



September 2020

Commercial Processing Example: Hot Smoked Salmon Fillets (farm-raised), Reduced-Oxygen Packed, Refrigerated

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 Controls Guidance* (4th Edition, 2020) and additional information available since the 2011 edition. 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 Smoked Fish Company, Anywhere, USA
Acceptable Market Name	Atlantic salmon (<i>Salmo salar</i>)
Source of Fishery Product	Farm-raised salmon purchased from primary processors.
Describe the Finished Food Product	Hot smoked salmon fillets
Method of Receiving, Storage and Distribution	Raw salmon are received and stored frozen. Finished smoked products in vacuum packages are stored and distributed refrigerated ≤40°F (4.4°C).
Finished Packaging Type	Smoked Atlantic salmon fillets packed in reduced oxygen packaging (vacuum packed)
Intended Use and Consumer	Cooked ready-to-eat smoked product, to be consumed by the general public.

Description of Process

Receive and storage packaging materials: Packaging materials are delivered in clean, well maintained and covered vehicles. All materials are checked for integrity and specifications before assigning lot codes for future use. All accepted materials are held in separate dry storage areas according to assigned lot codes.

Receive and Store dry ingredients – Salt and sugar are received from approved vendors in 50-pound containers. Salt and sugar are stored in original containers in dry storage area.

Receive and Store frozen salmon – Frozen headed and gutted farmed salmon (pelleted feed) are received from primary processors. After receipt, frozen salmon are moved into a storage freezer set at -10°F (-23.3°C) until needed for processing.

Thaw - Salmon is thawed in raw processing room in tanks with continuously flowing cold water for up to 2 hours.

Process room temperature is between 50°F (10°C) and 70°F (21°C).

Fillet/Trim - Employees fillet, trim and sort thawed salmon by size in the raw processing room. A uniform size will be sorted to suit the validated brining and smoking process. This operation takes less than one hour.

Brine - Up to 50 pounds of fillets, no larger than 5 pounds each, or thicker than 4cm, are placed into a tank. A quantity of 50 gallons of brine solution that has a minimum 60-degree salinometer reading is added. Each batch is brined for at least 24 hours under refrigeration in a dedicated cooler at ≤ 40°F (4.4°C). No additional ingredients or food additives are used with this product other than salt or sugar in the brine.

Note: Brining time, brine concentration, weight and thickness of each fish and amount of fish are based on a pre-determined validation study that demonstrates that this batch process will result in a minimum water phase

salt concentration of not less than 3.5% in the final finished product sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F.

Drain- Brined fillets are rinsed with ambient water temperature and then placed onto stainless steel racks for draining and surface drying prior to smoking. This step occurs in a designated refrigerated cooler maintained at $\leq 40^{\circ}\text{F}$ (4.4°C) or below and takes approximately one to two hours.

Hot Smoke/Cook - After draining, the racks are rolled into the smoker. The fish are processed through a pre-programmed drying, smoking and cooking cycle for approximately six hours. Using three probes inserted in the thickest part of 3 fillets located at the coolest spot in the smoker, the product achieves an internal temperature of 145°F (62.8°C) for 30 continuous minutes.

Note: The pre-programmed hot smoke/cook cycle time and temperature limits is based on a validated study that demonstrates that smoking salmon fillets at the predetermined ambient temperature during the pre-program cycle for 6 hrs., and in the predetermined coolest spot in the cooker, the product will achieve an internal product temperature of 145°F (62.8°C) for 30 minutes to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F.

Note: Moisture lost in the hot smoke cooking process will also impact the end product water phase salt

Cool - After smoking, the racks are removed from the smoker and allowed to cool at ambient temperature between 50°F (10°C) and 70°F (21°C) for up to 30 minutes. The racks are moved into a designated refrigerated cooler.

Refrigerated Storage -The product remains here at 40°F (4.4°C) or below until the next day when product is packaged.

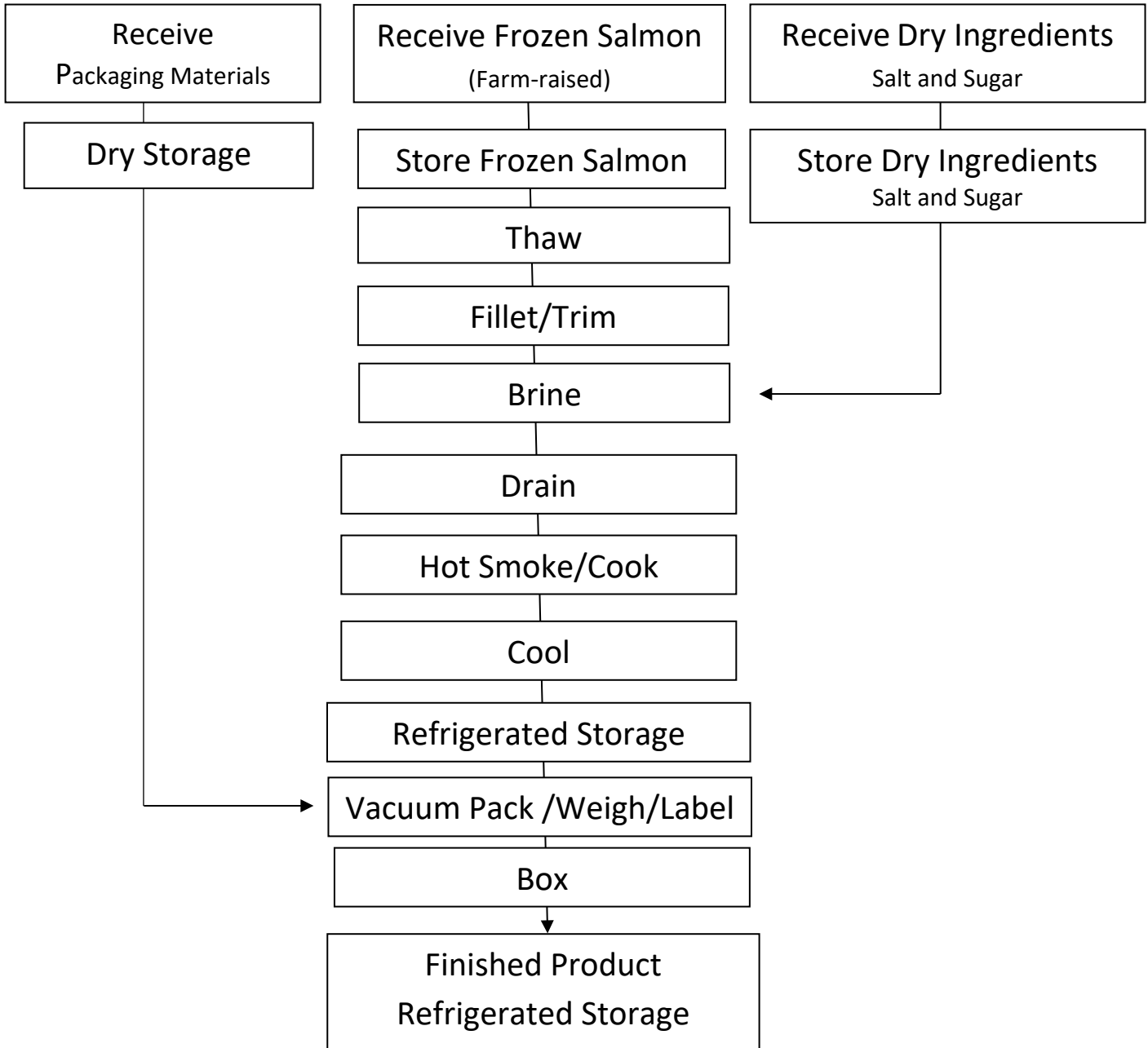
Vacuum Pack/Weigh/Label - Racks of chilled smoked salmon are removed from the cooler and the smoked fillets are individually placed into pre-labeled packages. The packages are vacuum sealed. This step takes less than 30 minutes.

Box – Packages of smoked fish are placed into 25-pound master boxes. These boxes are palletized. This step takes less than 30 minutes.

Finished product refrigerated storage – Pallets of packaged smoked fish are stored in a cooler at $\leq 40^{\circ}\text{F}$ (4.4°C) until distribution (to control the growth of *C. botulinum* type A and proteolytic types B and F). Finished packaged product may remain in refrigerated storage up to 48 hours before distribution.

Refrigerated Reduced Oxygen Packed Hot Smoked Salmon

Process Flow Diagram



Commercial Processing Example: *Hot Smoked Atlantic Salmon*

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 Smoked Fish Company																					
	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: <i>Salmon (farm-raised)</i> Market Name: <i>Atlantic Salmon</i> Scientific Name: <i>Salmo salar</i>			√			√				√				√					√		√	

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

The FDA recommendations indicate **8** potential hazards that are species (Table 3-2) or process-related (Table 3-4). Each potential hazard must be addressed in the Hazard Analysis.

1. Environmental Chemicals (species-related, chapter 9)
2. Aquaculture Drugs (species-related, chapter 11)
3. Pathogenic bacteria growth – temperature abuse (process-related, chapter 12)
4. *C. botulinum* Toxin (process-related, chapter 13)
5. Pathogenic bacteria survival through cooking and pasteurization (process-related hazard, chapter 16, Hot smoked fish)
6. Food Allergens (process-related, chapter 19)
7. Food Intolerances Substances (process-related, chapter 19)
8. Metal Inclusion (process-related, chapter 20)

Hazards Not Considered in the Hazard Analysis: Parasites (species-related hazard, chapter 5) do not need to be identified in the hazard analysis because the supplier for ABC Smoked Fish Company identifies the use of pelleted feed in the aquaculture operation that supplies the fish. As per Table 3-2, superscript 4 “fish raised only on pelleted feed in an aquaculture operation do not have the same parasite hazard as wild-caught.”

Instructors Note: There are other options for the control of parasites: 1) A secondary processor could receive fish with documented assurance that the supplier has killed parasites using freezing time and temperature controls. Or 2). A secondary processor with a cooking CCP can control the parasite hazard in their HACCP plan at the cooking step.

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 Smoked Fish Company</i>	Product Description: <i>Hot smoked Atlantic salmon in reduced oxygen package</i>
Firm Location: <i>Anywhere, USA</i>	Method of Storage & Distribution: <i>Refrigerated at ≤ 40°F (4.4°C).</i>
	Intended Use & Consumer: <i>Ready-to-eat product to be consumed by general public without further cooking</i>

(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)
Receive Packaging Materials	Environmental chemicals	No	Not reasonably likely to occur in packaging materials		
	Aquaculture drugs	No	Not reasonably likely to occur in packaging materials		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely to occur in packaging materials		
	Pathogenic bacteria survival through cooking	No	Not reasonably likely to occur in packaging materials		
	<i>C. botulinum</i> toxin	No	Not reasonably likely to occur in packaging materials		
	Undeclared Food Allergens	No	Not reasonably likely to occur in packaging materials		
	Food Intolerance Substances	No	Not reasonably likely to occur in packaging materials		
	Metal inclusion	No	Not reasonably likely to occur in packaging materials		
Store Packaging Materials	Environmental chemicals	No	Not reasonably likely to occur in packaging materials		
	Aquaculture drugs	No	Not reasonably likely to occur in packaging materials		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely to occur in packaging materials		
	Pathogenic bacteria survival through cooking	No	Not reasonably likely to occur in packaging materials		
	<i>C. botulinum</i> toxin	No	Not reasonably likely to occur in packaging materials		
	Undeclared Food Allergens	No	Not reasonably likely to occur in packaging materials		

(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)
	Food Intolerance Substances	No	Not reasonably likely to occur in packaging materials		
	Metal Inclusion	No	Not reasonably likely to occur in packaging materials		
Receive Dry Ingredients (Salt and Sugar)	Environmental chemicals	No	Not reasonable likely to occur in ingredients		
	Aquaculture drugs	No	Not reasonably likely to occur in ingredients		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely to occur in ingredients		
	Pathogenic bacteria survival through cooking	No	Not reasonably likely to occur at this step		
	<i>C. botulinum</i> toxin	No	Not reasonably likely to occur in dry ingredients		
	Undeclared Food Allergens	No	Salt & sugar are not food allergens		
	Food Intolerance Substances	No	No additives are used		
	Metal Inclusion	No	Not likely to occur at this step; not likely source		
Store Dry Ingredients (Salt & Sugar)	Environmental chemicals	No	Not reasonably likely to occur at this step		
	Aquaculture drugs	No	Not reasonably likely to occur at this step		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely to occur at this step		
	Pathogenic bacteria survival through cooking	No	Not reasonably likely to occur at this step		
	<i>C. botulinum</i> toxin	No	Not reasonably likely to occur at this step		
	Undeclared Food Allergens	No	Salt and sugar are not food allergens		
	Food Intolerance Substances	No	No additives are used		
	Metal Inclusion	No	Not reasonably likely to occur at this step		

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Receive Frozen Salmon	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely in frozen salmon		
	Pathogenic bacteria survival through cooking	No	Cooking occurs later in process		
	<i>C. botulinum</i> toxin	No	Not reasonably likely to occur in frozen salmon; not packaged in ROP		
	Undeclared Food Allergens	Yes	Salmon is a major food allergen	Finished product label applied at vacuum pack/ weigh/label step will identify fish market name (Atlantic salmon).	No
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		
	Metal inclusion	No	Not likely to occur at this step; not likely source		
Store Frozen Salmon	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely in frozen salmon		
	Pathogenic bacteria survival through cooking	No	Cooking occurs later in process		
	<i>C. botulinum</i> toxin	No	Not reasonably likely to occur in frozen salmon; not packaged in ROP		
	Undeclared Food Allergens	Yes	Salmon is a major food allergen	Finished product label applied at vacuum pack/ weigh/label step will identify fish market name (Atlantic salmon).	No
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		
	Metal inclusion	No	Not likely to occur at this step; not likely source		

(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)
Thaw	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely to occur during processing time below 70°F (FDA Guidance, p. 234)		
	Pathogenic bacteria survival through cooking	No	Cooking occurs later in process		
	<i>C. botulinum</i> toxin	No	Not reasonably likely to occur in frozen salmon; not packaged in ROP		
	Undeclared Food Allergens	Yes	Salmon is a major food allergen	Finished product label applied at vacuum pack/ weigh/label step will identify fish market name (Atlantic salmon).	No
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		
	Metal inclusion	No	Not likely to occur at this step; not likely source		
Fillet/Trim	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely to occur during processing time below 70°F and short process (FDA Guidance, p. 234)		
	Pathogenic bacteria survival through cooking	No	Cooking occurs later in process		
	<i>C. botulinum</i> toxin	No	No reduced oxygen package at this step		
	Undeclared Food Allergens	Yes	Salmon is a major food allergen	Finished product label applied at vacuum pack/ weigh/label step will identify fish market name (Atlantic salmon).	No
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		
	Metal Inclusion	No	Not reasonably like to occur with handheld utensils/knives (FDA Guidance, p. 386)		

(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)
Brine	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	Yes	Pathogens could grow if time/temperature abuse occurs	Temperature control during brining (40°F (4.4°C) or below)	Yes
	Pathogenic bacteria survival through cooking	No	Cooking occurs later in process		
	<i>C. botulinum</i> toxin	Yes	<i>C. botulinum</i> toxin could form in finished product which is in a reduced oxygen package	Brine (to achieve 3.5% water phase salt in finished products as a hurdle to <i>C. bot.</i> toxin production)	Yes
	Undeclared Food Allergens	Yes	Salmon is a major food allergen	Finished product label applied at vacuum pack/weigh/label step will identify fish market name (Atlantic salmon).	No
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		
	Metal Inclusion	No	Not likely to occur at this step; not likely source		
Drain	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely to occur during processing time below 70°F (FDA Guidance, p. 234)		
	Pathogenic bacteria survival through cooking	No	Cooking occurs later in process		
	<i>C. botulinum</i> toxin	No	No reduced oxygen environment at this step		
	Undeclared Food Allergens	Yes	Salmon is a major food allergen	Finished product label applied at vacuum pack/weigh/label step will identify fish market name (Atlantic salmon).	
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		No
	Metal Inclusion	No	Not likely to occur at this step; not likely source		

(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)
Hot Smoke/ Cook	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	Yes	Pathogens could grow if time/temperature abuse occurs	Established time and temp cooking procedures (to reach internal temp. of at least 145°F (62.8°C) for 30 min)	
	Pathogenic bacteria survival through cooking	Yes	Proper hot smoking (cooking) required to eliminate pathogens	Established time and temp cooking procedures (to reach internal temp. of at least 145°F (62.8°C) for 30 min)	Yes
	<i>C. botulinum</i> toxin	Yes	<i>C. botulinum</i> toxin could form in finished product which is in a reduced oxygen package	Established time and temp cooking procedures to achieve WPS of 3.5% or greater (to reach internal temp of at least 145°F (62.8°C) for 30 min, with drying) as a hurdle with brining to prevent <i>C. botulinum</i> Type E	Yes
	Undeclared Food Allergens	Yes	Salmon is a major food allergen	Finished product label applied at vacuum pack/weigh/label step will identify fish market name (Atlantic salmon).	Yes
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		No
Cool	Metal Inclusion	No	Not likely to occur at this step; not likely source		
	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely to occur; Pathogens eliminated at smoke/cook step; insufficient time for growth in cooler; and re-contamination controlled by SCPs.		
	Pathogenic bacteria survival through cooking	No	Prior hot smoking (cooking) step eliminated pathogens		
<i>C. botulinum</i> toxin	No	No reduced oxygen package 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)
	Undeclared Food Allergens	Yes	Salmon is a major food allergen	Finished product label applied at vacuum pack/weigh/label step will identify fish market name (Atlantic salmon).	No
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		
	Metal Inclusion	No	Not likely to occur at this step; not likely source		
Refrigerated storage	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	Yes	Time/temperature abuse could allow pathogens to grow if product is re-contaminated	Temperature Control. (Cooler at temperature at 40°F (4.4°C) or below)	Yes
	Pathogenic bacteria survival through cooking	No	Prior hot smoking (cooking) step eliminated pathogens		
	<i>C. botulinum</i> toxin	No	Not in ROP at this step; prior brining and hot smoking steps provided additional barrier for <i>C. botulinum</i> growth; re-contamination controlled by SCPs		
	Undeclared Food Allergens	Yes	Salmon is a major food allergen	Finished product label applied at vacuum pack/weigh/label step will identify fish market name Atlantic salmon.	No
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		
Metal inclusion	No	Not likely to occur at this step; not likely source			
Vacuum Pack/ Weigh/Label	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step; re-contamination controlled by SCPs		
	Pathogenic bacteria survival through cooking	No	Prior hot smoking (cooking) step eliminated pathogens		

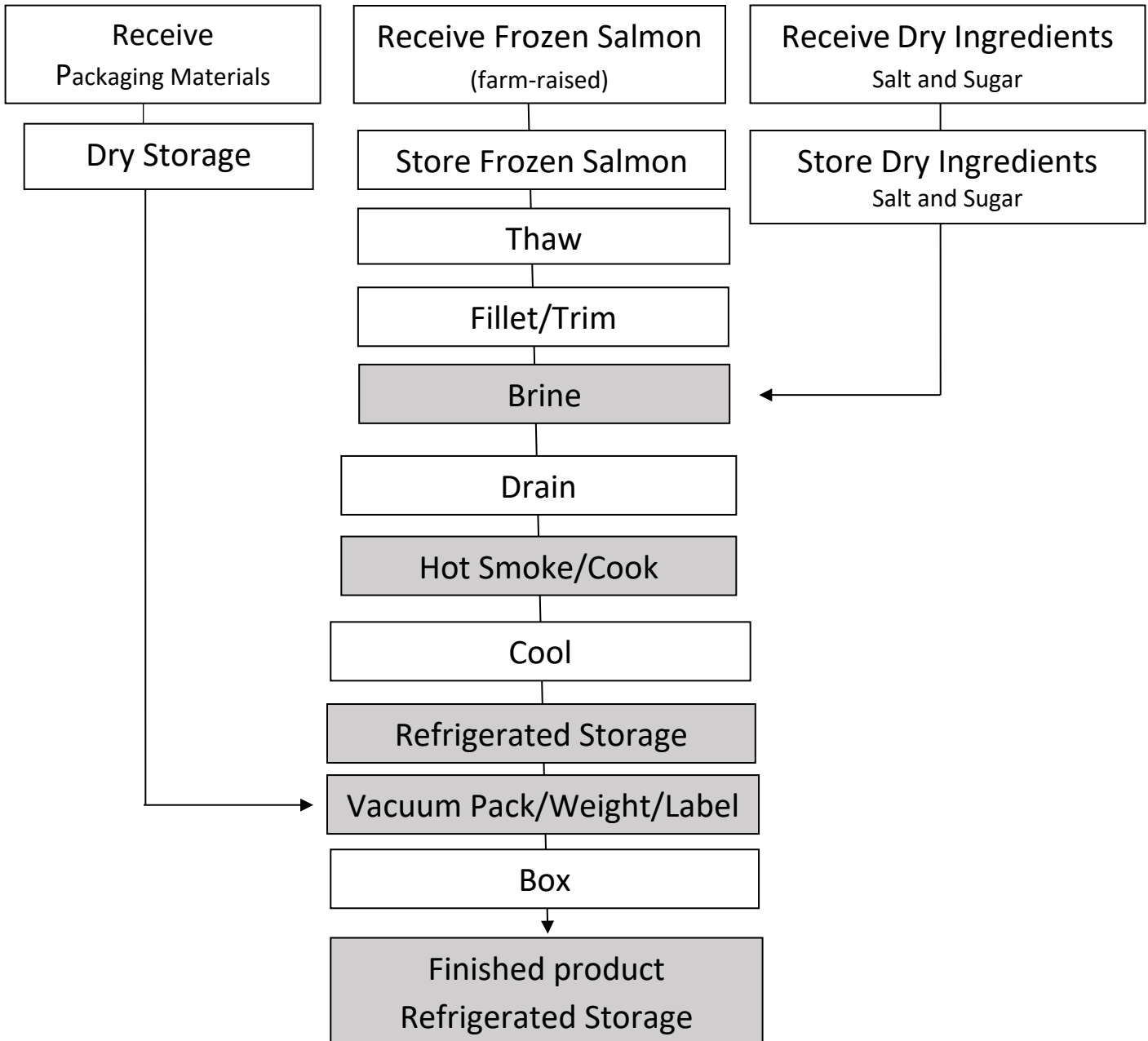
(1) Processing Step	(2) List all potential food safety hazards that could be associated with this product and process.	(3) Is the potential food safety hazard significant (introduced, enhanced or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent this significant hazard?	(6) Is this step a Critical Control Point? (Yes or No)
	<i>C. botulinum</i> toxin <i>(Note: some states require a label statement that product must be kept below 38°F. In this situation this step would be a CCP for this hazard.)</i>	No	Not reasonably likely to occur due to short time at this step and prior brining and hot smoking steps provided additional barrier for <i>C. botulinum</i> growth; re-contamination controlled by SCPs		
	Undeclared Food Allergens	Yes	Salmon is a major food allergen	Labels applied at this step must contain the market name "Atlantic Salmon"	Yes
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		
	Metal Inclusion	No	Not likely to occur at this step; not likely source		
Box	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		
	Pathogenic bacteria growth – temperature abuse	No	Not reasonably likely to occur due to short time at this step		
	Pathogenic bacteria survival through cooking	No	Prior hot smoking (cooking) step eliminated pathogens		
	<i>C. botulinum</i> toxin	No	Not reasonably likely to occur due to short time at this step and prior brining and hot smoking steps provided additional barrier for <i>C. botulinum</i> growth		
	Undeclared Food Allergens	No	Already controlled at labeling step		
	Food Intolerance Substances	No	No additives are used		
Finished Product Refrigerated Storage	Environmental chemicals	No	Controlled by primary processor		
	Aquaculture drugs	No	Controlled by primary processor		

(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	Yes	Time/temperature abuse could allow pathogens to grow if product is re-contaminated	Temperature Control (cooler at temperature at 40°F (4.4°C) or below)	Yes
	Pathogenic bacteria survival through cooking	No	Prior hot smoking (cooking) step eliminated pathogens		
	<i>C. botulinum</i> toxin	Yes	<i>C. botulinum</i> toxin could form in finished product which is in a reduced oxygen package exposed to excessive time and temperature abuse	Temperature Control (Although prior brining and hot smoking steps provided additional barrier for <i>C. botulinum</i> growth, the product should be stored in cooler at temperatures at 40°F (4.4°C)* or below to provide an additional hurdle to growth for <i>C. botulinum</i>)	Yes
	Undeclared Food Allergens	No	Already controlled at labeling step		
	Food Intolerance Substances	No	No additives are used in primary or secondary processing		
	Metal Inclusion	No	Not likely to occur at this step; not likely source		

Instructors Note: *In some states, the critical limit is 38°F (3.3°F) or below and not 40°F (4.4°C) or below. Check with your State for required critical limit for safety.

Reduced Oxygen Packed Hot Smoked Salmon Process Flow Diagram

Shaded steps are Critical Control Points



HACCP Plan Form

Firm Name <i>ABC Smoked Fish Company</i>		Product Description <i>Hot smoked salmon in reduced oxygen package</i>
Firm Location <i>Anywhere USA</i>		Method of Storage & Distribution <i>Refrigerated at ≤40°F(4.4°C).</i>
		Intended Use & Consumer <i>Ready- to-eat product to be consumed by general public without further cooking</i>
Critical Control Point (CCP)	CCP 1: BRINE Brining time, brine concentration, weight of each fish, thickness of each fish and amount of fish are based on a pre-determined validation study that demonstrates that this batch process will result in a minimum water phase salt (WPS) concentration of not less than 3.5% in the final finished product. And brine is performed at refrigerated temperatures of 40 F (4.4°C) or below.	
Significant Hazard(s)	<ol style="list-style-type: none"> 1. <i>C. botulinum</i> toxin 2. Pathogenic bacteria growth- temperature abuse 	
Critical Limits for each Control Measure	<ol style="list-style-type: none"> 1. a). Minimum brining time of 24 hours; b). 50 gallons of brine with a minimum 60° salinometer reading at start of process; c). No more than 50 pounds of fish fillets; d). fillet not larger than 5 pounds and no thicker than 4 cm each added to brine tank (ensures not less than 3.5% WPS); and, 2. Fish are brined in refrigeration at a temperature of 40°F (4.4°C) or below 	
Monitoring	What	<ol style="list-style-type: none"> 1. a) Start and end time in brine; and, b) Volume of brine and degrees salt; and c) Total weight of fillets in brine tank and, d) Weight and thickness of largest fillet; and 2. Cooler temperature
	How	<ol style="list-style-type: none"> 1. Visual check of time; Visual salinometer scale reading; Fill to pre-measured mark; scale for fish weight. 4 cm gap tool to pass fish through. 2. Continuous recording thermometer
	When	<ol style="list-style-type: none"> 1. Each batch at the start of the brine process 2. Continuous with visual check once per batch
	Who	Brine Manager or designee
Corrective Action	<ol style="list-style-type: none"> 1. IF Brining time is not met; THEN, hold in brine until 24 hours is reached; If brining formulation is not right, then add more salt and mix until salinometer reads 60°; Divert fillets > 5 pounds or fillets thicker than 4 cm to another batch process. Adjust /Remove fillets until weight is 50 lbs. or less; Move brine tanks to another cooler and fix cooler or adjust thermostat. Retrain involved staff. 2. Determine safety of product based on time and temperature exposure. Discard product if not safe. 	
Verification	<ol style="list-style-type: none"> 1. Quarterly lab analysis to verify that finished products have 3.5% water phase salt; Daily accuracy check of scale; and Annual calibration of scale 2. Check accuracy of thermometer before initial use and then daily, and then annual calibration. Brine validation study used to develop brine recipe & time Weekly review of brine logs, and corrective action records. 	
Records	Brine Logs Temperature recording chart and Temperature Log Corrective action records Brine/WPS Validation Study Accuracy check and calibration records Training Records	
Signature:		Date:

HACCP Plan Form

Firm Name <i>ABC Smoked Fish Company</i>	Product Description <i>Hot smoked salmon in reduced oxygen package</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Refrigerated at ≤40° F (4.4°C).</i>
	Intended Use & Consumer <i>Ready- to-eat product to be consumed by general public without further cooking</i>

Critical Control Point (CCP)	CCP 2: HOT SMOKE/ COOK
Significant Hazard(s)	Pathogenic bacteria growth and survival <i>C. botulinum</i> toxin
Critical Limits for each Control Measure	Internal fish temperature at least 145°F (62.8°C) for at least 30 continuous minutes
Monitoring	What Internal fish temperature at the thickest portion of largest fish taken from three fish; Time fish are at target internal temperature
	How Continuous temperature recording device with three temperature probes
	When Continuous with visual check of recording chart for each batch
	Who Smoker operator
Corrective Action	IF proper time and internal temperature is not reached, THEN re-cook at 145°F (62.8°C) for 30 minutes or destroy batch and adjust or repair equipment. Retrain involved staff.
Verification	Weekly review of monitoring and corrective action records Check accuracy of temperature recording device before initial use and before each batch. Calibrate recording device annually Validate cooking process
Records	Time and Temperature Recording Chart and Smoker Log Accuracy check and calibration records; AND; corrective action records. Validation of cooking process Training Records

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Smoked Fish Company</i>	Product Description <i>Hot smoked Atlantic salmon in reduced oxygen package</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Refrigerated at ≤40°F (4.4°C).</i>
	Intended Use & Consumer <i>Ready- to-eat product to be consumed by general public without further cooking</i>

Critical Control Point (CCP)	CCP 3: Refrigerated Storage
Significant Hazard(s)	Pathogenic bacteria growth – temperature abuse
Critical Limits for each Control Measure	Cooler temperature is maintained at 40°F (4.4°C) or below
Monitoring	What Cooler temperature
	How Continuous recording thermometer with visual checks
	Frequency Continuous with visual check of recording chart once a day
	Who Cooler Manager or designee
Corrective Action	<p>IF cooler temperature is above 40°F (4.4°C), THEN move product to another cooler or ice and hold for evaluation. Adjust or repair cooler as necessary. Evaluate product safety by determining cumulative exposure temperature and time above 40°F (4.4°C).</p> <p>Destroy if necessary.</p> <p>Retrain involved staff.</p>
Verification	<p>Weekly review of monitoring and corrective action records.</p> <p>Check accuracy of time temperature recorder daily.</p> <p>Calibrate temperature recorder once per year</p>
Records	<p>Cooler Temperature Log</p> <p>Time /temperature recording chart</p> <p>Corrective action records.</p> <p>Accuracy check and calibration records; AND;</p> <p>Training Records</p>

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Smoked Fish Company</i>	Product Description <i>Hot smoked salmon in reduced oxygen package</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Refrigerated at ≤40° F (4.4°C).</i>
	Intended Use & Consumer <i>Ready- to-eat product to be consumed by general public without further cooking</i>

Critical Control Point (CCP)	CCP 4: Vacuum Pack/Weigh/Label	
Significant Hazard(s)	Undeclared Food Allergens	
Critical Limits for each Control Measure	All product labels will contain "Atlantic Salmon" in the ingredient list	
Monitoring	What	The ingredients listing on labels of finished product
	How	Visual comparison of the label against the product specification for accuracy
	Frequency	At the start of the production lot AND At least every 2 hours.
	Who	Packing supervisor or designee
Corrective Action	<p>IF the label does not have 'Atlantic salmon' in the ingredient list, THEN hold and isolate labeled product since the last acceptable inspection of labels; AND inspect 100% of affected product and relabel mislabeled product; AND inspect the remaining labels staged for use and remove inaccurate labels from processing area; AND review a representative sample of labels in storage, and hold and isolate inaccurate labels, if appropriate.</p> <p>Discontinue use of label supplier until practices have been corrected. Modify labeling procedures, if appropriate.</p> <p>Retrain involved staff</p>	
Verification	<p>Weekly review of monitoring and corrective action record.</p> <p>Verify the product specification against raw material ingredients' label declaration at least annually and when changes to suppliers or formulation occur.</p>	
Records	<p>Label Check monitoring record</p> <p>Corrective Action record</p> <p>Training Records</p>	

Signature:	Date:
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HACCP Plan Form

Firm Name <i>ABC Smoked Fish Company</i>	Product Description <i>Hot smoked salmon in reduced oxygen package</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Refrigerated at ≤40° F (4.4°C).</i>
	Intended Use & Consumer <i>Ready- to-eat product to be consumed by general public without further cooking</i>

Critical Control Point (CCP)		CCP 5: Finished Product Refrigerated Storage
Significant Hazard(s)		Pathogenic bacteria growth – temperature abuse <i>C. botulinum</i> growth and toxin formation
Critical Limits for each Control Measure		Cooler temperature is maintained at 40°F (4.4°C) * or below
Monitoring	What	Cooler temperature
	How	Continuous recording thermometer with visual checks
	Frequency	Continuous with visual check of recording chart once a day
	Who	Cooler Manager or designee
Corrective Action		IF cooler temperature is above 40°F (4.4°C), THEN move product to another cooler or ice and hold for evaluation. Adjust or repair cooler as necessary. **Evaluate product safety by determining cumulative exposure temperature and time above 40°F (4.4°C). Destroy if necessary. Retrain involved staff.
Verification		Weekly review of monitoring and corrective action records. Check accuracy of time temperature recorder daily. Calibrate temperature recorder once per year
Records		Cooler Temperature Log Time /temperature recording chart Accuracy check and calibration records; AND; corrective action records. Training Records

Signature:	Date:
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***Instructors Note:** In some states, this is 38°F (3.3°C) or below and not 40°F (4.4°C) or below. Check with your State for required critical limit for safety.

Firm Name <i>ABC Smoked Fish Company</i>	Product Description <i>Hot smoked salmon in reduced oxygen package</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Refrigerated at ≤40°F (4.4°C).</i>
	Intended Use & Consumer <i>Ready-to-eat product to be consumed by general public without further cooking</i>

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
CCP 1: Brine (Brining time, brine concentration, weight of each fish, thickness of each fish and amount of fish are based on a pre-determined validation study that demonstrates that this batch process will result in a minimum water phase salt (WPS) concentration of not less than 3.5% in the final finished product. And brine is performed at refrigerated temperatures of 40 F (4.4°C) or below.)	<i>C. botulinum</i> growth and toxin formation	Minimum brining time of 24 hours; 50 gallons of brine with a minimum 60° salinometer reading at start of process; No more than 50 pounds of fish fillets; fillet not larger than 5 pounds and no thicker than 4cm each added to brine tank (ensures not less than 3.5% WPS); and,	Start and end time in brine; and Volume of brine and degrees salt; and Total weight of largest fillet and Thickness of largest fillet	Visual check of time; Visual salinometer scale reading; Fill to pre-measured mark; scale for fish weight. 4 cm gap tool to pass fish through.	Each batch at the start of the brine process	Brine Manager or designee	IF Brining time is not met; THEN , hold in brine until 24 hours is reached; If brining formulation is not right, then add more salt and mix until salinometer reads 60°; Divert fillets > 5 pounds or fillets thicker than 4 cm to another batch process. Adjust /Remove fillets until weight is 50 lbs. or less; Move brine tanks to another cooler and fix cooler or adjust thermostat. Retrain involved staff.	Quarterly lab analysis to verify that finished products have 3.5% water phase salt; Daily accuracy check of scale; and Annual calibration of scale Check accuracy of thermometer before initial use and then daily, and then annual calibration. Brine validation study used to develop brine recipe & time Weekly review of brine logs, and corrective action records.	Brine Logs Temperature recording chart and Temperature Log Corrective action records Brine/WPS Validation Study Accuracy check and calibration records Training Records
	Pathogenic bacteria growth-temp abuse	Fish are brined in refrigeration at a temperature of 40°F (4.4°C) or below.	Cooler temperature	Continuous recording thermometer	Continuous with visual check once per batch	Determine safety of product based on time and temperature exposure. Discard if not safe.			

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
CCP 2: Hot Smoke/Cook	Pathogenic bacteria growth and survival C. <i>botulinum</i> growth and toxin formation	Internal fish temperature at least 145°F (62.8°C) for at least 30 continuous minutes	Internal fish temperature at the thickest portion of largest fish taken from three fish; Time fish are at target internal temperature	Continuous temperature recording device with three temperature probes	Continuous with visual check of recording chart for each batch	Smoker operator	IF proper time and internal temperature is not reached, THEN re-cook at 145°F (62.8°C) for 30 minutes or destroy batch and adjust or repair equipment. Retrain involved staff.	Weekly review of monitoring and corrective action records Verify the product specification against raw material ingredients' label declaration at least annually and when changes to suppliers or formulation occur.	Label Check monitoring record Corrective Action record Training Records
CCP 3: Refrigerated Storage	Pathogenic bacteria growth – temperature abuse	Cooler temperature is maintained at 40°F (4.4°C) or below	Cooler temperature	Continuous recording thermometer with visual checks	Continuous with visual check of recording chart once a day	Cooler Manager or designee	IF cooler temperature is above 40°F (4.4°C), THEN move product to another cooler or ice and hold for evaluation. Adjust or repair cooler as necessary. Evaluate product safety by determining cumulative exposure temperature and time above 40°F (4.4°C). Destroy if necessary. Retrain involved staff.	Weekly review of monitoring and corrective action records. Check accuracy of time temperature recorder daily. Calibrate temperature recorder once per year	Cooler Temperature Log Time /temperature recording chart Corrective action records. Accuracy check and calibration records; AND; Training Records

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
CCP 4: Vacuum Pack/ Weigh/Label	Undeclared Food Allergens	All product labels will contain "Atlantic Salmon" in the ingredient list	The ingredients listing on labels of finished product	Visual comparison of the label against the product specification for accuracy	At the start of the production lot AND At least every 2 hours.	Packing supervisor or designee	<p>IF the label does not have 'Atlantic salmon' in the ingredient list, THEN hold and isolate labeled product since the last acceptable inspection of labels; AND inspect 100% of affected product and relabel mislabeled product; AND inspect the remaining labels staged for use and remove inaccurate labels from processing area; AND review a representative sample of labels in storage, and hold and isolate inaccurate labels, if appropriate.</p> <p>Discontinue use of label supplier; Modify labeling procedures, if appropriate. Retrain involved staff.</p>	Weekly review of monitoring and corrective action records	Label Check Report Training Records

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
CCP 5: Finished Product Refrigerated Storage	Pathogenic bacteria growth – temperature abuse <i>C. botulinum</i> growth and toxin formation	Cooler temperature is *40°F(4.4°C)** or less	Cooler temperature	Continuous recording thermometer with visual checks	Continuous with visual check of recording chart once a day	Cooler manager or designee	IF cooler temperature is above 40°F (4.4°C), THEN move product to another cooler or ice and hold for evaluation. Adjust or repair cooler as necessary. **Evaluate product safety by determining cumulative exposure temperature and time above 40°F (4.4°C). Destroy if necessary. Retrain involved staff.	Weekly review of monitoring and corrective action records. Check accuracy of time temperature recorder daily. Calibrate temperature recorder once per year	Cooler Temperature Log Time /temperature recording chart Accuracy check and calibration records; AND; corrective action records. Training Records

***Instructors Note:** In some states, the critical limit is 38°F (3.3°F) or below and not 40°F (4.4°C) or below. Check with your State for required critical limit for safety.

**** Instructors Note:** The Corrective action strategy for finished product cooler storage that is provided in this model is based on Table A-2 of the FDA *Hazards Guide*. For germination, growth and toxin formation for *C. bot* Type E and nonproteolytic Types B & F the maximum cumulative exposure at 38-41°F (3.3-5°C) is 7 days and from 42-50°F (6-10°C) is 2 days.