



REVISED SEPTEMBER 2017

## Commercial Processing Example: Fish Sticks, Breaded Frozen

**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* (4<sup>th</sup> Edition, 2011) and additional information available since the 2011 edition. It was produced by the National Seafood HACCP Alliance (SHA) strictly as an example for training. This Model does not represent a specific requirement or recommendation from FDA. Keep in mind that this model may not apply to all situations.

### Narrative

<b>Company</b>	ABC Breaded Fish Company, Anywhere, USA
<b>Market Name</b>	Pollock (Atlantic pollock – <i>Pollachius virens</i> )
<b>Source of Fishery Product</b>	Wild, ocean caught; purchased from another processor who block freezes at sea.
<b>Describe the Food</b>	Frozen raw battered and breaded fish sticks.
<b>Method of Receiving, Storage and Distribution</b>	Pollock blocks are received, stored and subsequently distributed in the frozen state.
<b>Finished Packaging Type</b>	Frozen raw breaded fish sticks are packaged in cardboard boxes which are oxygen permeable.
<b>Intended Use and Consumer</b>	Frozen raw breaded fish sticks are intended to be cooked prior to consumption and are intended for the general public.

### Description of Process

**Receive -fish blocks** – Frozen blocks of raw, minced ocean-caught Atlantic Pollock are received via a freezer truck. Transit times can exceed 24 hours.

**Frozen storage** - Fish blocks are immediately placed in a frozen storage unit that is maintained at -10°F. The frozen blocks are stored on a first in first out basis. Frozen blocks may remain in storage up to 3 months prior to processing.

**Receive - dry ingredients** – Dry ingredients, batter, breading, frying oil, and packaging materials are delivered to the plant by truck. All products are supplied by approved vendors.

**Dry storage** – All dry ingredients are placed in dry storage on a first-in, first-out basis.

**Cut** – On an as needed basis, frozen fish blocks are removed from the freezer, the blocks are uncased and cut into pre-determined stick size on band saws. Ambient room temperatures are between 70-75°F/21-24°C.

**Cull** - The frozen fish sticks are then placed on a conveyor belt where they are culled (removed from production) for uniformity. Culled product is diverted to non-food use.

**Batter/Bread** – Batter with ingredients (i.e., wheat flour with egg and milk). Batter is hydrated with potable tap water, mixed and immediately placed into the batter reservoir.

The batter is re-circulated and chilled to 55°F/12.8°C. Frozen fish sticks continue on the conveyor belt into the mechanical batter and breading machine. Batter is not used for more than 12 hours. After 12 hour period, equipment is cleaned and sanitized, and new hydrated batter mix is placed into the batter reservoir. There is no use of food additives.

**Fry** - After the breading application, the portions continue on the conveyor belt into a fryer unit containing 'refined' soy bean oil (non-allergen confirmed on delivery of cooking oil) where they are fried for less than one minute at 400°F/204.4°C. This sets the batter and breading, but does not cook the fish. The fish sticks remain frozen throughout production.

Total processing time from the cut step through the fry step is no more than 20 minutes.

**IQF Freeze** - After exiting the fryer, the breaded fish sticks enter a nitrogen tunnel for individual quick freezing. The

nitrogen tunnel freezer is set at -120°F/-84.5°C and the product is solidly frozen in 6 to 10 minutes.

**Pack/Weigh/Label** - The finished product is packaged into oxygen permeable cardboard consumer packages (either 8 ounce or 22 ounce) or large food-service cartons (10 pounds). The packages are then labeled.

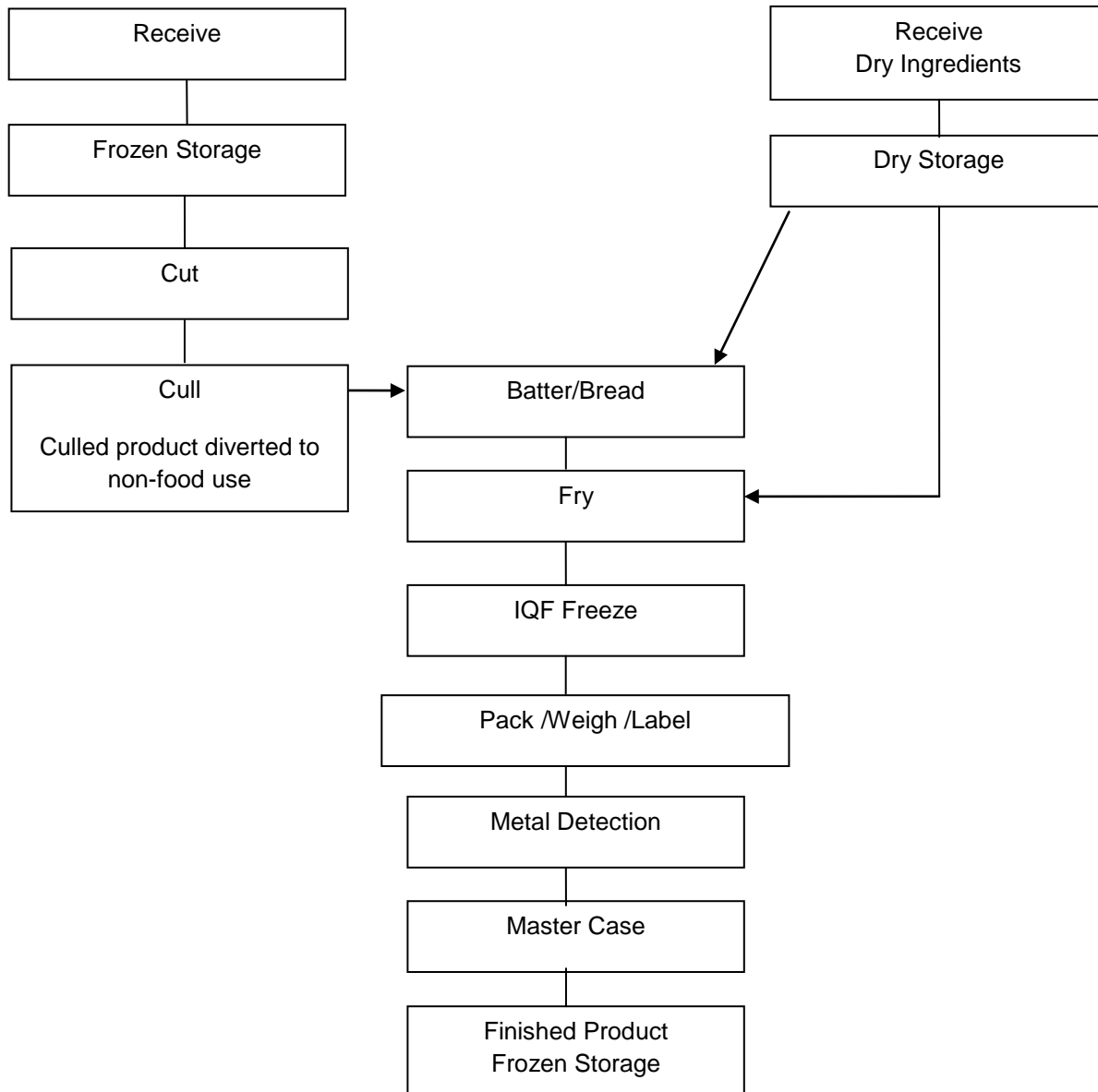
**Metal detection** – All packaged products are passed through a metal detector.

**Master case** - Packages are packed into master cases and palletized.

**Finished product frozen storage** – Pallets of finished packaged product is stored in the freezer at -10°F/-23.3°C. Finished products may be stored up to 2 months. Product is shipped on freezer trucks to retail or food-service distribution centers.

Total processing time from the IQF Freeze step to the Finished Product Frozen Storage Step is no more than 20 minutes.

### Breaded Fish Sticks Process Flow Chart



## Commercial Processing Example: Fish Sticks, Frozen Raw Battered and Breaded

**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 Breaded Fish																					
	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: Atlantic pollock Market Name: Atlantic pollock Scientific Name: <i>Pol-lachius virens</i>			√			√					√					√		√			√	

\*ROP = Reduced Oxygen Packaging

\*RTE = Ready-to Eat

**Potential Food Safety Hazards:** All potential food safety hazards based on the product description and processing flow diagram associated with this product and process are identified using Tables 3-2 (species-related hazards) and 3-4 (process-related hazards) in the *FDA Hazards and Controls Guidance* (2011 edition). 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. For instance, when a breaded/battered fishery product processor packages their finished products in Reduced Oxygen Packaging, the potential hazard of *C. botulinum* toxin must be considered.

The FDA recommendations indicate 5 potential hazards that that are species or process related. Likewise, the battering and breading operations use wheat flour which can also be a food allergen hazard that was not specifically addressed in the FDA Guidance. Each potential hazard must be addressed in the Hazard Analysis, excepting the potential hazard "parasites" which does not apply because the product is intended to be cooked before consumption by the consumer (see Table 3-2 in *FDA Hazards and Controls Guidance* (2011 edition), footnote v<sup>3</sup>).

1. *S. aureus* Toxin – Batter (process-related, chapter 15)
2. Food Allergens (2 potential allergens; fish (process-related); and Wheat flour with egg and milk, chapter 19)
3. Food Additives (process-related, chapter 19)
4. Metal Inclusion (if used in packaging) – (process-related, chapter 20)

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

## Hazard Analysis Worksheet

Firm Name <i>ABC Breaded Fish Company</i>	Product Description: <i>Fish sticks, Frozen raw battered and breaded</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution: <i>Received, stored and distributed frozen in an oxygen permeable package</i>
	Intended Use & Consumer: <i>Raw battered and breaded fish sticks are intended to be fully cooked and consumed by general public.</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 <b>significant</b> (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 <b>Critical Control Point?</b> (Yes or No)
Receive (frozen fish blocks)	<i>S. aureus</i> toxin - batter	No	Not applicable at this step		
	Food Allergens (Pollock)	Yes	Fish is a food allergen	Finished product label applied at pack/weigh/label step will identify fish market name (pollock) in the ingredient statement.	No
	Food Allergens (Wheat flour)	Yes	Wheat flour with egg and milk is a food allergen	Not introduced at this step	No
	Food Additives	No	No food additives are used		
	Metal Inclusion	No	Not reasonably likely to occur at this step		
Frozen Storage	<i>S. aureus</i> toxin - batter	No	Not applicable at this step.		
	Food Allergens (Pollock)	Yes	Fish is a food allergen	Finished product label applied at pack/weigh/label step will identify fish market name (pollock) in the ingredient statement.	No
	Food Allergens (Wheat flour)	Yes	Wheat flour with egg and milk is a food allergen	Not introduced at this step	No
	Food Additives	No	No food additives are used		
	Metal Inclusion	No	Not reasonably likely to occur at this step		
Receive Dry Ingredients	<i>S. aureus</i> toxin - batter	No	Not reasonably likely to occur at this process step; batter is not yet hydrated.		
	Food Allergens (Pollock)	Yes	Fish is a food allergen	Finished product label applied at pack/weigh/label step will identify fish market name (pollock) in the ingredient statement.	No
	Food Allergens (Wheat flour)	Yes	Wheat flour with egg and milk is a food allergen	Finished product label applied at pack/weigh/label step will identify wheat flour with egg and milk in the ingredient statement.	No

(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 Additives	No	No food additives are used		
	Metal Inclusion	No	Not reasonably likely to occur in dry ingredients		
Dry Storage	<i>S. aureus</i> toxin - batter	No	Not reasonably likely to occur at this process step; batter is not yet hydrated.		
	Food Allergens (Pollock)	No	Fish are not present.		No
	Food Allergens (Wheat flour)	Yes	Wheat flour with egg and milk is a food allergen	Finished product label applied at pack/weigh/label step will identify wheat flour with egg and milk in the ingredient statement.	No
	Food Additives	No	No food additives are used		
	Metal Inclusion	No	Not reasonably likely to occur at this step		
Cut	<i>S. aureus</i> toxin - batter	No	Not applicable at this step.		
	Food Allergens (Pollock)	Yes	Fish is a food allergen	Finished product label applied at pack/weigh/label step will identify fish market name (pollock) in the ingredient statement.	No
	Food Allergens (Wheat flour)	Yes	Wheat flour with egg and milk is a food allergen	Finished product label applied at pack/weigh/label step will identify wheat flour with egg and milk in the ingredient statement.	No
	Food Additives	No	No food additives are used		
	Metal Inclusion	Yes	Band saw blades can break and cause metal contamination	Metal detection at the metal detection step.	No
Cull	<i>S. aureus</i> toxin - batter	No	Not reasonably likely to occur at this process step		
	Food Allergens (Pollock)	Yes	Fish is a food allergen	Finished product label applied at pack/weigh/label step will identify fish market name (pollock) in the ingredient statement.	No
	Food Allergens (Wheat flour)	Yes	Wheat flour with egg and milk is a food allergen	Finished product label applied at pack/weigh/label step will identify wheat flour with egg and milk in the ingredient statement.	No
	Food Additives	No	No food additives are used		
	Metal Inclusion	Yes	Wire mesh conveyor belts can break and cause metal contamination	Metal detection at the metal detection step.	No

(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)
Batter/Bread	<i>S. aureus</i> toxin - batter	Yes	<i>S. aureus</i> can grow and form toxins if batter is time - temperature abused above 51°F for 12 hrs. or above 70°F for 3 hrs.	Time and temperature controls of the batter.	Yes
	Food Allergens (Pollock)	Yes	Fish is a food allergen	Finished product label applied at pack/weigh/label step will identify fish market name (pollock) in the ingredient statement.	No
	Food Allergens (Wheat flour)	Yes	Wheat flour with egg and milk is a food allergen	Finished product label applied at pack/weigh/label step will identify wheat flour with egg and milk in the ingredient statement.	No
	Food Additives	No	No food additives are used		
	Metal Inclusion	Yes	Wire mesh conveyor belts can break and cause metal contamination	Metal detection at the metal detection step.	No
Fry	<i>S. aureus</i> toxin - batter	No	<i>S. aureus</i> will not likely grow and produce toxin due to short time at this process step		
	Food Allergens (Pollock)	Yes	Fish is a food allergen	Finished product label applied at pack/weigh/label step will identify fish market name (pollock) in the ingredient statement.	No
	Food Allergens (Wheat flour)	Yes	Wheat flour with egg and milk is a food allergen	Finished product label applied at pack/weigh/label step will identify wheat flour with egg and milk in the ingredient statement.	No
	Food Additives	No	No food additives are used		
	Metal Inclusion	Yes	Wire mesh conveyor belts can break and cause metal contamination	Metal detection at the metal detection step.	No
IQF Freeze	<i>S. aureus</i> toxin - batter	No	<i>S. aureus</i> will not likely grow and produce toxin due to short time at this process step		
	Food Allergens (Pollock)	Yes	Fish is a food allergen	Finished product label applied at pack/weigh/label step will identify fish market name (pollock) in the ingredient statement.	No
	Food Allergens (Wheat flour)	Yes	Wheat flour with egg and milk is a food allergen	Finished product label applied at pack/weigh/label step will identify wheat flour with egg and milk in the ingredient statement.	No
	Food Additives	No	No food additives are used		
	Metal Inclusion	Yes	Wire mesh conveyor belts can break and cause metal contamination	Metal detection at the metal detection step.	No

(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)
Pack/Weigh/Label	<i>S. aureus</i> toxin - batter	No	<i>S. aureus</i> is not reasonably likely to neither grow nor produce toxin at frozen temperatures.		
	Food Allergens (Pollock)	Yes	Fish and other food allergen ingredients are present in this product	Finished product label applied at pack/weigh/label step will identify major food allergens and will list the fish market name (Pollock).	Yes
	Food Allergens (Wheat Flour)	Yes	Wheat flour with egg and milk is a food allergen	Finished product label applied at pack/weigh/label step will identify wheat flour with egg and milk in the ingredient statement.	Yes
	Food Additives	No	No food additives are used		
	Metal Inclusion	No	Not reasonably likely to occur at this step		
Metal Detection	<i>S. aureus</i> toxin - batter	No	<i>S. aureus</i> will not likely grow and produce toxin due to short time at this process step		
	Food Allergens	No	Undeclared allergens are not reasonably likely to occur; fish and other food allergens were already labeled at the prior pack/weigh/label step.		
	Food Additives	No	No food additives are used		
	Metal Inclusion	Yes	Although this hazard will not occur at the metal detector step, metal inclusion from previous steps will be controlled here.	Metal Detection	Yes
Master Case	<i>S. aureus</i> toxin - batter	No	<i>S. aureus</i> will not likely grow and produce toxin due to short time at this process step		
	Food Allergens	No	Undeclared allergens are not reasonably likely to occur; fish and other food allergens were already labeled at the prior pack/weigh/label step.		
	Food Additives	No	No food additives are used		
	Metal Inclusion	No	Not reasonably likely to occur at this step		

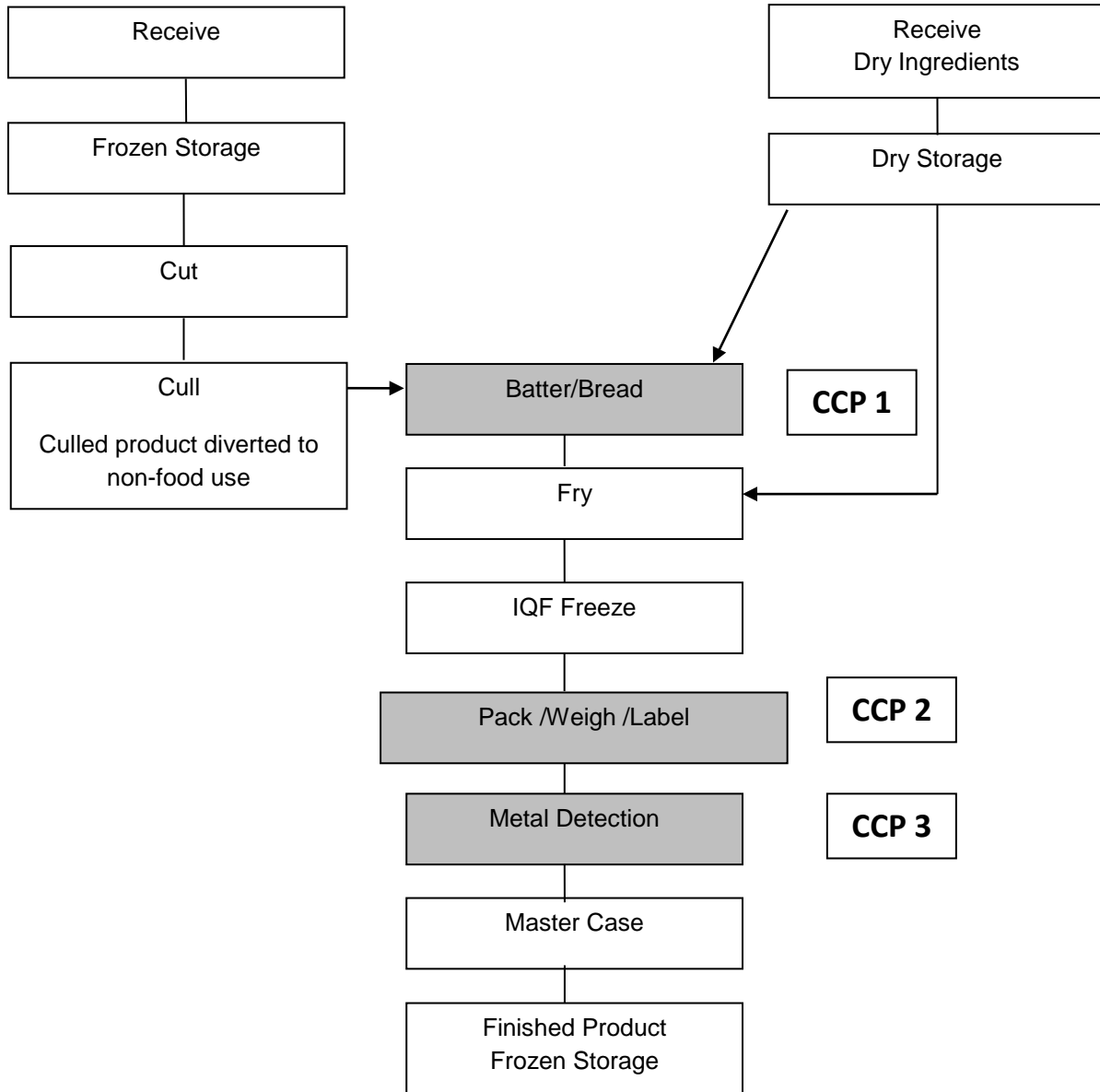
(1) Processing Step	(2) List all potential <b>food safety hazards</b> that could be associated with this product and process.	(3) Is the potential food safety hazard <b>significant</b> (introduced, enhanced or eliminated) at this step? (Yes or No)	(4) <b>Justify the decision</b> that you made in column 3	(5) What <b>control measure(s)</b> can be applied to prevent this significant hazard?	(6) Is this step a <b>Critical Control Point?</b> (Yes or No)
Frozen Storage	<i>S. aureus</i> toxin - batter	No	Not reasonably likely to occur during frozen storage		
	Food Allergens	No	Not reasonably likely to occur; fish and other food allergens were already properly labeled at the prior pack/weigh/label step.		
	Food Additives	No	No food additives are used		
	Metal Inclusion	No	Not reasonably likely to occur at this step		



# Breaded Fish Sticks

## Process Flow Chart

(Shaded steps indicate critical control points)



## HACCP Plan Form

Firm Name <i>ABC Breaded Fish Company</i>	Product Description <i>Frozen raw battered and breaded fish sticks in oxygen permeable package</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Frozen</i>
	Intended Use & Consumer <i>Product to be fully cooked and consumed by general public</i>

<b>Critical Control Point (CCP)</b>	<b>CCP 1: Batter/Bread</b>								
<b>Significant Hazard(s)</b>	<i>S. aureus</i> growth and toxin formation								
<b>Critical Limits for each Control Measure</b>	Hydrated batter mix will not be held for more than 12 hours, cumulatively, at temperatures above 50°F/10°C as long as no more than 3 of the 12 hours are above 70°F/21.1°C								
<b>Monitoring</b>	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; padding: 5px; text-align: center;"><b>What</b></td> <td style="padding: 5px;">Temperature of hydrated batter mix <b>AND</b> Time of exposure at temperatures above 50°F/10°C and above 70°F/21.1°C.</td> </tr> <tr> <td style="padding: 5px; text-align: center;"><b>How</b></td> <td style="padding: 5px;">Continuous temperature recording device <b>AND</b> Observe exposure time (batter batch start and end time)</td> </tr> <tr> <td style="padding: 5px; text-align: center;"><b>Frequency</b></td> <td style="padding: 5px;">Continuous monitoring device with a visual check of recorded data at least once per day. Each batch of batter</td> </tr> <tr> <td style="padding: 5px; text-align: center;"><b>Who</b></td> <td style="padding: 5px;">Batter Quality Control Person</td> </tr> </table>	<b>What</b>	Temperature of hydrated batter mix <b>AND</b> Time of exposure at temperatures above 50°F/10°C and above 70°F/21.1°C.	<b>How</b>	Continuous temperature recording device <b>AND</b> Observe exposure time (batter batch start and end time)	<b>Frequency</b>	Continuous monitoring device with a visual check of recorded data at least once per day. Each batch of batter	<b>Who</b>	Batter Quality Control Person
	<b>What</b>	Temperature of hydrated batter mix <b>AND</b> Time of exposure at temperatures above 50°F/10°C and above 70°F/21.1°C.							
	<b>How</b>	Continuous temperature recording device <b>AND</b> Observe exposure time (batter batch start and end time)							
	<b>Frequency</b>	Continuous monitoring device with a visual check of recorded data at least once per day. Each batch of batter							
<b>Who</b>	Batter Quality Control Person								
<b>Corrective Action</b>	<b>IF</b> the critical limits are exceeded, <b>THEN</b> hold the affected batter mix and product until the hydrated batter mix can be sampled and analyzed for the presence of staphylococcal enterotoxin. <b>AND</b> make repairs or adjustments to the hydrated batter mix refrigeration equipment. Retrain involved staff.								
<b>Verification</b>	Weekly review of monitoring and corrective action records Check accuracy of temperature recording device prior to use Daily accuracy check of temperature recording device Yearly calibration of temperature recording device								
<b>Records</b>	Temperature recording chart and daily Batter Check Log								

Signature:	Date:
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## HACCP Plan Form

Firm Name <i>ABC Breaded Fish Company</i>	Product Description <i>Frozen raw battered and breaded fish sticks in oxygen permeable package</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Frozen</i>
	Intended Use & Consumer <i>Product to be fully cooked and consumed by general public</i>

Critical Control Point (CCP)	<b>CCP 2:Pack/Weigh/Label</b>	
Significant Hazard(s)	Food allergens	
Critical Limits for each Control Measure	Finished product labels must accurately list the major food allergens: Pollock, wheat, soy, eggs and milk.	
Monitoring	What	Labels on finished product packages for comparison with the product formula (ingredients list).
	How	Visual examination of the finished product labels and product formula (ingredients list).
	Frequency	A representative number of packages from each lot of a finished product.
	Who	Packing Supervisor
Corrective Action	<p><b>IF</b> the label does not list the major food allergens, <b>THEN</b> segregate and re-label improperly labeled product.</p> <p>Modify label procedures as appropriate. Retrain staff involved.</p>	
Verification	Weekly review of monitoring and corrective action records	
Records	Pack room report	

Signature:	Date:
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## HACCP Plan Form

Firm Name <i>ABC Breaded Fish Company</i>	Product Description <i>Frozen raw battered and breaded fish sticks in oxygen permeable package</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Frozen</i>
	Intended Use & Consumer <i>Product to be fully cooked and consumed by general public</i>

<b>Critical Control Point (CCP)</b>		<b>CCP 3: Metal Detection</b>
<b>Significant Hazard(s)</b>		Metal inclusion
<b>Critical Limits for each Control Measure</b>		All product passes through an operating metal detector AND No detectable metal fragments in finished products that pass through the metal detector.
<b>Monitoring</b>	<b>What</b>	Presence of an operating metal detector AND Presence of metal fragments in finished product
	<b>How</b>	Visual examination for the presence of operating metal detector AND Product monitoring performed by the equipment itself.
	<b>Frequency</b>	Check that equipment is in place and operating at the start of each production day AND Continuous monitoring by metal detector itself
	<b>Who</b>	Metal Detection operator
<b>Corrective Action</b>		<p><b>IF</b> the metal detector was not operational, <b>THEN</b> 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.</p> <p><b>IF</b> product is rejected by metal detector, <b>THEN</b> 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.</p>
<b>Verification</b>		<p>Validation study that identifies the appropriate equipment settings (from manufacturer)</p> <p>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.</p> <p>Weekly review of monitoring and corrective action records</p>
<b>Records</b>		Metal detector log

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

Firm Name <i>ABC Breaded Fish Company</i>	Product Description <i>Frozen raw battered and breaded fish sticks in oxygen permeable pack-age</i>
Firm Location <i>Anywhere USA</i>	Method of Storage & Distribution <i>Frozen</i>
	Intended Use & Consumer <i>Product to be fully cooked and consumed by general public</i>

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
<b>Batter/Bread</b>	<i>S. aureus</i> growth and toxin formation	Hydrated batter mix will not be held for more than 12 hours, cumulatively, at temperatures above 50°F/10°C as long as no more than 3 of the 12 hours are above 70°F/21.1°C	Temperature of hydrated batter mix  <b>AND</b> Time of exposure at temperatures above 50°F/10°C and above 70°F/21.1°C.	Continuous temperature recording device  <b>AND</b> Observe exposure time (batter batch start and end time)	Continuous monitoring device with a visual check of recorded data at least once per day.  Each batch of batter	Batter Quality Control Person	<b>IF</b> the critical limits are exceeded, <b>THEN</b> hold the affected batter mix and product until the hydrated batter mix can be sampled and analyzed for the presence of staphylococcal enterotoxin.  <b>AND</b> make repairs or adjustments to the hydrated batter mix refrigeration equipment. Retrain involved staff.	Weekly review of monitoring and corrective action records  Check accuracy of temperature recording device prior to use  Daily accuracy check of temperature recording device  Yearly calibration of temperature recording device	Temperature recording chart and daily Batter Check Log
<b>Pack/Weigh/Label</b>	Food allergens	Finished product labels must accurately list the major food allergens: Pollock, wheat, soy, eggs and milk.	Labels on finished product packages for comparison with the product formula (ingredients list).	Visual examination of the finished product labels and product formula (ingredients list).	A representative number of packages from each lot of a finished product.	Packing Supervisor	<b>IF</b> the label does not list the major food allergens, <b>THEN</b> segregate and re-label improperly labeled product.  Modify label procedures as appropriate. Retrain staff involved.	Weekly review of monitoring and corrective action records	Pack room report

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification	Records
			What	How	When	Who			
<b>Metal Detection</b>	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	<b>IF</b> the metal detector was not operational, <b>THEN</b> 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.  <b>IF</b> product is rejected by metal detector, <b>THEN</b> 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

<b>Signature:</b>	<b>Date:</b>
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