperature checks with thermometer to verify that proper icing procedures are being used. Check the accuracy of the thermometer used to measure the internal temperature of fish before each use. Calibrate this thermometer annually or according to manufacturer specifications.
Records	Daily Receiving Log; Corrective Action Reports; and Thermometer Accuracy Check and Calibration Log

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Amberjack (Yellowtail), Bluefish, Mahi-mahi, Swordfish and Yellowfin Tuna</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 AND LABEL
Significant Hazard(s)	Undeclared Food Allergens
Critical Limits for each Control Measure	All containers or packages of fish must be identified with their market name
Monitoring	What Label on Product Containers
	How Visual check to determine that each container is labeled with the correct market name
	Frequency Each container for each delivery
	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 Action Reports once per week</p> <p>Train packing room workers to correctly identify all products with correct market name labels</p>
Records	Packing Log and Corrective Action Reports

Signature:	Date:
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HACCP Plan Form (*landscape format*)

Firm Name <i>ABC Wholesale Company</i>	Product Description <i>Amberjack, Bluefish, Mahi-mahi, Swordfish and Yellowfin Tuna</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	Frequency				Who
CCP 1A Receiving (All species delivered surrounded by ice in refrigerated truck)	Scombrototoxin	All products are completely surrounded with ice at the time of delivery	The adequacy of ice surrounding the product at the time of delivery	Visual check of the adequacy of ice in a representative number of containers from throughout the shipment at delivery	Every shipment	Receiving Manager	IF: containers do not have enough ice; THEN: reject product To regain control: Call supplier to let them know CL was not met and provide product delivery specifications and standards. Discontinue use of supplier until their transport procedures are corrected. Retrain involved staff.	Review Daily Receiving Log and Corrective Action Reports once per week. Conduct quarterly internal product temperature checks with a thermometer to verify that proper icing procedures are being used by each supplier. Check thermometer accuracy before quarterly temperature checks for proper icing. Calibrate thermometer at least once per year.	Daily Receiving Log; Corrective Action Reports; and Thermometer Accuracy Check and Calibration Log
CCP 1B Receiving (Tuna delivered by air freight using gel packs to maintain product temperature)	Scombrototoxin	There is an adequate quantity of frozen gel packs surrounding the fish at the time of delivery, AND The internal temperature of the fish at the time of delivery is 40°F or below	The quantity and frozen status of gel packs at the time of delivery, and The internal temperature of the fish at the time of delivery	Visual observation of the adequacy and frozen state of the gel packs in a representative number of containers throughout the shipment at the time of delivery, and	Every shipment of tuna by air freight	Receiving Manager	IF: containers do not have enough gel packs or the gel packs are not frozen or the internal temperature of the fish in any container is above 40°F; THEN: reject product To regain control: Call supplier to let them know CL was not met and provide product delivery specifications and standards; Discontinue use	Review Daily Receiving Log and Corrective Action Reports once per week. Check the accuracy of the thermometer used to measure the internal temperature of fish before each use. Calibrate this thermometer annually or according to manufacturer specifications.	Daily Receiving Log; Corrective Action Reports; and Thermometer Accuracy Check and Calibration Log

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring			Corrective Action	Verification	Records	
			What	How	Frequency				Who
<p>CCP 1C Receiving (Seasonal deliveries of bluefish and swordfish surrounded by ice delivered in an unrefrigerated open-bed truck)</p>	Scombrotoxin	All fish are completely surrounded with ice at the time of delivery, AND The internal temperature of the fish at the time of delivery is 40°F or below	The adequacy of ice surrounding the fish at the time of delivery, and The internal temperature of the fish at the time of delivery	Visual observation of the adequacy of ice in a representative number of containers throughout the shipment at the time of delivery, AND Use a thermometer to measure the internal temperature in a representative number of fish from throughout the shipment at delivery	Every shipment of bluefish and mackerel received in an unrefrigerated open bed truck	Receiving Manager	<p>IF: containers do not have adequate ice or the internal temperature of the fish in any container is above 40°F; THEN: reject product To regain control: Call supplier to let them know CL was not met and provide product delivery specifications and standards; Discontinue use of supplier until their transport procedures are corrected. Retrain involved staff.</p>	Review Daily Receiving Log and Corrective Action Reports once per week. Check the accuracy of the thermometer used to measure the internal temperature of fish before each use. Calibrate this thermometer annually or according to manufacturer specifications.	Daily Receiving Log; Corrective Action Reports; and Thermometer Accuracy Check and Calibration Log

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring			Corrective Action	Verification	Records	
			What	How	Frequency				Who
Refrigerated Storage (Initial and Final)	Scombrotoxin	All products are completely surrounded with ice while stored in the cooler	The adequacy of ice surrounding fish stored in the cooler	Visual check of representative number of containers stored throughout the cooler	Every 4 hours during business operating hours	Cooler manager	<p>IF the amount of ice is not adequate, THEN: Chill and hold the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations. Reject suspect and obviously abused products</p> <p>To regain control, determine and document the cause for improper icing; document the problem and corrections through further training of involved staff.</p>	Review Daily Cooler Log and Corrective Action Reports once per week. Conduct quarterly internal product temperature checks with thermometer to verify that proper icing procedures are being used. Check the accuracy of the thermometer used to measure the internal temperature of fish before each use. Calibrate this thermometer annually or according to manufacturer specifications.	Daily Receiving Log; Corrective Action Reports; and Thermometer Accuracy Check and Calibration Log
Pack / Repack and Label	Undeclared Food Allergens	All containers or packages of fish must be identified with their market name	Label on Product Containers	Visual check to determine that each container is labeled with the correct market name	Each container for each delivery	Packing Supervisor	<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>	Review Packing Log and Corrective Action Reports once per week Train packing room workers to correctly identify all products with correct market name labels	Packing Log and Corrective Action Reports
Signature:			Date:						

* All five fish species are shipped from suppliers throughout the year by refrigerated truck in containers in which the product is thoroughly iced. Weekly shipments of tuna are received from one supplier by air freight. The tuna shipped by air is surrounded by frozen gel packs in insulated containers. Bluefish and mackerel are received during times of seasonal availability from a local supplier in a non-refrigerated open-bed truck in containers that are thoroughly iced.