September 2020

Commercial Processing Example: *Tilapia (farm-raised), Fresh and Frozen*

(based on 3rd Party Quality Assurance Program)

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 on the FDA website. This model was produced by the National Seafood HACCP Alliance (SHA) strictly as an example for training and does not represent a specific requirement or recommendation from FDA. Keep in mind that this model may not apply to all situations.

Narrative

Company	ABC TILAPIA Company, Anywhere, World
Market Name	Tilapia (Genius- *Oreochromis* spp.; *Sarotherodon* spp.; or *Tilapia* spp.)
Source of Fishery Product	Tilapia are obtained directly from farmed harvest (cages or ponds). The sources can be from **Integrated Farms** (owned and operated by ABC Tilapia Company), or **Non-Integrated Farms** (owned and operated by a separate or independent farm). The harvest is collected by **Producer** (individual farm) or **Supplier** (agent or broker gathering tilapia from one or more farms) for direct delivery to one processing operation.
Describe the Food Products	Whole fish, skin-on (headed and eviscerated tilapia) and skinned fillets (bones removed)
Method of Receiving, Storage and Distribution	Received in ice; stored and distributed iced or frozen depending on market form
Finished Packaging Type	Fresh (never frozen) or frozen products packaged in atmospheric conditions (no reduced oxygen packaging)
Intended Use and Consumer	Cooked consumption by the general public

Description of Process

Receive Whole Tilapia, live or fresh (iced; never frozen) – Commercial lots of tilapia are obtained directly from various farms (cages or ponds). The tilapia is delivered on the same day of harvest. At receiving, the incoming tilapia are identified and assigned lot numbers according to farm source, date of harvest, and sequenced plan for processing.

Butchering - Incoming tilapia are initially held in temporary iced refrigeration prior to immediate processing. The iced fish are bleed with a gill cut, then scaled in special tumblers prior to butchering by hand with knifes to remove the head, eviscerate, and fillets depending on market form. The fillets are hand trimmed and mechanically skinned. The total time for these butchering procedures is less than 60 minutes per assigned batch and ice is used to control product temperature.

Sorting, Packing and Labeling - The resulting products are sorted (hand-graded) by size and bagged prior to refrigeration or freezing. The bagged products are boxed and labeled according to product form. All products are labeled with market name (*Tilapia*) to designate product type.

Refrigerated Storage – Fresh, boxed tilapia are stored in refrigeration (≤ 40°F/4.4°C) for less than 48 hours before shipping.

Freezing and Frozen Storage – Freezing occurs in a blast unit with single layers of boxed product. Frozen storage is maintained ≤ 0°F/-18°C. All finished product inventory is distributed on a first-in/first-out basis.

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

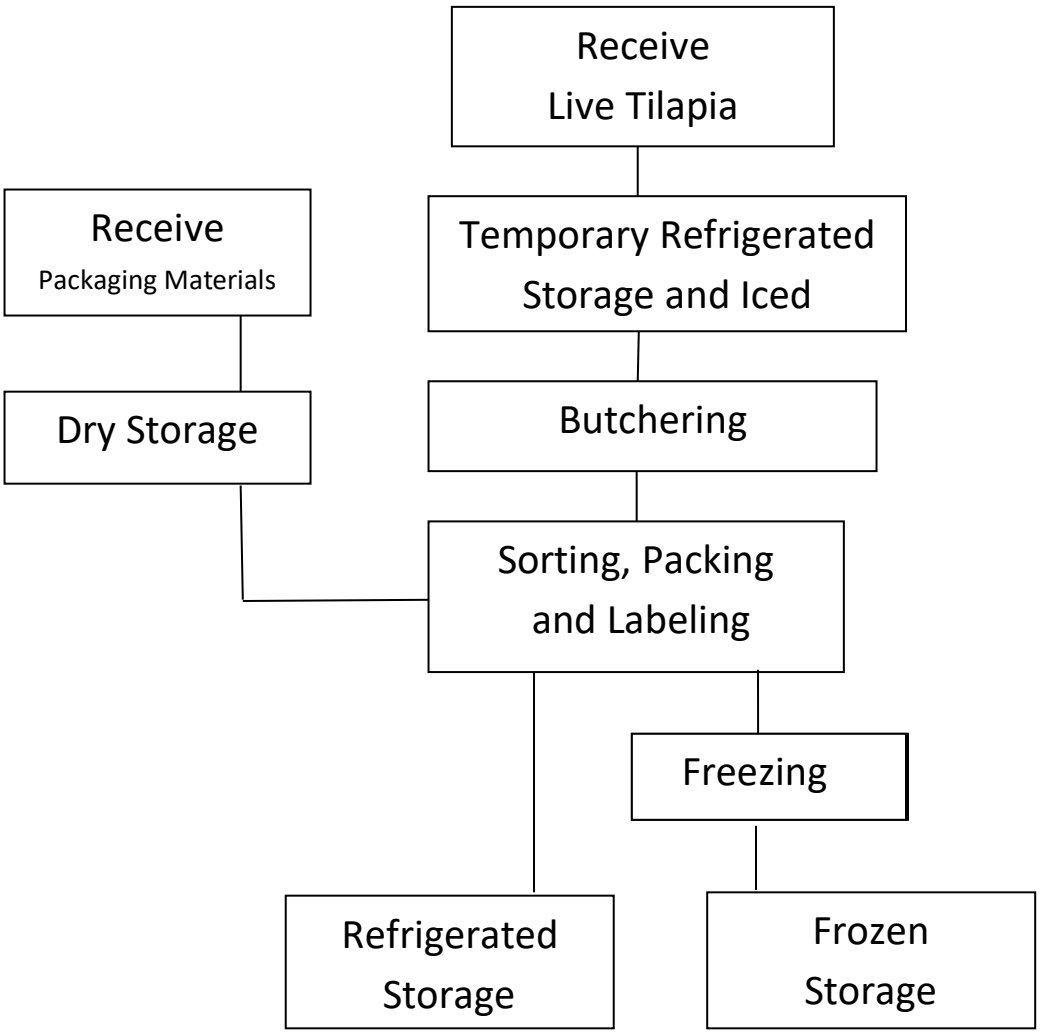
DEFINITIONS

These terms are defined to clarify the content and intentions of the HACCP plan.

Farm Lot is defined as the amount of tilapia involved in one harvest from cages or ponds from a single farm as designated by the supplying farm (**Producer**) or the agent/broker (**Supplier**) collecting tilapia from one or more farms. The designated **'Farm Lot'** can be further distinguished from a **'batch'** as assigned by the processing operations for internal tracking of the tilapia through processing steps. **Third Party Quality Assurance Program** involves oversight of pertinent food safety controls through contracted services by a recognized independent firm.

ABC Tilapia Company

Process Flow Diagram



Commercial Processing Example: *Tilapia (farm-raised), Fresh and Frozen*

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 World Shrimp 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
Market Name: *Tilapia* **Scientific Names:** *Oreochromis; Sarotherodon; Tilapia spp.*		√			√ *				√	√			√	√		√		√			√	

*Some deliveries from the farm can be live fish

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 *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 7 potential hazards that are species or process related. The hazard analysis addressed all hazards pertinent to the current processing operations.

1. Parasite Hazard – (species-related, chapter 5)
2. Environmental Chemicals (contaminants) – (species-related, chapter 9)
3. Aquaculture Drugs (residuals from illegal or improper application) – (species-related, chapter 11)
4. Pathogenic bacteria growth - (process-related, chapter 12)
5. Food Allergens (natural; no additional ingredients) – (process-related, chapter 19)
6. Food Intolerance Substances (Food Additives) - (process-related, chapter 19)
7. 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 Tilapia Company*	**Finished Product Description:** *Fresh (never frozen) and Frozen Tilapia*
Firm Address: *Anywhere, USA*	**Method of Storage & Distribution:** *Refrigerated and 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	Parasite hazard	No	Products intended to be cooked before consumption		
	Environmental chemicals	No	No prior exposure to environmental chemicals		
	Aquaculture drugs	No	No prior exposure to aquaculture drugs		
	Pathogenic bacteria growth-Temp. abuse	No	Products intended to be cooked before consumption		
	Food allergens	No	Packaging materials do not introduce allergens		
	Food Intolerance Substances	No	Additives are not used on the farm or introduced at this step		
	Metal inclusion*	No	Not reasonably likely in packaging materials		
Dry Storage	Parasite hazard	No	Products intended to be cooked before consumption		
	Environmental chemicals	No	No prior exposure to environmental chemicals		
	Aquaculture drugs	No	No prior exposure to aquaculture drugs		
	Pathogenic bacteria growth-Temp. abuse	No	Products intended to be cooked before consumption		
	Food allergens	No	Dry storage does not introduce allergens		
	Food Intolerance Substances	No	Additives are not used on the farm or introduced at this step		
	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)**
Receiving Live Tilapia	Parasite hazard	No	Products intended to be cooked before consumption		
	Environmental chemicals	Yes	Chemical contaminates can occur in the farm environment	Letter of Assurance from a 3rd Party-audited QA program that covers potential environmental chemical contaminants	Yes
	Aquaculture drugs	Yes	Illegal or improper level of drug residues may be in farm-raised tilapia	Letter of Assurance from a 3rd Party-audited QA program that covers aquaculture drug usage	Yes
	Pathogenic bacteria growth-Temp. abuse	No	Products intended to be cooked before consumption		
	Food allergens	Yes	Tilapia is a potential food allergen; hazard is introduced at receiving	Product label applied at Packing step will identify 'Tilapia'	No
	Food Intolerance Substances	No	Additives are not used on the farm or introduced at this step		
	Metal inclusion*	No	Not likely to occur at this step		
Temporary Refrigerated Storage and Iced	Parasite hazard	No	Products intended to be cooked before consumption		
	Environmental chemicals	No	Potential Environmental chemical contaminates controlled at Receiving Step		
	Aquaculture drugs	No	Potential Aquaculture drugs controlled at Receiving Step		
	Pathogenic bacteria growth-Temp. abuse	No	Products intended to be cooked before consumption		
	Food allergens	Yes	Tilapia is a potential food allergen; hazard is introduced at receiving	Product label applied at Packing step will identify 'Tilapia'	No
	Food Intolerance Substances	No	Additives are not used on the farm or introduced at this step		
	Metal inclusion*	No	Not likely to occur at this step		
Butchering	Parasite hazard	No	Products intended to be cooked before consumption		
	Environmental chemicals	No	Potential Environmental chemical contaminates controlled at Receiving Step		
	Aquaculture drugs	No	Potential Aquaculture drugs controlled at Receiving Step		

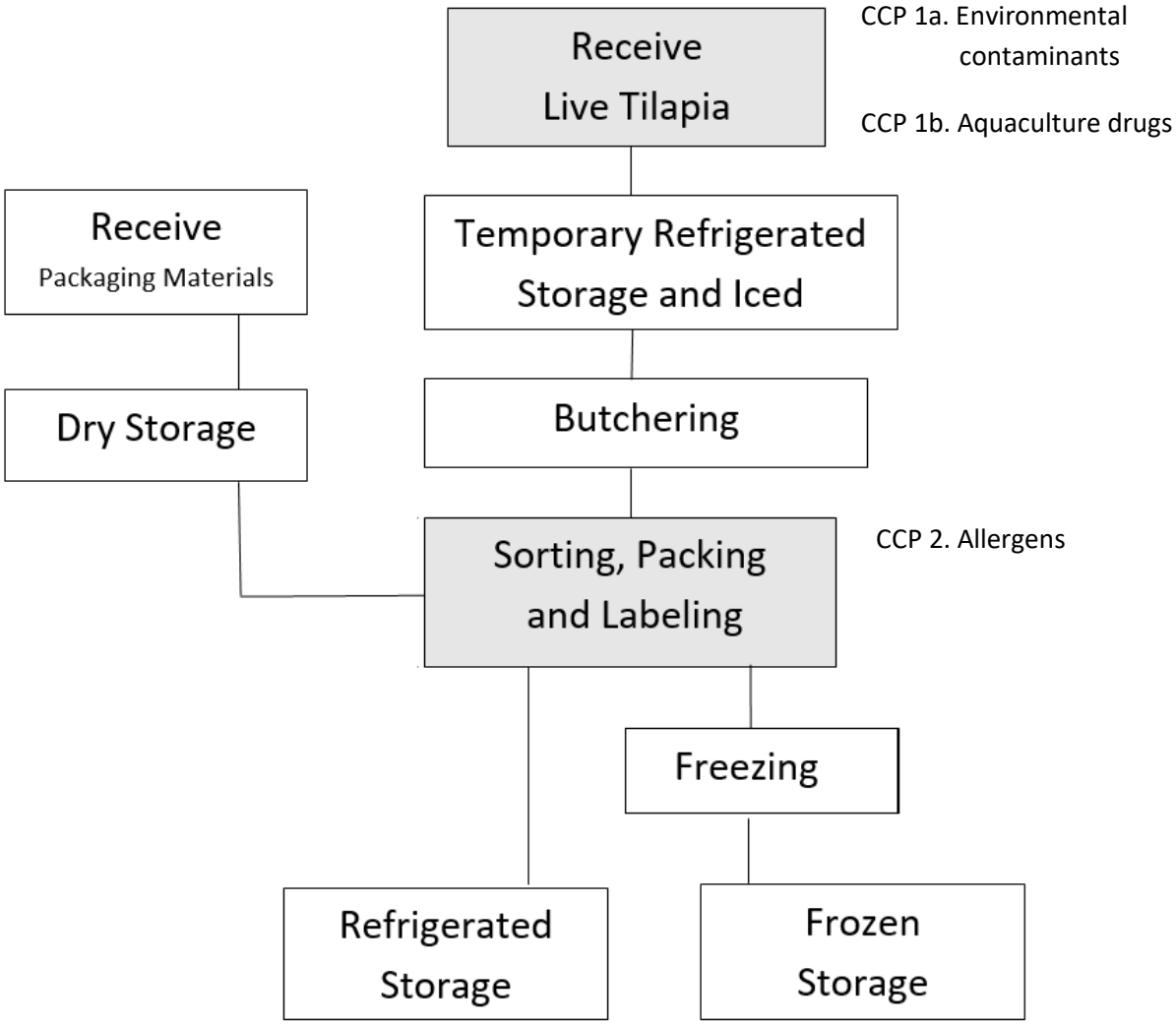
(1) **Processing Step**	(2) List all potential **food safety hazards** that could be associated with this product and process.	(3) Is the potential food safety hazard **significant** (introduced, enhanced or eliminated) at this step? **(Yes or No)**	(4) **Justify the decision** that you made in column 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)**
	Pathogenic bacteria growth-Temp. abuse	No	Products intended to be cooked before consumption		
	Food allergens	Yes	Tilapia is a potential food allergen; hazard is introduced at receiving	Product label applied at Packing step will identify 'Tilapia'	No
	Food Intolerance Substances	No	Additives are not used on the farm or introduced at this step		
	Metal inclusion*	No	Not likely to occur at this step		
Sorting, Packing and Labeling	Parasite hazard	No	Products intended to be cooked before consumption		
	Environmental chemicals	No	Potential Environmental chemical contaminates controlled at Receiving Step		
	Aquaculture drugs	No	Potential Aquaculture drugs controlled at Receiving Step		
	Pathogenic bacteria growth-Temp. abuse	No	Products intended to be cooked before consumption		
	Food allergens	Yes	Tilapia is a potential food allergen; hazard is introduced at receiving	Product label applied at this step will identify 'Tilapia'	Yes
	Food Intolerance Substances	No	Additives are not used on the farm or introduced at this step		
	Metal inclusion*	No	Not likely to occur at this step		
Refrigerated Storage	Parasite hazard	No	Products intended to be cooked before consumption		
	Environmental chemicals	No	Potential Environmental chemical contaminates controlled at Receiving Step		
	Aquaculture drugs	No	Potential Aquaculture drugs controlled at Receiving Step		
	Pathogenic bacteria growth-Temp. abuse	No	Products intended to be cooked before consumption		
	Food allergens	No	Tilapia is a potential food allergen; controlled at prior Packing Step		
	Food Intolerance Substances	No	Additives are not used on the farm or 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*	No	Not likely to occur at this step		
Freezing	Parasite hazard	No	Products intended to be cooked before consumption		
	Environmental chemicals	No	Potential Environmental chemical contaminates controlled at Receiving Step		
	Aquaculture drugs	No	Potential Aquaculture drugs controlled at Receiving Step		
	Pathogenic bacteria growth-Temp. abuse	No	Products intended to be cooked before consumption		
	Food allergens	No	Tilapia is a potential food allergen; controlled at prior Packing Step		
	Food Intolerance Substances	No	Additives are not used on the farm or introduced at this step		
	Metal inclusion*	No	Not likely to occur at this step		
Frozen Storage	Parasite hazard	No	Products intended to be cooked before consumption		
	Environmental chemicals	No	Potential Environmental chemical contaminates controlled at Receiving Step		
	Aquaculture drugs	No	Potential Aquaculture drugs controlled at Receiving Step		
	Pathogenic bacteria growth-Temp. abuse	No	Products intended to be cooked before consumption		
	Food allergens	No	Tilapia is a potential food allergen; Controlled at prior Packing Step		
	Food Intolerance Substances	No	Additives are not used on the farm or introduced at this step		
	Metal inclusion*	No	Not likely to occur at this step		

* ***Metal Inclusion*** would not be reasonably likely to expect in products processed by hand-labor with cutting utensils (FDA Guidance Chapter 20, page 386)

ABC Tilapia Company

Process Flow Diagram with Identified CCPs



HACCP Plan Form

Firm Name: *ABC Tilapia Company*	Product: *Fresh (never frozen) and Frozen Tilapia*
Address: *Anywhere, Any Country*	Method Storage & Distribution: *Refrigerated and Frozen*
Signature: <required signature> Printed (printed signature for clarity>	Intended Use: *Cooked consumption by the general public* Date: <date validated and signed>

CRITICAL CONTROL POINT 1a – Environmental Chemicals		
Critical Control Point (CCP)		**RECEIVING**
Significant Hazard		Potential exposure to chemical contamination from environmental sources
Critical Limits		Individual Producer or a Supplier written and signed Letter of Assurance accompanying each 'farm lot' of incoming tilapia from individually farms that indicate the farmed production operated under a 3rd-Party Quality Assurance (QA) program that assures controls to prevent contamination from environmental sources
Monitoring	**What**	Presence of Letter of Assurance accompanying farm lots.
	How	Visual check for farm and farm lot identity, and presence of accompanying Letter of Assurance
	When	Every farm lot in every delivery at Receiving
	Who	Assigned Coordinator for Receiving
Corrective Action		**IF** there is no Letter of Assurance present and/or the corresponding farm cannot be identified for any individual (each) incoming farm lot, **THEN** reject the lot(s) in question. **OR** the specific lot in question can be held for 24 hours with refrigeration to allow time for the proper Letter of Assurance to be provided; If not provided within 24 hours, THEN reject the lot(s) in question. **AND - To regain control**, discontinue use of the Producer or Supplier until evidence is obtained that the Producer or Supplier can comply with the critical limit for control.
Verifications		Review of all receiving, monitoring, corrective action and verification records within one week of initial recording; **PLUS** periodic review of the 3rd-Party QA program and results of periodic audits (at least annually).
Records		Copy of 3rd-Party QA Letters of Assurance; plus associated records for monitoring, corrective action and verification

HACCP Plan Form

Firm Name: *ABC Tilapia Company*	Product: *Fresh (never frozen) and Frozen Tilapia*
Address: *Anywhere, Any Country*	Method Storage & Distribution: *Refrigerated and Frozen*
Signature: <required signature> Printed (printed signature for clarity>	Intended Use: *Cooked consumption by the general public* Date: <date validated and signed>

CRITICAL CONTROL POINT 1b - Aquaculture Drugs		
Critical Control Point (CCP)		**RECEIVING**
Significant Hazard		Aquaculture drug residuals in the farmed tilapia due to use of unapproved drugs or misuse of approved drugs
Critical Limits		Individual Producer or a Supplier written and signed Letter of Assurance accompanying each 'farm lot' of incoming tilapia from individually farms that indicate the farmed production operated under a 3rd-Party Quality Assurance (QA) program that assures controls for any aquaculture drug use.
Monitoring	**What**	Presence of Letter of Assurance accompanying farm lots
	How	Visual check for farm and farm lot identity, and presence of accompanying Letter of Assurance
	When	Every farm lot in every delivery at Receiving
	Who	Assigned Coordinator for Receiving
Corrective Action		**IF** there is no Letter of Assurance present and/or the corresponding farm cannot be identified for any individual (each) incoming farm lot, **THEN** reject the lot(s) in question. **OR** the specific lot in question can be held for 24 hours with refrigeration to allow time for the proper Letter of Assurance to be provided; If not provided within 24 hours, THEN reject the lot(s) in question. **AND - To regain control**, discontinue use of the Producer or Supplier until evidence is obtained that the Producer or Supplier can comply with the critical limit for control.
Verifications		Review of all receiving, monitoring, corrective action and verification records within one week of initial recording; **PLUS** periodic review of the 3rd-Party QA program and results of periodic audits (at least annually).
Records		Copy of 3rd-Party QA Letters of Assurance; plus associated records for monitoring, corrective action and verification

HACCP Plan Form

Firm Name: *ABC Tilapia Company*	Product: *Fresh (never frozen) and Frozen Tilapia*
Address: *Anywhere, Any Country*	Method Storage & Distribution: *Refrigerated and Frozen*
Signature: <required signature> Printed (printed signature for clarity>	Intended Use: *Cooked consumption by the general public* Date: <date validated and signed>

CRITICAL CONTROL POINT 2 - Allergens		
Critical Control Point (CCP)		**SORTING, PACKING and LABELING**
Significant Hazard		Food Allergen - Tilapia
Critical Limits		All packaged units for sale will include product common market name, 'tilapia'
Monitoring	**What**	Finished product labels
	How	Visual examination of the finished product labels
	When	Representative number of packaged and labeled units per lot or processing batch.
	Who	Assigned Coordinator for Packaging
Corrective Action		**IF** the packaged units do not have labels or labels with 'Tilapia' **THEN** Identify, segregate and relabel the improperly labeled packages. Determine the cause for the problem and correct by removing and destroying the supply of incorrect labels and review the label specifications with the label supplier. Retrain involved staff.
Verifications		Weekly review of packing log records and corrective action records; and annual review of label specifications, OR whenever labels are changed or replaced
Records		Packing Report logs and corrective actions; copy of correct labels and label specifications; **PLUS** training records for Coordinator for Packing.

HACCP Plan Form (*landscape format)*

Firm Name *ABC Tilapia Company*	**Product Description** *Fresh (never frozen) and Frozen Tilapia*
Firm Location *Anywhere USA*	**Method of Storage & Distribution** *Refrigerated and Frozen*
	Intended Use & Consumer *To be cooked for consumption by the general public*

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
CCP1a **RECEIVING** **Environmental Chemicals**	Potential exposure to chemical contamination from environmental sources	Individual Producer or a Supplier written and signed Letter of Assurance accompanying each 'farm lot' of incoming tilapia from individually farms that indicate the farmed production operated under a 3rd-Party Quality Assurance (QA) program that assures controls to prevent contamination from environmental sources	Presence of Letter of Assurance accompanying farm lots	Visual check for farm and farm lot identity, and presence of accompanying Letter of Assurance	Every farm lot in every delivery at Receiving	Assigned Coordinator for Receiving	IF there is no Letter of Assurance present, THEN reject the lot(s) in question. OR the specific lot in question can be held for 24 hours with refrigeration to allow time for the proper Letter of Assurance to be provided; If not provided within 24 hours, THEN reject the lot in question. To regain control, discontinue use of the Producer and/or Supplier until evidence is obtained that the Producer and/or Supplier can comply with the critical limit for control.	Review of all receiving, monitoring, corrective action and verification records within one week of initial recording; **PLUS** periodic review of the 3rd-Party QA program and results of periodic audits (at least annually).	Copy of 3rd-Party QA Letters of Assurance; plus associated records for monitoring, corrective action and verification

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
CCP 1b **RECEIVING** **Aquaculture Drugs**	Aquaculture drug residuals in the farmed tilapia due to use of unapproved drugs or misuse of approved drugs	Individual Producer or a Supplier written and signed Letter of Assurance accompanying each 'farm lot' of incoming tilapia from individually farms that indicate the farmed production operated under a 3rd-Party Quality Assurance (QA) program that assures controls for any aquaculture drug use.	Presence of Letter of Assurance accompanying farm lots	Visual check for farm and farm lot identity, and presence of accompanying Letter of Assurance	Every farm lot in every delivery at Receiving	Assigned Coordinator for Receiving	IF there is no Letter of Assurance present, THEN reject the lot(s) in question. OR the specific lot in question can be held for 24 hours with refrigeration to allow time for the proper Letter of Assurance to be provided; If not provided within 24 hours, THEN reject the lot in question. To regain control, discontinue use of the Producer and/or Supplier until evidence is obtained that the Producer and/or Supplier can comply with the critical limit for control.	Review of all receiving, monitoring, corrective action and verification records within one week of initial recording; **PLUS** periodic review of the 3rd-Party QA program and results of periodic audits (at least annually).	Copy of 3rd-Party QA Letters of Assurance; plus associated records for monitoring, corrective action and verification
CCP 2 **SORTING, PACKING and LABELING** **Food Allergen**	Tilapia is a potential food allergen	All packaged units for sale will include product common market name, 'tilapia'	Finished product labels	Visual examination of the finished product labels	Representative number of packaged and labeled units per lot or processing batch	Assigned Coordinator for Packaging	IF the packaged units do not have labels for 'Tilapia'; THEN Identify, segregate and relabel Determine the cause for the problem and correct by removing and destroying the supply of incorrect labels and review the label specifications with the label supplier. Retrain involved staff.	Weekly review of packing log records and corrective action records; and annual review of label specifications, OR whenever labels are changed or replaced	Packing Report logs and corrective actions; plus copy of correct labels and label specifications; PLUS training records for Coordinator for Packing.

Signature:	**Date:**