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Commercial Processing Example: *Trout (aquaculture), Raw, Frozen*

Model based on Supplier Certification Control Strategy

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 information available since the 2020 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	A to Z World Fish Company, Anywhere, World
Market Name	Aquaculture Rainbow trout (frozen), species *Oncorhynchus mykiss*
Source of Fishery Product	Whole aquaculture Rainbow trout are obtained directly from one aquaculture farm that is owned and operated by A to Z World Fish Company (Integrated Production).
Describe the Food	Raw, eviscerated, IQF (individually quick frozen) aquaculture Rainbow trout
Method of Receiving, Storage and Distribution	Rainbow trout are received live. After processing, they are stored and distributed frozen.
Finished Packaging Type	Frozen trout packed in oxygen permeable bags held in boxes
Intended Use and Consumer	Intended to be cooked prior to consumption by the general public

Description of Process

Receive 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.

Dry-store packaging materials – All accepted materials are held in separate dry storage areas according to assigned lot codes.

Receive live trout – Commercial lots of live Rainbow trout are obtained directly from the integrated aquaculture farm. At receiving, the incoming farm lots of Rainbow trout are identified and assigned batch numbers according to date of harvest and segregation plan for processing.

Stunning/Bleeding– Adhering to animal welfare protocol, live fish are stunned and killed through a water pump stunning/bleeding system (link).

Time from Receiving to Grading is less than 30 minutes.

Grading (combined steps) – Whole trout are placed in a hopper of cold flowing water and graded for size through an auto grading machine. The total time for grading is less than 10 minutes per assigned batch.

Evisceration – Rainbow trout are placed on a mounting bracket and conveyed through an evisceration machine. Total time for this process is less than 5 minutes per batch.

Processing/Filleting - Rainbow trout are filleted through an automated filleting machine. Total time for this process is less than 5 minutes per batch.

Individually Quick Frozen (IQF) – individual fillets are moved by conveyor belt through an IQF freezer; 2500 lbs. of fish fillets are individually quick frozen in 15 minutes.

Weigh/Pack/Label - After freezing, the finished product is conveyed via plastic conveyors to the packing station where the product is weighed, packed, and labeled in an automated packaging line. A computerized system weighs the correct amount of product into plastic oxygen permeable bags. Primary packages contain date code, batch number and proper ingredient labeling. All primary packages are master-cased as specified by the customer. This is a short step that typically takes less than 30 minutes.

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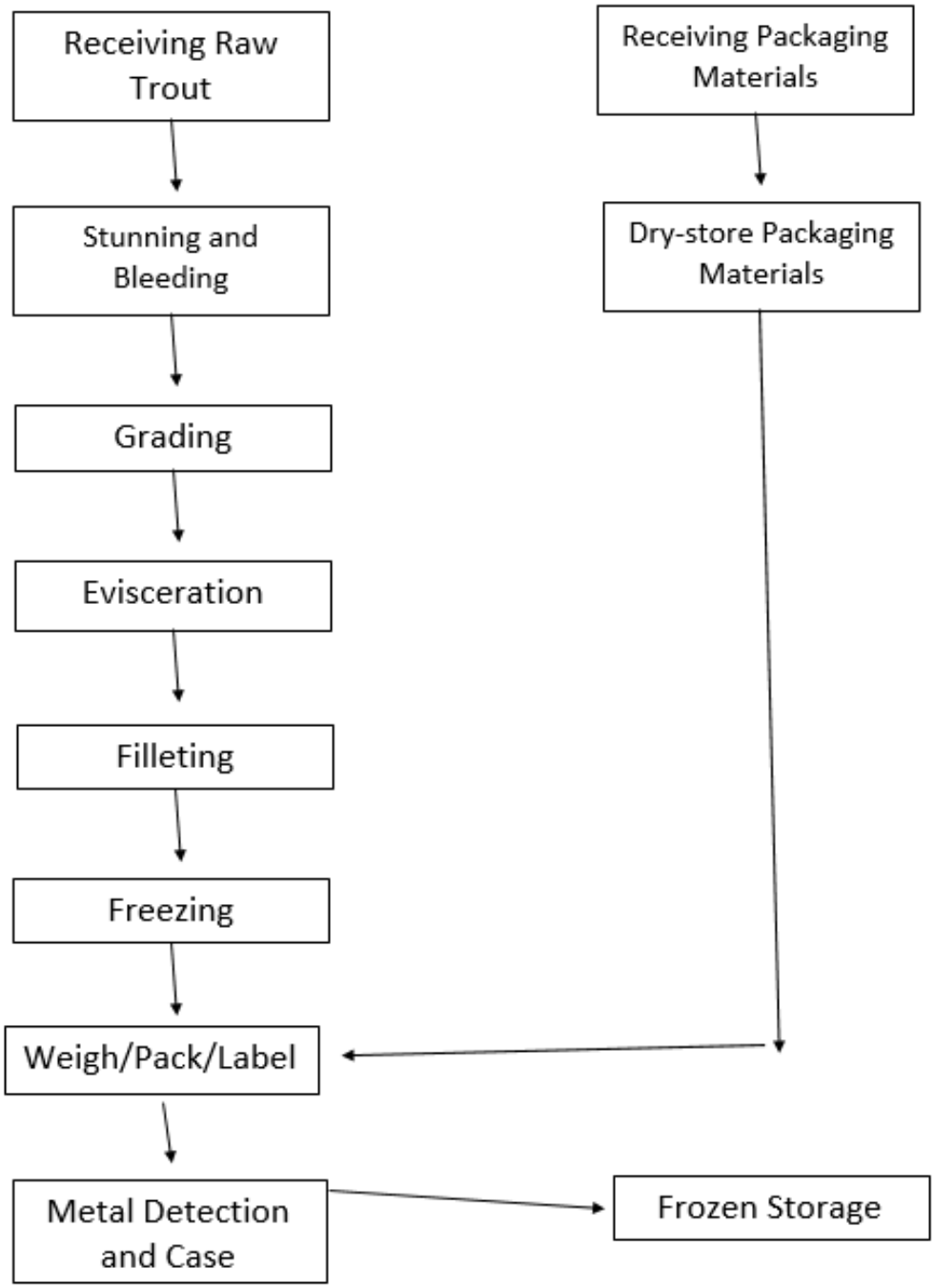
Metal Detection and Master Case - Packages are conveyed through a metal detector and packed into master cases. Each master case is marked with identical production date codes and batch numbers as used on the primary packages. As each master case is packed, it is palletized immediately in accordance with customer or company criterion. This step takes less than 30 minutes.

Frozen Storage – All finished product pallets are placed immediately into frozen storage prior to distribution. Products may be held up to 3 months prior to distribution.

A to Z World Fish Company

Process Flow Diagram – Raw Frozen Aquaculture Trout



Commercial Processing Example: *Trout (aquaculture), Frozen*

Example: For Illustrative Purposes Only. Models are based on current guidance contained in FDA's *Fish and Fishery Products Hazards and Control Guidance* (4th ed., 2020). Keep in mind that this model does not apply to all situations.

Description	**Company: A to Z World Fish Company**																				
	Where Product Is Purchased			How Product Is Received				How Product Is Stored				How Product Is Shipped				How Product is Packaged		Intended Use		Intended Consumer		
Fish or Shellfish Species	From Fisherman	From Fish Farm	From Processor	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Refrigerated	Iced	Frozen	Shelf-Stable	Air Packed	ROP*	Raw to be cooked	Raw RTE*	Cooked RTE*	General Public	At Risk Population
Common Name: Rainbow Trout (farm raised) **Market Name:** Trout **Scientific Name:** *O. mykiss*		√		√	√			√		√				√		√		√			√	

*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 3-3 (species-related hazards) and 3-4 (process-related hazards) in the FDA *Fish and Fishery 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 Guide indicates 6 potential hazards that are species- or process-related. The hazard analysis addresses all hazards pertinent to the current processing operations.

1. Environmental Chemicals (contaminants) – (species-related, chapter 9)
2. Aquaculture Drugs (residuals from illegal or improper application) – (species-related, chapter 11)
3. Pathogenic bacteria growth – temperature abuse – (process-related, chapter 12)
4. Food Allergens – (process-related, chapter 19)
5. Food Intolerance Substances– (process-related, chapter 19)
6. Metal Inclusion – (process-related, chapter 20)

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

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Hazard Analysis Worksheet

Firm Name *A to Z World Fish Co.*	**Product Description:** *Raw Aquaculture Trout*
Firm Location *Anywhere, World*	**Method of Storage & Distribution:** *Frozen*
	Intended Use & Consumer: *Cooked consumption by the general public*

(1) Processing Step	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
Receive Packaging Materials	Environmental chemicals	No	No prior exposure to environmental chemicals		
	Aquaculture drugs	No	No prior exposure to aquaculture drugs		
	Pathogenic bacteria growth – temperature abuse	No	Packing materials do not introduce pathogenic bacteria.		
	Food allergens	No	Packaging materials do not introduce allergens.		
	Food Intolerance Substances	No	No prior exposure to Food Intolerance Substances		
	Metal inclusion	No	Not reasonably likely in packaging materials		
Dry-Store Packaging Materials	Environmental chemicals	No	No prior exposure to environmental chemicals		
	Aquaculture drugs	No	No prior exposure to aquaculture drugs		
	Pathogenic bacteria growth – temperature abuse	No	Packing materials do not introduce pathogenic bacteria.		
	Food allergens	No	Dry storage does not introduce allergens		
	Food Intolerance Substances	No	No prior exposure to Food Intolerance Substances		
	Metal inclusion	No	Not reasonably likely during dry storage		

(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 Live Aquaculture Trout	Environmental chemicals	Yes	Chemical contaminants can occur in the farm environment	Lot-by-lot supplier's certification for environmental chemical controls.	Yes
	Aquaculture drugs	Yes	Illegal or improper level of drug residues may be in aquaculture farm-raised trout	Drug usage control records for each delivery that show that aquaculture drugs used are approved by FDA and used in accordance with all labeled conditions.	Yes
	Pathogenic bacteria growth – temperature abuse	No	Not likely to cause illness as the intended use is for the products to be cooked for or by the consumer prior to consumption.		
	Food allergens	Yes	Trout is a potential food allergen; hazard is introduced at receiving	Product label applied at Packing step will identify trout	No
	Food Intolerance Substances	No	Additives are not used on the farm or introduced at this step.		
	Metal inclusion	No	Not reasonably likely to occur at this step.		
Stunning/ Bleeding	Environmental chemicals	No	Not introduced, enhanced or controlled at this step		
	Aquaculture drugs	No	Not introduced, enhanced or controlled at this step		
	Pathogenic bacteria growth – temperature abuse	No	Not likely to cause illness as the intended use is for the products to be cooked for or by the consumer prior to consumption		
	Food allergens	Yes	Trout is a potential food allergen; hazard is introduced at receiving	Product label applied at Packing step will identify trout	No
	Food Intolerance Substances	No	Additives are not introduced at this step.		
	Metal inclusion	Yes	Introduction of metal fragments is likely to occur at this step	Use of Metal Detection at a later step	No
Grading	Environmental chemicals	No	Not introduced, enhanced or controlled at this step		
	Aquaculture drugs	No	Not introduced, enhanced or controlled at this step		

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(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
	Pathogenic bacteria growth – temperature abuse	No	Not likely to cause illness as the intended use is for the products to be cooked for or by the consumer prior to consumption		
	Food allergens	Yes	Trout is a potential food allergen; hazard is introduced at receiving	Product label applied at Packing step will identify trout	No
	Food Intolerance Substances	No	Additives are not introduced at this step.		
	Metal inclusion	No	Introduction of metal fragments is not reasonably likely to occur by the equipment types located at this step.		
Evisceration	Environmental chemicals	No	Not introduced, enhanced or controlled at this step		
	Aquaculture drugs	No	Not introduced, enhanced or controlled at this step		
	Pathogenic bacteria growth – temperature abuse	No	Not likely to cause illness as the intended use is for the products to be cooked for or by the consumer prior to consumption		
	Food allergens	Yes	Trout is a potential food allergen; hazard is introduced at receiving	Product label applied at Packing step will identify trout	No
	Food Intolerance Substances	No	Additives are not introduced at this step.		
	Metal inclusion	Yes	Introduction of metal fragments is likely to occur at this step	Use of Metal Detection at later step	No
Processing/ Fillet	Environmental chemicals	No	Not introduced, enhanced or controlled at this step		
	Aquaculture drugs	No	Not introduced, enhanced or controlled at this step		
	Pathogenic bacteria growth – temperature abuse	No	Not likely to cause illness as the intended use is for the products to be cooked for or by the consumer prior to consumption		
	Food allergens	Yes	Trout is a potential food allergen; hazard is introduced at receiving	Product label applied at Packing step will identify trout	No
	Food Intolerance Substances	No	Additives are not introduced 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)**
	Metal inclusion	Yes	Introduction of metal fragments is likely to occur at this step	Use of Metal Detection at later step	No
Freezing	Environmental chemicals	No	Not introduced, enhanced or controlled at this step		
	Aquaculture drugs	No	Not introduced, enhanced or controlled at this step		
	Pathogenic bacteria growth – temperature abuse	No	Not likely to cause illness as the intended use is for the products to be cooked for or by the consumer prior to consumption		
	Food allergens	Yes	Trout is a potential food allergen; hazard is introduced at receiving	Product label applied at Packing step will identify trout	No
	Food Intolerance Substances	No	Additives are not introduced at this step.		
	Metal inclusion	Yes	Introduction of metal fragments is likely to occur at this step – metal conveyor belt.	Use of Metal Detection at later step	No
Weigh/ Pack/ Label	Environmental chemicals	No	Not introduced, enhanced or controlled at this step		
	Aquaculture drugs	No	Not introduced, enhanced or controlled at this step		
	Pathogenic bacteria growth – temperature abuse	No	Not likely to cause illness as the intended use is for the products to be cooked for or by the consumer prior to consumption		
	Food allergens	Yes	Trout is a potential food allergen; hazard is introduced at receiving	Product label applied at Packing step will identify trout	No
	Food Intolerance Substances	No	Additives are not introduced at this step.		
	Metal inclusion	Yes	Introduction of metal fragments is likely to occur at this step – metal conveyor belt.	Use of Metal Detection at later step	No
Metal Detection and Case	Environmental chemicals	No	Not introduced, enhanced or controlled at this step		
	Aquaculture drugs	No	Not introduced, enhanced or controlled at this step		

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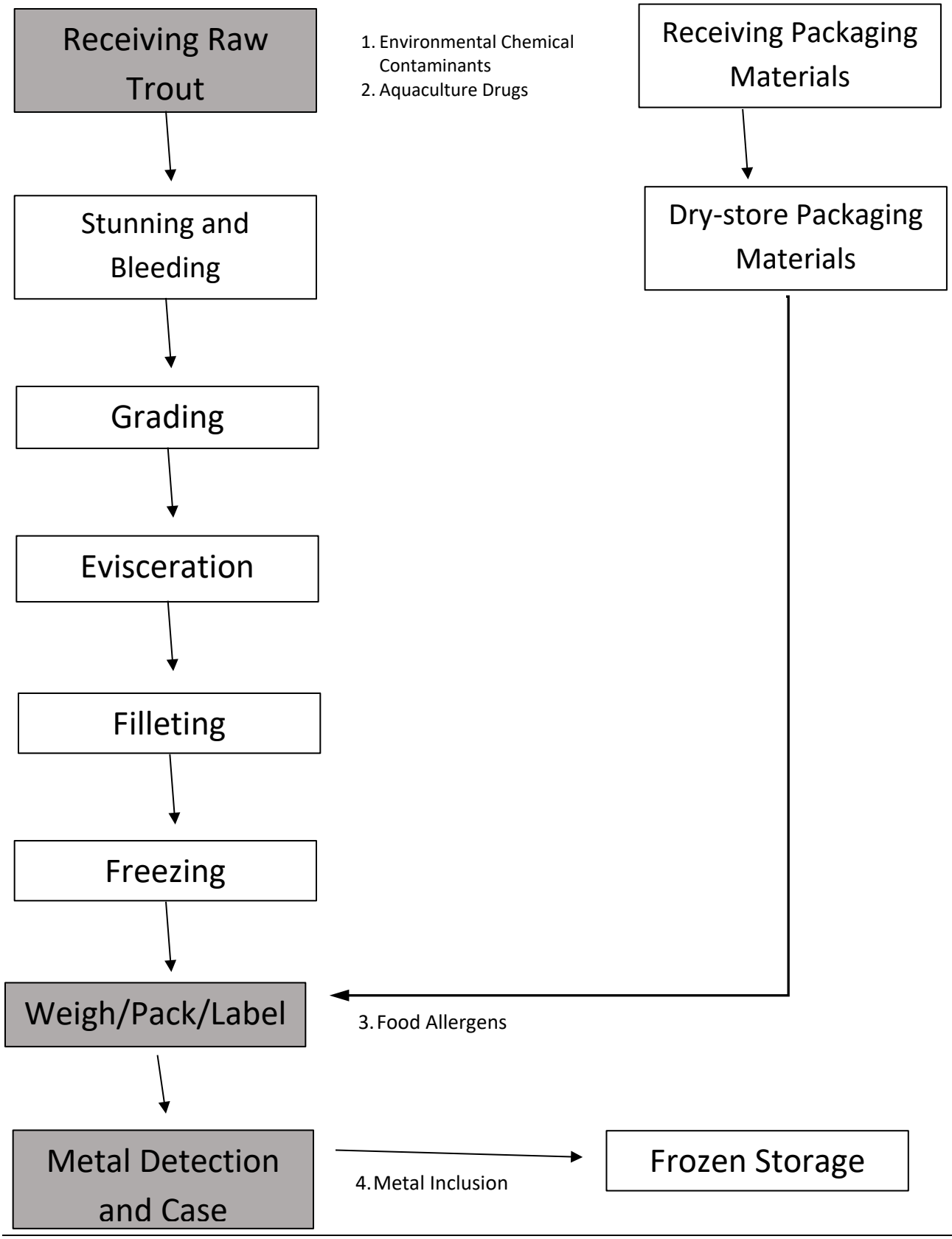
(1) Processing Step	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 3	(5) What **control measure(s)** can be applied to prevent this significant hazard?	(6) Is this step a **Critical Control Point**? **(Yes or No)**
	Pathogenic bacteria growth – temperature abuse	No	Not likely to cause illness as the intended use is for the products to be cooked for or by the consumer prior to consumption		
	Food allergens	No	Controlled at Packing Step		No
	Food Intolerance Substances	No	Additives are not introduced at this step.		
	Metal inclusion	Yes	Introduction of metal fragments is not likely to occur at this step, but it is controlled here.	Use of Metal Detection	Yes
Frozen Storage	Environmental chemicals	No	Not introduced, enhanced or controlled at this step		
	Aquaculture drugs	No	Not introduced, enhanced or controlled at this step		
	Pathogenic bacteria growth – temperature abuse	No	Not likely to cause illness as the intended use is for the products to be cooked for or by the consumer prior to consumption		
	Food allergens	No	Controlled at Packing Step		
	Food Intolerance Substances	No	Additives are not introduced at this step.		
	Metal inclusion	No	Introduction of metal fragments not reasonably likely to occur at this step		

Raw Frozen Aquaculture

Process Flow Chart

(Shaded steps indicate critical control points)



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HACCP Plan Form

Firm Name *A to Z World Fish Company*	**Product Description** *Individually quick frozen Rainbow trout fillets Oncorhynchus mykiss (O. mykiss)*
Firm Location *Anywhere World*	**Method of Storage & Distribution** *Frozen*
	Intended Use & Consumer *Product to be fully cooked and consumed by general public*

Critical Control Point (CCP)		**CCP 1: Receiving Step**
Significant Hazard(s)		Environmental Chemicals
Critical Limits for each Control Measure		A lot-by-lot Supplier certificate accompanying all lots received that indicates that fish were not harvested from contaminated waters that could cause the levels in fish tissue to exceed the established federal tolerance and action levels (refer to Table 9-1).
Monitoring	**What**	Presence of a Supplier certificate indicating harvesting from uncontaminated waters.
	How	Visual check for the presence of a Supplier certificate
	Frequency	Each lot received
	Who	Receiving team member
Corrective Action		**If** the Supplier certificate does not accompany an incoming lot**, then:** 1. Hold the lot until a certificate can be provided; **OR,** **2.** Hold and analyze the lot for those environmental chemical contaminants and pesticides that are reasonably likely to be present; **OR,** 3. Reject the lot; **AND** Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls.
Verification		Collect a representative sample of the raw material, in-process product, or finished product at least quarterly, and analyze it for those environmental chemical contaminants and pesticides that are reasonably likely to be present **AND** Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed
Records		Receiving Log – Supplier's Certification

Signature:	**Date:**

HACCP Plan Form

Firm Name *A to Z World Fish Company*	**Product Description** *Individually quick frozen Rainbow trout fillets Oncorhynchus mykiss (O. mykiss)*
Firm Location *Anywhere World*	**Method of Storage & Distribution** *Frozen*
	Intended Use & Consumer *Product to be fully cooked and consumed by general public*

Critical Control Point (CCP)		**CCP 1a: Receiving**
Significant Hazard(s)		Aquaculture Drugs
Critical Limits for each Control Measure		Aquaculture drugs used are identified, approved by FDA and used in accordance with all labeled conditions *(Please note: INAD drugs not used)* *Sulfamerazine to control for furunculosis*
Monitoring	**What**	Supplier Records of on-farm drug use
	How	Visual check of drug use records
	Frequency	Each lot received
	Who	Receiving Team Member
Corrective Action		**If** the drug usage records fail to (1) identify the drugs used, (2) reference FDA Approval or (3) are used in a manner that is not in accordance with labeled instructions, **then** the lot will be rejected. **AND** Discontinue use of the supplier until evidence is obtained that drug treatment practices have changed and/or the Suppler will comply with the certification controls.
Verification		Weekly review of monitoring and corrective action records
Records		Producer's drug usage records **AND** Receiving Record showing lots received, and absence or presence of adequate Supplier drug usage documentation.

Signature:	**Date:**

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HACCP Plan Form

Firm Name *A to Z World Fish Company*	**Product Description** *Individually quick frozen Rainbow trout fillets Oncorhynchus mykiss (O. mykiss)*
Firm Location *Anywhere World*	**Method of Storage & Distribution** *Frozen*
	Intended Use & Consumer *Product to be fully cooked and consumed by general public*

Critical Control Point (CCP)		**CCP 2: Weigh/Pack/Label/Seal and Case**
Significant Hazard(s)		Food Allergens
Critical Limits for each Control Measure		Finished product labels must accurately list the major food allergen (Rainbow trout)
Monitoring	**What**	Labels on finished product packages for comparison with the fish species (Rainbow trout).
	How	Visual examination of the finished product labels.
	Frequency	At the start of production and every 2 hours after that.
	Who	Packing Supervisor
Corrective Action		**IF** the label does not list the major food allergen, **THEN** segregate and re-label improperly labeled product. **AND** Modify label procedures as appropriate. Retrain staff involved.
Verification		Weekly review of monitoring and corrective action records
Records		Weigh/Pack/Label/Seal Report

Signature:	**Date:**

HACCP Plan Form

Firm Name *A to Z World Fish Company*	**Product Description** *Individually quick frozen Rainbow trout fillets Oncorhynchus mykiss (O. mykiss)*
Firm Location *Anywhere World*	**Method of Storage & Distribution** *Frozen*
	Intended Use & Consumer *Product to be fully cooked and consumed by general public*

Critical Control Point (CCP)		**CCP 2: Metal Detection**
Significant Hazard(s)		Metal Inclusion
Critical Limits for each Control Measure		All product passes through an operating metal detector **AND** No detectable metal fragments in finished products that pass through the metal detector.
Monitoring	**What**	Presence of an operating metal detector AND Presence of metal fragments in finished product
	How	Visual examination for the presence of operating metal detector AND Product monitoring performed by the equipment itself.
	Frequency	Check that equipment is in place and operating at the start of each production day AND Continuous monitoring by metal detector itself
	Who	Metal Detection operator
Corrective Action		**IF** the metal detector was not operational, **THEN** hold all product affected by the deviation and run through a functioning metal detector; AND, correct operating procedures to ensure that the product is not processed without an operating metal detection device. Retrain involved staff. **IF** product is rejected by metal detector, **THEN** hold and evaluate rejected product, AND, attempt to locate and correct the source of the fragments found in the product by the metal detector. Retrain involved staff.
Verification		Validation study that identifies the appropriate equipment settings (from manufacturer) Challenge the metal detector using validated sensitivity standards daily; at the start of production and every four hours during operation, when processing factors change and at the end of processing. Weekly review of monitoring , corrective action and Verification records
Records		Metal detector log

Signature:	**Date:**

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HACCP Plan Form (*landscape format)*

Firm Name *A to Z World Fish Company*	**Product Description** *Individually quick frozen Rainbow trout fillets Oncorhynchus mykiss (O. mykiss)*
Firm Location *Anywhere World*	**Method of Storage & Distribution** *Frozen*
	Intended Use & Consumer *Product to be fully cooked and consumed by general public*

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Receiving Step	Environmen-tal Chemi-cals	A lot-by-lot Supplier certificate accompanying all lots received that indicates that fish were not harvested from contaminated waters that could cause the levels in fish tissue to exceed the established federal tolerance and action levels (refer to Table 9-1).	Presence of a Supplier certificate indicating harvesting from uncontami nated waters.	Visual check for the presence of a Supplier certificate	Each lot received	Receiving team member	**If** the Supplier certificate does not accompany an incoming lot**, then:** 1. Hold the lot until a certificate can be provided; **OR**, **2.** Hold and analyze the lot for those environmental chemical contaminants and pesticides that are reasonably likely to be present; **OR,** 3. Reject the lot; **AND** Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls.	Collect a representative sample of the raw material, in-process product, or finished product at least quarterly, and analyze it for those environmental chemical contaminants and pesticides that are reasonably likely to be present **AND** Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed	Receiving Log – Supplier's Certification

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Receiving Step	Aquaculture Drugs	Aquaculture drugs used are identified, approved by FDA and used in accordance with all labeled conditions *(Please note: INAD drugs not used)* *Sulfamerazine to control for furunculosis*	Supplier Records of on-farm drug use	Visual check of drug use records	Each lot received	Receiving Team Member	**If** the drug usage records fail to (1) identify the drugs used, (2) reference FDA Approval or (3) are used in a manner that is not in accordance with labeled instructions, **then** the lot will be rejected. **AND** Discontinue use of the supplier until evidence is obtained that drug treatment practices have changed and/or the Suppler will comply with the certification controls.	Weekly review of monitoring and corrective action records	Producer's drug usage records **AND** Receiving Record showing lots received, and absence or presence of adequate Supplier drug usage documentation.
Weigh/ Pack/ Label/ Seal and Case	Food Allergens	Finished product labels must accurately list the major food allergen (Rainbow trout)	Labels on finished product packages for comparison with the fish species (Rainbow trout).	Visual examination of the finished product labels.	At the start of production and every 2 hours after that.	Packing Supervisor	**IF** the label does not list the major food allergen, **THEN** segregate and re-label improperly labeled product. **AND** Modify label procedures as appropriate. Retrain staff involved.	Weekly review of monitoring and corrective action records	Weigh/Pack/Label/ Seal Report

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Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
Metal Detection	Metal inclusion	All product passes through an operating metal detector **AND** No detectable metal fragments in finished products that pass through the metal detector.	Presence of an operating metal detector **AND** Presence of metal fragments in finished product	Visual examination for the presence of operating metal detector **AND** Product monitoring performed by the equipment itself.	Check that equipment is in place and operating at the start of each production day **AND** Continuous monitoring by metal detector itself	Metal Detection operator	**IF** the metal detector was not operational, **THEN** hold all product affected by the deviation and run through a functioning metal detector **AND** correct operating procedures to ensure that the product is not processed without an operating metal detection device. Retrain involved staff. **IF** product is rejected by metal detector, **THEN** hold and evaluate rejected product. **AND** attempt to locate and correct the source of the fragments found in the product by the metal detector. Retrain involved staff.	Validation study that identifies the appropriate equipment settings (from manufacturer) Challenge the metal detector using validated sensitivity standards daily; at the start of production and every four hours during operation, when processing factors change and at the end of processing. Weekly review of monitoring and corrective action records	Metal detector log

Signature:	**Date:**