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Seafood HACCP Plan

Manufacturing Site: International Provisions, Inc.

Address: 12 Hamden Park Drive Hamden, CT 06517

FDA Registration #: 17320339638

Revised: 10.22.2021

Prepared By:

Whitney Cordano, Quality Manager

I hereby indicate that I understand and have accepted for implementation the preceding Hazard Analysis Critical Control Point (HACCP) program for GOODFISH, Inc. to meet the Federal regulations 21 CFR Part 123 and the pre-requisite programs that accompany the regulations such as Good Manufacturing Practices (cGMPs 21 CFR 110) and Sanitation Standard Operating Procedures (SSOP's).

Approved By:

Signature: _____

Date: _____

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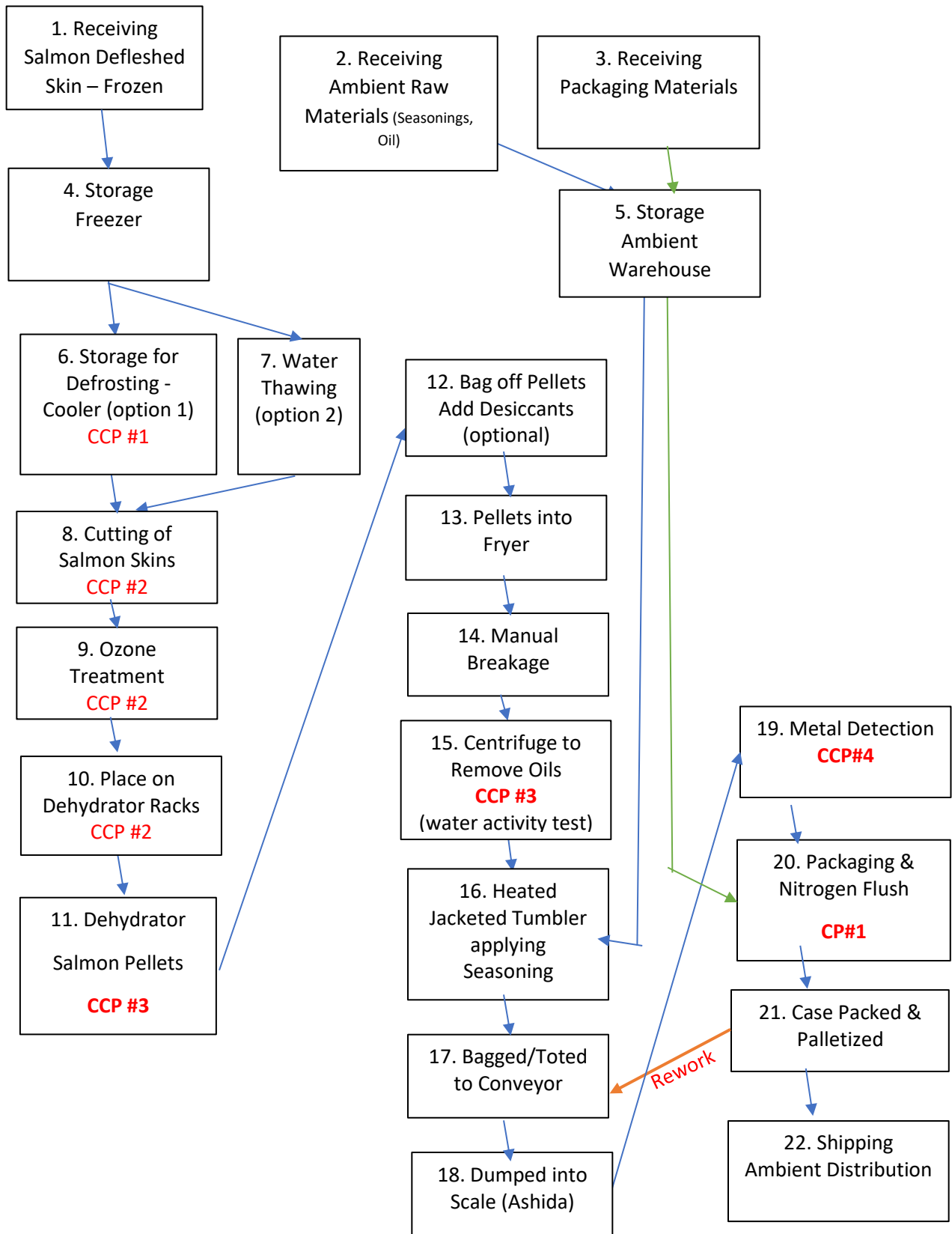
PRODUCT DESCRIPTIONS

Product Name(s)	<p>GOODFISH Crispy Salmon Skins</p> <ul style="list-style-type: none"> ● Sea Salt (6 and 8 packs) ● Chili Lime (6 and 8 packs) ● Barbecue (6 and 8 packs) ● Tart Cranberry (6 and 8 packs) ● Sriracha Lemongrass (6 and 8 packs) ● Salt and Vinegar (6 and 8 packs) ● Miso Teriyaki (6 and 8 packs) ● Wasabi Ginger (6 and 8 packs) ● Variety pack (2SS, 2CL, 2BBQ, 2 TC) ● Discovery Pack (1SS, 1CL, 1BBQ, 1 TC) ● Hot Variety Pack (2SS, 2CL, 2BBQ, 2 SL) ● Best Seller Pack (2SS, 2SV, 2BBQ, 2SL)
Product Description	Crispy Salmon Skins. Seasoned fried shelf-stable ready-to-eat salty snacks.
Type of Seafood	Wild Caught IQF Salmon Skins
Ingredients	Salmon Skin with Salt and/or Seasoning
Allergens	Fish (Salmon) All SKU's Soy for Chili Lime SKU
Packaging Used/Sizes	<p>Each bag is 15g</p> <ul style="list-style-type: none"> ● Sea Salt (6 and 8 packs) ● Chili Lime (6 and 8 packs) ● Barbecue (6 and 8 packs) ● Tart Cranberry (6 and 8 packs) ● Sriracha Lemongrass (6 and 8 packs) ● Salt and Vinegar (6 and 8 packs) ● Miso Teriyaki (6 and 8 packs) ● Wasabi Ginger (6 and 8 packs) ● Variety pack (2SS, 2CL, 2BBQ, 2 TC) ● Discovery Pack (1SS, 1CL, 1BBQ, 1 TC) ● Hot Variety Pack (2SS, 2CL, 2BBQ, 2 SL) ● Best Seller Pack (2SS, 2SV, 2BBQ, 2SL)
Intended Use	Ready to Eat for General Public, Ecommerce and Retail
Intended Consumers	General Public, Ecommerce, and Retail
Shelf Life	6 months
Labeling Instructions	None
Storage and Distribution	Ambient and Shelf Stable
Country of Origin	United States

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PROCESS FLOW CHART

Good Fish Crispy Salmon Skins (Salt, Seasoned)



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PRODUCT: Good Fish Crispy Salmon Skins (Salt, Seasoned)

HAZARD ANALYSIS

(1)	(2)		(3)		(4)	(5)	(6)	
Ingredient / Processing Step	Identify potential biological, chemical and physical hazards associated with this product and process		Are any food safety hazards significant at this step? (Yes/No)		Justify your decision for column 3	What preventive measure(s) can be applied for the significant hazard? <i>e.g. Process including CCPs, Allergen, Sanitation, Supply-chain, other Preventive Control</i>	Is this step a critical control point? (Yes/No)	
	Hazard Type	Hazard	Yes	No			Yes	No
1. Receiving Salmon Defleshed Skin - Frozen	Biological	Pathogens Parasites	X		Non-Scrombroid Fish, Approved Supplier Program. Product will be received refrigerated and/or in frozen gel packs/ice and will not exceed 40°F (4.4°C) or less during transport and receiving. Fish intended to be fully cooked before consumption	Temperature checks and visual inspection		X
	Chemical	Allergen – Fish (Salmon)	X		Salmon must be declared on the label	Allergen Preventive Control applied at later step		X
	Physical	Foreign Material – Bones, Metal	X		Approved Supplier Programs, Specs, Further inspection and processing	CCP applied at a later step – Metal Detection		X

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2. Receiving Ambient Raw Materials (Seasonings, Oils)	Biological	Salmonella	X		Approved Supplier Program with COA's to ensure free of Salmonella	Prerequisite - Supply Chain Management – Monitoring of COA's		X
	Chemical	Pesticides Unapproved Additives/Colors Allergen: Soy		X	Approved Supplier Program, Specs Allergen Control Plan – Storage, Labeling	Prerequisite – Allergen Management		X
	Physical	Foreign Material	X		FM could come in from our supplier, pre-req to inspect upon opening	CCP applied at a later step – Metal Detection		X
3. Receiving Packaging Materials	Biological	None		X	Approved Suppliers, Letter of Guarantees			
	Chemical	None		X	Approved Suppliers, Letter of Guarantees			
	Physical	None		X	Approved Suppliers, Letter of Guarantees			
4. Storage Freezer	Biological	Pathogen Growth		X	Pre-Requisite to ensure Freezer is at temperature			
	Chemical	None		X	Product is protected and GMP's apply			
	Physical	None		X	Product is protected and GMP's apply			
5. Storage Ambient Warehouse	Biological	None		X	Product is protected and GMP's apply			
	Chemical	None		X	Product is protected and GMP's apply			
	Physical	None		X	Product is protected and GMP's apply			
6. Storage for Defrosting -	Biological	Pathogen Growth	X		Product will be kept in the cooler at 40°F (4.4°C) or less during defrosting,	CCP –Thawing	X CCP #1	

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Cooler (option 1)					monitored and time tracked with chart thermometer. Fish intended to be dehydrated and fried before consumption.			
	Chemical	None		X	Product is protected and GMP's apply			
	Physical	None		X	Product is protected and GMP's apply			
7. Water Thawing (option 2)	Biological	Pathogen Growth	X		Product will be defrosted with agitated water. Product internal temperature will be maintained at 50°F (4.4°C) or less during defrosting, monitored and time tracked. Fish intended to be dehydrated and fried before consumption.	CCP – Unrefrigerated Process Control	CCP #2	
	Chemical	None		X	Product is protected and GMP's apply			
	Physical	None		X	Product is protected and GMP's apply			
8. Cutting of Salmon Skins	Biological	Pathogen Growth	X		Product internal temperature will be maintained at 50°F or less during processes leading up to dehydration. Fish intended to be dehydrated and fried before consumption.	CCP- Unrefrigerated Process Control	CCP #2	
	Chemical	None		X	Water used will be potable and not reused and containers protected, GMP's apply.			
	Physical	Foreign Material - Metal	X		Metal from the knives are controlled through daily check-in/out procedure and log.	CCP applied at a later step – Metal Detection		X

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9. Ozone Treatment (Used for Quality Purposes)	Biological	Pathogen Growth	X		Product internal temperature will be maintained at 50°F or less during processes leading up to dehydration. Fish intended to be dehydrated and fried before consumption.	CCP- Unrefrigerated Process Control	CCP #2	
	Chemical	None		X	Water used will be potable and not reused and containers protected, GMP's apply.			
	Physical	None		X	Product is protected and GMP's apply.			
10. Place on Dehydrator Racks	Biological	Pathogen Growth	X		Product internal temperature will be maintained at 50°F or less during processes leading up to dehydration. Fish intended to be dehydrated and fried before consumption.	CCP- Unrefrigerated Process Control	CCP #2	
	Chemical	None		X	Product is protected and GMP's apply.			
	Physical	None		X	Product is protected and GMP's apply.			
11. Dehydrator Salmon Pellets	Biological	Pathogenic Bacterial grown and toxin formation	X		Product will be dehydrated to a targeted water activity <0.65 which is sufficient to prevent growth of the targeted pathogen, S. Aureus. Other pathogens and toxins of concerns are also controlled at this water activity.	CCP – Dehydration Water activity testing performed on finished product.	X CCP #3	
	Chemical	None		X	No exposure to chemicals or other allergens			
	Physical	Foreign Material - Metal	X		Metal could enter the processing stream due to equipment, PM schedules and visual inspection in place for other foreign material	CCP applied at a later step – Metal Detection		X

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12. Bag off Pellets Add Desiccants (optional)	Biological	Pathogen contamination	X		Post-Process environmental contamination could occur if sanitation controls not in place. Gloves in use as per GMP's	Prerequisite – Sanitation Program		X
	Chemical	None		X	Product is protected and GMP's apply.			
	Physical	None		X	Product is protected and GMP's apply.			
13. Pellets into Fryer	Biological	Salmonella or Listeria mono.	X		Pathogens may be present from product or environment. Frying temperature will preclude pathogen growth and for quality.	Prerequisite – Sanitation Program		X
	Chemical	Aldehyde and Hydrocarbon Formation in Oil		X	Oil is refreshed at mid run and dumped at the end of the day			
	Physical	Foreign Material - Metal	X		Metal could enter the processing stream due to equipment, PM schedules and visual inspection in place for other foreign material	CCP applied at a later step – Metal Detection		X
14. Manual Breakage	Biological	Pathogen contamination	X		Post-Process environmental contamination could occur if sanitation controls not in place. Gloves in use as per GMP's	Prerequisite – Sanitation Program		X
	Chemical	None		X	Product is protected and GMP's apply.			
	Physical	Foreign Material - Gloves		X	Pre-requisite, visual inspection and GMP's apply.			
15. Centrifuge to Remove Oils	Biological	Pathogen Contamination	X		Post-Process environmental contamination could occur if sanitation controls not in place	Prerequisite – Sanitation Program		X

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	Chemical	None		X	Product is protected and GMP's apply.			
	Physical	Foreign Material - Metal	X		Metal could enter the processing stream due to equipment, PM schedules and visual inspection in place for other foreign material	CCP applied at a later step – Metal Detection		X
16. Heated Jacketed Tumbler applying Seasoning	Biological	Pathogen Contamination	X		Post-Process environmental contamination could occur if sanitation controls not in place. Seasoning risk was addressed at the receiving step.	Prerequisite – Sanitation Program		V
	Chemical	Allergen: Soy	X		Allergen Cross-Contact could occur with shared Tumbler if not adequately cleaned	Prerequisite – Sanitation Program		X
	Physical	Foreign Material - Metal	X		Metal could enter the processing stream due to equipment, PM schedules and visual inspection in place for other foreign material	CCP applied at a later step – Metal Detection		X
17. Bagged/Toted to Conveyor	Biological	Pathogen Contamination	X		Post-Process environmental contamination could occur if sanitation controls not in place.	Prerequisite – Sanitation Program		X
	Chemical	Allergen: Soy	X		Allergen Cross-Contact could occur with shared Tumbler if not adequately cleaned	Prerequisite – Sanitation Program		X
	Physical	Foreign Material - Metal	X		Metal could enter the processing stream due to equipment, PM schedules and visual inspection in place for other foreign material	CCP applied at a later step – Metal Detection		X
18. Dumped into Scale (Ashida)	Biological	Pathogen Contamination	X		Post-Process environmental contamination could occur if sanitation controls not in place	Prerequisite -Sanitation Program		X
	Chemical	Allergen: Soy	X		Allergen Cross-Contact could occur with shared Tumbler if not adequately cleaned	Prerequisite – Sanitation Program		X

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	Physical	Foreign Material - Metal	X		Metal could enter the processing stream due to equipment, PM schedules and visual inspection in place for other foreign material	CCP applied at a later step – Metal Detection		X
19. Metal Detection	Biological	Pathogen Contamination	X		Post-Process environmental contamination could occur if sanitation controls not in place as product is not packaged at this point	Prerequisite – Sanitation Program		X
	Chemical	Allergen: Soy	X		Allergen Cross-Contact could occur with shared Tumbler if not adequately cleaned	Prerequisite – Sanitation Program		X
	Physical	Foreign Material - Metal	X		Detection and removal of foreign material	CCP – Metal Detection	X CCP #4	
20. Packaging & Nitrogen Flush	Biological	Pathogen Contamination	X		Post-Process environmental contamination could occur if sanitation controls not in place	Prerequisite – Sanitation Program		X
	Chemical	Allergen Fish – Salmon, Soy	X		Salmon is an allergen that must be declared on the label.	Allergen Management Program (Labeling)	X CP#1	
			X		Equipment must be adequately cleaned to prevent cross-contact.	Prerequisite - Sanitation Program		X
			X		Approved supplier and specification on file. Nitrogen flush is for Quality only.			
Physical	None		X	Product and equipment are visually inspected during packaging to ensure no foreign material enters during the packaging				
21. Case Packed &	Biological	None		X	Product is shelf stable, protected and GMP's apply.			

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Palletized								
	Chemical	None		X	Product is protected and GMP's apply.			
	Physical	None		X	Product is protected and GMP's apply.			
22. Shipping Ambient Distribution	Biological	None		X	Product is shelf stable, protected and GMP's apply.			
	Chemical	None		X	Product is protected and GMP's apply.			
	Physical	None		X	Product is protected and GMP's apply.			

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Critical Control Points

CCP #1

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Records	Verification
			What	How	Frequency	Who			
1. Cooler Storage (During, thawing and WIP)	Pathogenic bacteria growth and toxin formation	Cooler Temperature is maintained below 40°F	Cooler Temperature	Continuous temperature monitoring device. Handheld digital thermometer.	Continuous, with visual check of recorded data once daily.	Qualified Individual	Move to alternate cooler. Hold and evaluate based on total time temperature exposure. Maintenance of cooler if necessary.	Chart recorder printout Record of visual checks Daily thermometer calibration	Check the temperature recorder for accuracy and damage and to ensure that it is operational before putting into operation: and calibrate in annually. Review monitoring, corrective action, and verification records within one week of preparation.

CCP #2

Process Control Step	Hazard(s)	Critical Limits	Monitoring	Corrective Action	Records	Verification
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			What	How	Frequency	Who			
Unrefrigerated Processing	Pathogenic Bacteria Growth and Toxin Formation	The product is held at internal temperatures below 50°F (10°C) throughout processing (Thawing, Cutting, Ozone and Racking	The internal temperature only of the product.	Digital Thermometer	At least every two hours throughout the unrefrigerated process	Qualified Individuals	Chill and hold the affected product until an evaluation of the total time and temperature exposure is performed. Dehydrate the product to obtain a water activity of .85 or lower for the control of S. aureus. If product is above 70°F for 3 hours or more, discard the product. Divert the product to a non-food use. Modify the process as needed to reduce the time and temperature exposure.	Production Records Daily Thermometer Calibration	Check the digital thermometer for accuracy and damage and to ensure that it is operational before putting into operation. Check it daily and review monitoring

CCP #3

	Hazard(s)		Monitoring		Records	Verification
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Process Control Step		Critical Limits	What	How	Frequency	Who	Corrective Action		
11. Dehydrator	Pathogenic bacterial growth and toxin formation	water activity of .85 or less	Water activity of the finished product	Collect a finished product sample and conduct a water activity analysis	At the start of each centrifuge run, every hour ± 15 minutes, and at the end of each centrifuge run.	Qualified Individual	Place product on hold pending lab analysis Destroy the product Maintenance to the dehydrator if it is not functioning properly. Conduct investigation for root cause analysis to determine necessary preventive actions	Water Activity Records Calibration Log for the Water Activity meter Corrective Actions Report, if Deviations occur	Water activity meter calibration 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.

CCP #4

Process	Hazard(Critical Limits	Monitoring	Corrective	Verification	Records
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Control Step	s)		What	How	Frequency	Who	Action		
20. Metal Detection	Physical: Foreign Material - Metals	All of the product passes through an operating metal detector	Metal Detector is present and operating	Visual examination	Daily, at the start of operations	Qualified Individual	Hold all of the product produced since controls were last confirmed as functioning properly until it can be run through a metal detector.	Conduct a validation study to determine appropriate settings for the metal detector	Metal Detector Check Log
		7mm critical limit Operating Limits: 1.5mm Fe 2.0 NonFe 2.5 SS Fe	Metal detector is operable, calibrated and reject mechanism is working	Passing test pieces with product through the metal detector and product is rejected	Start of the run, every 2 hours, End of the run	Qualified Individual	If metal detector fails to detect and reject any of the test pieces, product must be held from the last good check, unit inspected and re-calibrated, and product repassed through. Repair of the metal detector if necessary.	develop metal detector sensitivity standards challenge the metal detector with sensitivity standards at the start of each	Calibration Certificates of Metal Detector and Test Pieces

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		No detectable metal fragments are in the product passing through the metal detector	The product for the presence of metal fragments	Metal Detector	Continuous	Equipment itself	Hold and evaluate the rejected product Attempt to locate and correct the source of the fragments found in the product by the metal detector	production run, every two hours, and at the end of each production run. review monitoring, corrective action, and verification records within one week of preparation	
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Allergen Management

CP #1

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
20. Packaging	Allergen – Fish (Salmon), Soy	Fish (Salmon) is Declared on the Label Soy (Chili Lime)	Ingredient Listing on Finished Product Labels	Visual comparison of the label against product specification	Start of the production lot and when new rolls of film are changed	Qualified Individual	<p>Notify Supervisor</p> <p>Hold and segregate labeled product until the last acceptable check.</p> <p>Inspect all affected product and repackage mislabeled product.</p> <p>Inspect the remaining rolls of film staged for use and in inventory for accuracy and separate affected rolls. Contact the film supplier to ensure corrections are made to prevent reoccurrence.</p>	<p>Finished Product Allergen Labeling Log, Reviewed Weekly</p> <p>Verify product specification against raw materials ingredient's label declaration at least annually and when changes to supplier or formulation occurs</p>	<p>Finished Product Allergen Labeling Log</p> <p>CAPA, if deviation occurs</p>

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							Modify label procedures as appropriate.	CAPA, if deviation occurs	
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Validation References:

1. FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food:
<https://www.fda.gov/media/99581/download>
2. Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry – Appendix 1: Potential Hazards for Foods and Processes
<https://www.fda.gov/media/99581/download>
3. FDA Fish and Fishery Guidance March 2020
<https://www.fda.gov/media/80637/download>
4. Time and Temperature Controls during Unrefrigerated Processing
<https://www.fda.gov/media/100329/download>
5. GMA Control of Salmonella in Low-Moisture Foods, February 4, 2009
<https://forms.consumerbrandsassociation.org/forms/store/ProductFormPublic/SalmonellaControlGuidance-Annex>
6. Minimum Water Activity Limits for Growth of Microorganisms, Anthony J. Fontana Jr.

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7. CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects
<https://www.fda.gov/media/71953/download>
8. Magnets for Metal Fragment Control and Food Safety – By Debby Newslow (D. L. Newslow & Associates, Inc.) and Kevin Baker (MAGNATTACK™ Global) and AMR Consulting
<https://fsgservices.com/wp-content/uploads/2017/06/Magnets-for-Metal-Fragment-Control-and-Food-Safety.pdf>
9. FDA Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry
<https://www.fda.gov/media/102633/download>
10. NIST Calibrated Traceable Thermometer https://www.amazon.com/Kessler-Thermometer-REFERENCE-THERMOMETER-Certificate/dp/B01LLYLJCG/ref=sr_1_3?dchild=1&keywords=nist+thermometer&qid=1619797295&sr=8-3
11. [Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products](http://www.foodprotect.org/issues/packets/2012packet/attachments/iii_018_all.pdf) (contains time/temp for 7-log *Salmonella* reduction).
http://www.foodprotect.org/issues/packets/2012packet/attachments/iii_018_all.pdf
12. [Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft guidance for Industry. Appendix 3: Bacterial Pathogen Growth and Inactivation.](https://www.fda.gov/media/99598/download) Table 3-A contains water activity level for preventing growth of *Listeria monocytogenes* & *Salmonella* spp. (0.92 and 0.94 respectively); Table 3-D contains time/temperature for lethality for *Listeria*. <https://www.fda.gov/media/99598/download>

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Hazard Risk Assessment – Determination of Severity vs Likelihood

The food safety team used the flow diagram to determine what hazards are reasonably likely to occur. The risk level of each hazard was identified using a matrix of hazard likelihood and severity, if uncontrolled. Hazards with a score of 1-3 require a preventive control. Use of preventive controls for hazards scoring 4-9 is at the discretion of the food safety team. Hazards scoring 10-18 are controlled by a pre-requisite program. The team should consider the use of pre-requisite programs to manage all low-risk hazards, or risks with a score of 19-25. Preventive control measures and the steps that they are applied at are noted on the hazard analysis.

The hazard risk analysis in this document was performed using the risk matrix below.

	Common Occurrence	Known to Occur	Can Occur	Unlikely to Occur	Practically Impossible
Fatality	1	2	4	7	11
Serious Injury/Illness	3	5	8	12	16
Product Recall	6	9	13	17	20
Consumer Complaint	10	14	18	21	23
Insignificant Damage	15	19	22	24	25

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Food Safety Team Training:

Person Name	Title	Training
Whitney Cordano	Quality Manager	USDA and FDA HACCP Certified (PCQI) SQF Practitioner
Nicholas Gustavis	Production Manager	HACCP Certified
Quinto Van Peborgh	Chief of Staff	Internal Food Safety Training
Douglas Riboud	CEO	Internal Food Safety Training
Denise Webster	Third Party Consultant	Lead Trainer FSMA Preventive Controls for Human Food

The HACCP plan is subject to review by the HACCP team annually, when new equipment or processes are introduced and when critical limits are frequently not met. The HACCP team will meet quarterly to discuss any changes that effect the HACCP Plan. Documented reviews and HACCP program records are kept for a minimum of 2 years.