REVISED September 2020

Commercial Processing Example: *Fresh Tuna Loins*

Example: This is a Special Training Model *f(or* illustrative purposes only. The SHA models are based on recommendations in the most current version of FDA's *Fish and Fishery Products Hazards and Control Guidance* (4th edition, 2020) available via 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

Company	ABC Tuna Company, Anywhere, USA
Market Name	Yellowfin tuna (*Thunnus albacares)*
Source of Fishery Product	Tuna are purchased directly from the fisherman
Describe the Food	Wild caught yellowfin tuna
Method of Receiving, Storage and Distribution	Iced
Finished Packaging Type	Tuna loins packed in ice held in waxed cartons
Intended Use and Consumer	Sold to general public to be cooked before consumption

Description of Process

Receive – Yellowfin tuna are caught by fishing vessels using longlines. The lines are only in the water for about 12 hours and the fish are landed alive. The fish are bled, headed (gills removed) and gutted (eviscerated) before being held in ice or chilled seawater (32°F) on the vessel. The tunas are chilled within 12 hours after live harvest. The harvested and iced tuna is delivered directly to the plant/processors dock. The delivered lot is the entire harvest or an identified portion of the harvest. The processing facility is where the tuna will be processed, more than 24 hours after they were caught.

At receipt, the harvest vessel records are obtained showing the environmental conditions at harvest, and time from catch to chilling.

The internal temperature of the fish is recorded on delivery, and sensory evaluations are conducted for all fish in the delivered lot.

Iced Storage – The eviscerated, whole tuna are buried in ice and temporarily placed in refrigerated storage below 40°F.

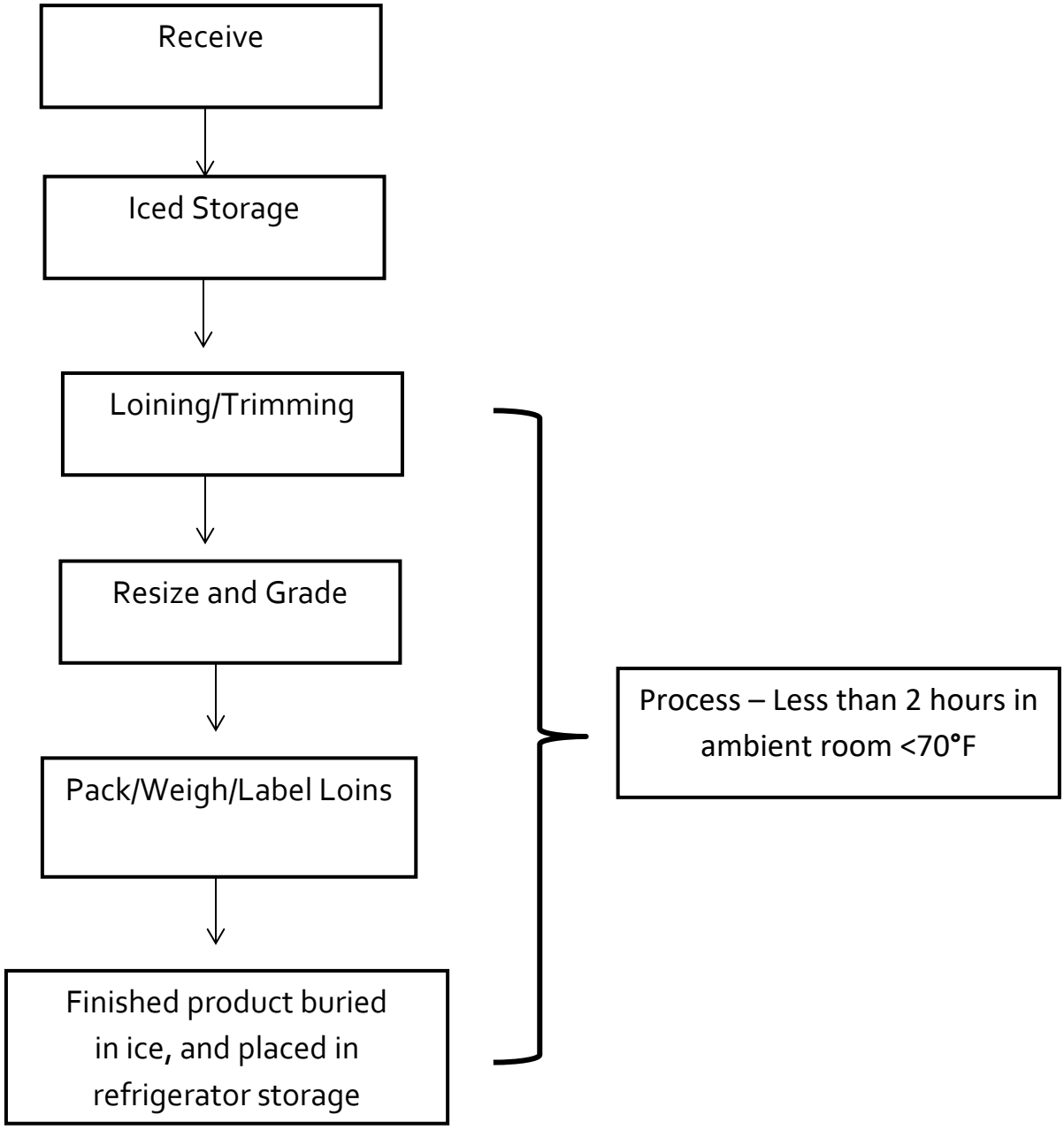
Loining/Trimming and Resize/Grade – The tuna are removed from iced storage for loining and trimming. The loined product is graded and sized in a processing room maintained below 70°F.

Pack/Weigh/Label Loins – The loined product is wrapped in oxygen permeable film and buried in ice held in a waxed cartons with a capacity for 40 to 60 pounds.

Finished Product Storage – The cartons are labeled and stored in refrigeration maintained below 40°F until shipment to the fresh retail markets for eventual sale to the general public to be cooked.

The cumulative processing time (see flow chart) is less than 2 hours (time out of refrigerated/iced storage and during product handling) in a temperature-controlled processing room maintained below 70°F.

Fresh Tuna Loins
Process Flow Chart



Commercial Processing Example: *Fresh Tuna Loins*

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:**																				
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: *Tuna* **Market Name:** *Tuna* **Scientific Name:** *Thunnus albacares*	√				√			√	√			√	√			√		√			√	

*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 Guide*. 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.

1. Scombrotoxin (Histamine) (species-related, chapter 5)
2. Food Allergens (natural) – (process-related, chapter 19)
3. Food Intolerance Substances -Food Additives (if used in processing) – (process related , chapter 19)
4. Metal Inclusion (if used in packaging) – (process-related, chapter 20)

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

Hazard Analysis Worksheet

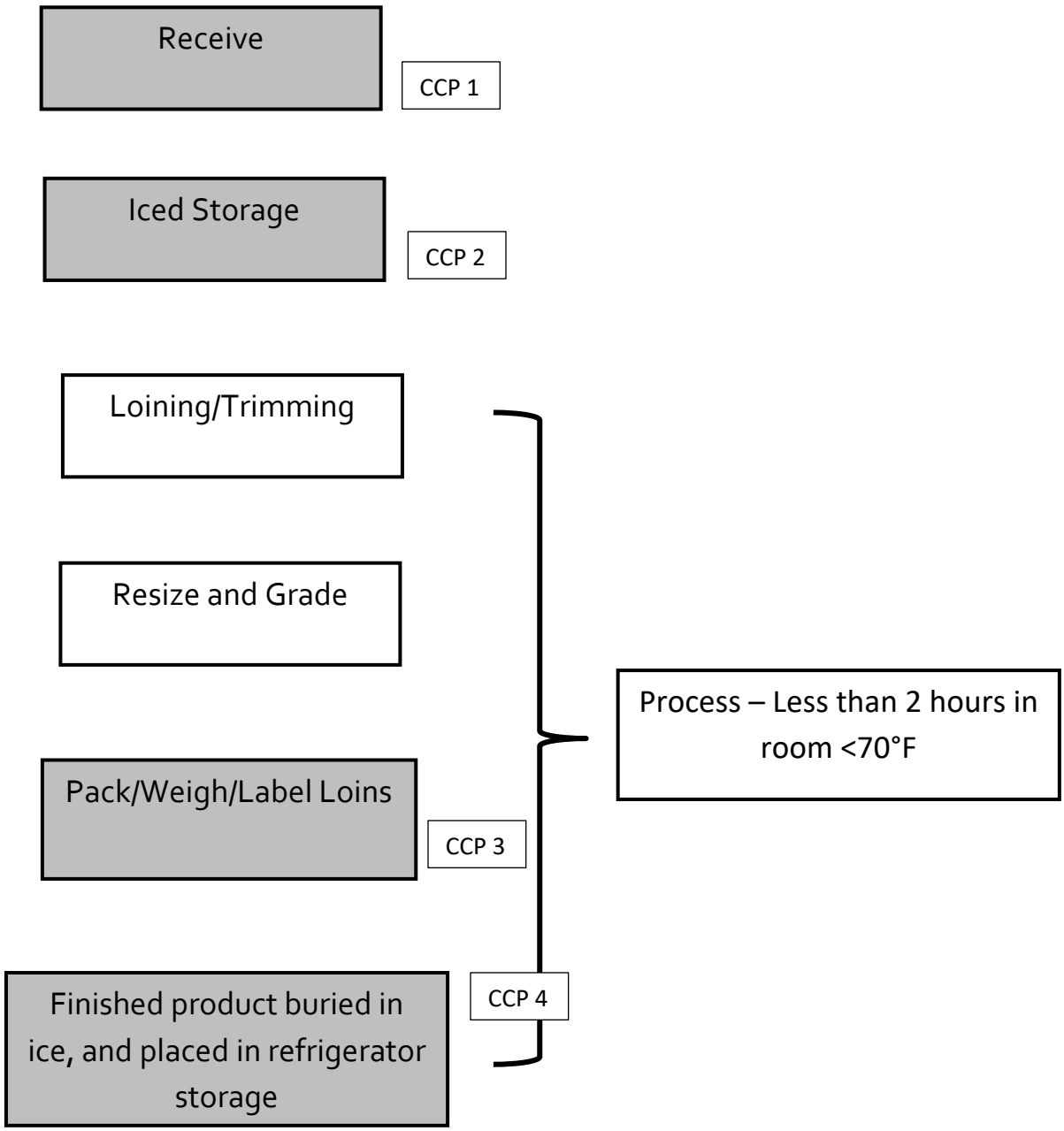
Firm Name: *ABC Tuna Company*	**Finished Product Description:** *Yellowfin tuna loins (wild caught)*
Firm Address: *Anywhere, USA*	**Method of Storage & Distribution:** *Stored and distributed packed in ice under refrigeration to retail operations*
	Intended Use & Consumer: *Raw fish to be cooked before eaten by 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 eviscerated tuna from harvest vessels	Histamine	Yes	Temperature abuse on the harvest vessel could cause histamine to form in tuna	Temperature control aboard harvest vessels	Yes
	Food Allergens	Yes	Fish is a food allergen	Labeled at weigh/pack/label step with correct market name	No
	Food Intolerance Substances	No	No food additives used in process		
	Metal inclusion	No	Not likely at this step		
Iced Storage	Histamine	Yes	Exposure to elevated temperatures can lead to histamine formation	Temperature control with ice	Yes
	Food Allergens	Yes	Fish is a food allergen	Labeled at weigh/pack/label step with correct market name	No
	Food Intolerance Substances	No	No food additives used in process		
	Metal inclusion	No	Not likely at this step		
Loining/ Trimming	Histamine	No	Total cumulative processing time less than 2 hours in ambient room temperature maintained less than 70°F. Histamine formation not reasonably likely.		
	Food Allergens	Yes	Fish is a food allergen	Cartons will be labeled with market name at the weigh/pack/label step	No
	Food Intolerance Substances	No	No food additives used in process		
	Metal inclusion	No	Fillet knives are not considered a metal hazard		

(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)**
Resize and Grade	Histamine	No	Total cumulative processing time less than 2 hours in ambient room temperature maintained less than 70°F. Histamine formation not reasonably likely.		
	Food Allergens	Yes	Fish is a food allergen	Cartons will be labeled with market name at the weigh/pack/label step	No
	Food Intolerance Substances	No	No food additives used in process		
	Metal inclusion	No	Not likely at this step		
Pack/Weigh/ Label Loins	Histamine	No	Total cumulative processing time less than 2 hours in ambient room temperature maintained less than 70°F. Histamine formation not reasonably likely.		
	Food Allergens	Yes	Fish is a food allergen	Cartons to be labeled with market name (proper labeling)	Yes
	Food Intolerance Substances	No	No food additives used in process		
	Metal inclusion	No	Not likely at this step		
Finished product storage	Histamine	Yes	Temperature abuse during storage could cause histamine to form in fish	Temperature control with ice during storage	Yes
	Food Allergens	No	Fish is a food allergen	Shipping cartons were labeled at prior step	
	Food Intolerance Substances	No	No food additives used in process		
	Metal inclusion	No	Not likely at this step		

Fresh Tuna Loins
Process Flow Chart

Shaded Steps are Critical Control Points



HACCP Plan Form

Firm Name *ABC Tuna Company*	**Product Description** *Yellowfin Tuna Loins (wild caught)*
Firm Location *Anywhere USA*	**Method of Storage & Distribution** *Chilled, stored and distributed packed in ice under refrigeration to retail operations*
	Intended Use and Consumer: *Raw fish to be cooked before eaten by general public*

Critical Control Point (CCP)		**CCP 1: RECEIVING FRESH, EVISCERATED TUNA FROM HARVESTER**		
Significant Hazard(s)		Scombrotoxin (histamine) formation		
Critical Limits for each Control Measure		All lots received with harvest vessel records that show: 1. Fish were gilled/gutted and chilling within 12 hours after death	At receipt (primary processor): 2. Less than 2.5% decomposition in each delivered lot (e.g. no more than 2 fish out of 118 fish)	3. Tuna internal temperature is ≤ 40°F
Monitoring	**What**	1. Harvest Vessel Records (Includes date and time of catch and chilling with ice.)	2. Amount of decomposition in each lot based on trained sensory evaluations	3. Date and time of offloading AND internal temperature of representative number of largest tuna in the delivered lot at off-loading (concentrating on any tuna showing signs of mishandling)
	How	1. Review of harvest vessel records	2. Sensory evaluation (at least 118 tuna from the delivered lot or all tuna for smaller lots)	3. Thermometer (1 fish/1000 lbs, minimum 12 fish per lot)
	When	Every delivered lot	Every delivered lot	Every delivered lot
	Who	Receiving supervisor	Receiving staff	Receiving supervisor
Corrective Action		**IF** lots with no or incomplete vessel records ***or*** when internal temperature has not been met **THEN** Chill and hold the lot of tuna, and test for histamine in 60 fish minimum, representatively selected throughout the same lot; reject the entire lot if any tuna (single fish) measures over 50ppm **OR:** Reject lot **IF:** Sensory assessments indicate > 2.5% decomposition **THEN:** Chill and hold the lot of tuna, and test for histamine in 60 fish minimum, representatively selected throughout the same lot; reject the entire lot if any tuna (single fish) measures over 50ppm **AND**: If the lot is accepted, perform 100% sensory on fish for decomposition to ensure that any decomposed fish is destroyed **OR:** Reject the lot **AND:** Discuss problems with boat captain and/or discontinue use of supplier if problem persists and proof of onboard practices have not improved		
Verification		Review monitoring and corrective action records within one week and verification records within reasonable time. Quarterly histamine testing on select suppliers; Training for anyone doing sensory assessment Daily accuracy checks of thermometers; Annual calibration of thermometers or per manufacturer's directions Annual sensory retraining for anyone that does sensory testing		
Records		Harvest vessel records; Receiving off-loading records; Receiving sensory records; Receiving internal temperature records; Corrective action records; Accuracy and calibration records; and Training records		

Signature:	**Date:**

HACCP Plan Form

Firm Name *ABC Tuna Company*	**Product Description** *Yellowfin Tuna Loins (wild caught)*
Firm Location *Anywhere USA*	**Method of Storage & Distribution** *Chilled, stored and distributed packed in ice under refrigeration to retail operations*
	Intended Use and Consumer: *Raw fish to be cooked before eaten by general public*

Critical Control Point (CCP)		**CCP 2: ICED STORAGE**
Significant Hazard(s)		Scombrotoxin (histamine) formation
Critical Limits for each Control Measure		Whole, eviscerated tuna completely surrounded by ice while stored
Monitoring	**What**	Adequacy of ice
	How	Visual check of representative number of containers in storage
	When	Beginning and end of each day during business operating hours
	Who	Cooler manager
Corrective Action		**IF** the amount of ice is not adequate **THEN:** Re-ice and move to another cooler if necessary. Evaluate fish for total time and temperature exposure. This includes exposures during processing operations using table 7-2, page 119 of the *FDA Hazard Guidance* (4th Edition) and continuous temperature recorder on cooler. **OR:** Chill and hold the lot of tuna, and test for histamine in 60 fish minimum, representatively selected throughout the same lot; reject the entire lot if any tuna (single fish) measures over 50ppm **OR:** Destroy lot **AND:** Determine and correct problem for inadequate icing. Retrain involved staff.
Verification		Review monitoring and corrective action records within one week and verification records within reasonable time. Periodic measurement of internal temperature of fish Daily accuracy checks of thermometers Annual calibration of thermometers or per manufacturer's directions
Records		Ice check log (including approximate number of containers in cooler and number of containers checked for ice) and Corrective Actions

Signature:	**Date:**

HACCP Plan Form

Firm Name *ABC Tuna Company*	**Product Description** *Yellowfin Tuna Loins (wild caught)*
Firm Location *Anywhere USA*	**Method of Storage & Distribution** *Chilled, stored and distributed packed in ice under refrigeration to retail operations*
	Intended Use and Consumer: *Raw fish to be cooked before eaten by general public*

Critical Control Point (CCP)		**CCP 3: PACK/WEIGH/LABEL**
Significant Hazard(s)		Food Allergens
Critical Limits for each Control Measure		All containers of fish must be identified with the correct market name
Monitoring	**What**	Label rolls Label on product containers
	How	Visual check of label roll Visual examination of labels on finished product
	When	One roll in each box of labels At beginning of production and representative number of containers over production period
	Who	Packing supervisor
Corrective Action		**IF:** Labels are inaccurate **THEN:** Return to producer for reprinting **AND:** Talk to producer to fix the issue and discontinue use if problem persists. **IF:** Container does not contain label or if improperly labeled **THEN:** Segregate and re-label **AND:** Modify label procedures as necessary. Retrain involved staff.
Verification		Review monitoring and corrective action records within one week and verification records within reasonable time.
Records		Label log; Packing log; Corrective Actions

Signature:	**Date:**

HACCP Plan Form

Firm Name *ABC Tuna Company*	**Product Description** *Yellowfin Tuna Loins (wild caught)*
Firm Location *Anywhere USA*	**Method of Storage & Distribution** *Chilled, stored and distributed packed in ice under refrigeration to retail operations*
	Intended Use and Consumer: *Raw fish to be cooked before eaten by general public*

Critical Control Point (CCP)		**CCP 4: FINISHED PRODUCT STORAGE**
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**	The temperature of the cooler
	How	Measure cooler temperature 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 once per day
	Who	Cooler manager
Corrective Action		**IF** the cooler temperature is exceeded, **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 using table 7-2, page 119 of the *FDA Hazards and Controls Guidance* (4th Edition). **OR:** Chill and hold the lot of loins, and test for histamine in 60 loins minimum, representatively selected throughout the same lot and reject the entire lot if any loin (single fish loin) measures over 50ppm; **OR:** Divert to a non-food use; **OR:** Destroy lot. **AND:** Prevent further deviation by moving the affected product in the malfunctioning cooler to another cooler and address the root cause deviation by making repairs or adjustments to the malfunctioning cooler.
Verification		Before a temperature-recording device is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. **AND:** Daily accuracy checks of thermometers **AND:** Annual calibration of thermometers or per manufacturer's instructions. **AND:** Review monitoring and corrective action records within one week and verification records within reasonable time.
Records		Refrigerated Storage Log and Corrective Action Log, accuracy and calibration Logs.

Signature:	**Date:**

HACCP Plan Form (*landscape format)*

Firm Name *ABC Tuna Company*	**Product Description** *Yellowfin Tuna Loins (wild caught)*
Firm Location *Anywhere USA*	**Method of Storage & Distribution** *Chilled, stored and distributed packed in ice under refrigeration to retail operations*
Signature	**Intended Use & Consumer** *Raw fish to be cooked before eaten by general public*
Date	

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Receive Fresh, Eviscerated Tuna from Harvester	Scombrotoxin (histamine) formation	<u>All lots received with harvest vessel records that show :</u> 1. Fish were gilled/gutted and chilling within 12 hours after death	1. Harvest Vessel Records (Includes date and time of catch and chilling with ice.)	1. Review of harvest vessel records	Every delivered lot	Receiving supervisor	**IF** lots with no or incomplete vessel records ***or*** when internal temperature has not been met **THEN** Chill and hold the lot of tuna, and test for histamine in 60 fish minimum, representatively selected throughout the same lot; reject the entire lot if any tuna (single fish) measures over 50ppm **OR:** Reject lot **IF:** Sensory assessments indicate > 2.5% decomposition	Review monitoring and corrective action records within one week and verification records within reasonable time. Quarterly histamine testing on select suppliers; Training for anyone doing sensory assessment Daily accuracy checks of thermometers; Annual calibration of thermometers or per manufacturer's directions Annual sensory retraining for anyone	Harvest vessel records; Receiving off-loading records; Receiving sensory records; Receiving internal temperature records; Corrective action records; Accuracy and calibration records; and Training records
		<u>At receipt (primary processor):</u> 2. Less than 2.5% decomposition in each delivered lot (e.g. no more than 2 fish out of 118 fish)	2. Amount of decomposition in each lot based on trained sensory evaluations	2. Sensory evaluation (at least 118 tuna from the delivered lot or all tuna for smaller lots)	Every delivered lot	Receiving staff			

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
		3. Tuna internal temperature is ≤ 40°F	3. Date and time of offloading AND internal temperature of representative number of largest tuna in the delivered lot at off-loading (concentrating on any tuna showing signs of mishandling)	3. Thermometer (1 fish/ 1000 lbs, minimum 12 fish per lot)	Every delivered lot	Receiving supervisor	**THEN:** Chill and hold the lot of tuna, and test for histamine in 60 fish minimum, representatively selected throughout the same lot; reject the entire lot if any tuna (single fish) measures over 50ppm **AND**: If the lot is accepted, perform 100% sensory on fish for decomposition to ensure that any decomposed fish is destroyed **OR:** Reject the lot **AND:** Discuss problems with boat captain and/or discontinue use of supplier if problem persists and proof of onboard practices have not improved	that does sensory testing	
Iced Storage	Scombrotoxin (histamine) formation	Whole, eviscerated tuna completely surrounded by ice while stored	Adequacy of ice	Visual check of representative number of containers in storage	Beginning and end of each day during business operating hours	Cooler manager	**IF** the amount of ice is not adequate **THEN:** Re-ice and move to another cooler if necessary. Evaluate fish for total time and temperature exposure. This includes exposures during processing operations using table 7-2, page	Review monitoring and corrective action records within one week and verification records within reasonable time. Periodic measurement of internal temperature of fish	Ice check log (including approximate number of containers in cooler and number of containers checked for ice) 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			
							119 of the *FDA Hazards and Controls Guidance* (4th Edition) and continuous temperature recorder on cooler. **OR:** Chill and hold the lot of tuna, and test for histamine in 60 fish minimum, representatively selected throughout the same lot; reject the entire lot if any tuna (single fish) measures over 50ppm **OR:** Destroy lot **AND:** Determine and correct problem for inadequate icing. Retrain involved staff.	Daily accuracy checks of thermometers Annual calibration of thermometers or per manufacturer's directions	

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Pack/ Weigh/ Label Loins	Food Allergens	All containers of fish must be identified with the correct market name	Label rolls Label on product containers	Visual check of label roll Visual examination of labels on finished product	One roll in each box of labels At beginning of production and representative number of containers over production period	Packing supervisor	**IF:** Labels are inaccurate **THEN:** Return to producer for reprinting **AND:** Talk to producer to fix the issue and discontinue use if problem persists. **IF:** Container does not contain label or if improperly labeled **THEN:** Segregate and re-label **AND:** Modify label procedures as necessary. Retrain involved staff.	Review monitoring and corrective action records within one week and verification records within reasonable time.	Label log; Packing log; Corrective Actions
Finished Product Storage	Scombrotoxin (histamine) formation	The product is held at a cooler temperature of 40°F (4.4°C) or below.	The temperature of the cooler	Measure cooler temperature using a continuous temperature-recording device	Continuous monitoring during storage is accomplished by the device itself, with a visual check of the recorded data once per day	Cooler manager	**IF** the cooler temperature is exceeded, **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 using table 7-2, page 119 of the *FDA Hazards and Controls Guidance* (4th Edition). **OR:** Chill and hold the lot of loins, and test for histamine in 60 loins minimum, representatively	Before a temperature-recording device is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. **AND:** Daily accuracy checks of thermometers **AND:** Annual calibration of thermometers or per manufacturer's instructions. **AND:** Review monitoring and corrective action records within one week and verification	Refrigerated Storage Log and Corrective Action Log; Accuracy and calibration Logs.

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
							selected throughout the same lot and reject the entire lot if any loin (single fish loin) measures over 50ppm; **OR:** Divert to a non-food use; **OR:** Destroy lot. **AND:** Prevent further deviation by moving the affected product in the malfunctioning cooler to another cooler and address the root cause deviation by making repairs or adjustments to the malfunctioning cooler.	records within reasonable time.	