;

True Fresh HPP

Food Safety Preventive Control Plan

Processing of Baby Food (NRTE)

Site: 6535-B Caballero Boulevard

Buena Park, CA 90620

Revised: September 18,2019

Prepared By:
Denise Webster M.S., CFS, PCQI

Approved By:
Grant Lorsung – President

Signature:_____ Date:_____
Malynn Porayanee M.Sc., PCQI – Quality Assurance Manager

Signature:_____ Date:_____
Maryam Nojoumi PCQI – Quality Assurance Manager

Signature:_____ Date:_____

Grant Lorsung – President
Signature:_____ Date:_____

Scope:

This Food Safety Plan is for the dedicated baby food manufacturing area in the True Fresh HPP Buena Park facility. The cooler and freezer spaces will be shared with the HPP facility but in dedicated areas for storing and tempering of the baby food raw materials prior to processing. The raw materials will then be transferred for processing into the dedicated room and packaged into pouches as Not-Ready-To Eat status. The pouches are then transferred to True Fresh HPP storage areas for further HPP processing within 24 hours, which is covered under their Ready-To-Eat FDA Perishable products Food Safety Plan (HACCP + Preventive Controls).

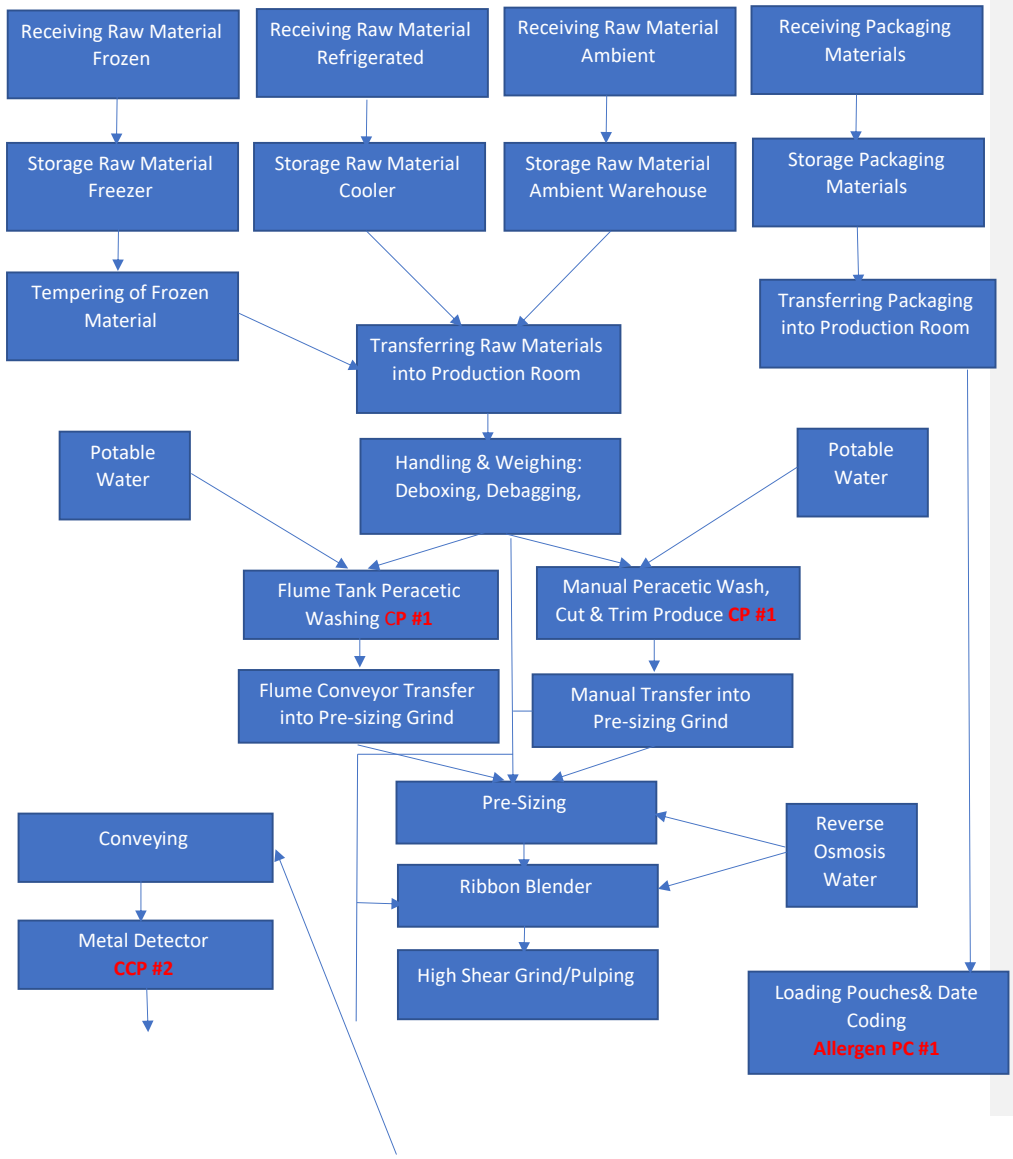
Company Details:

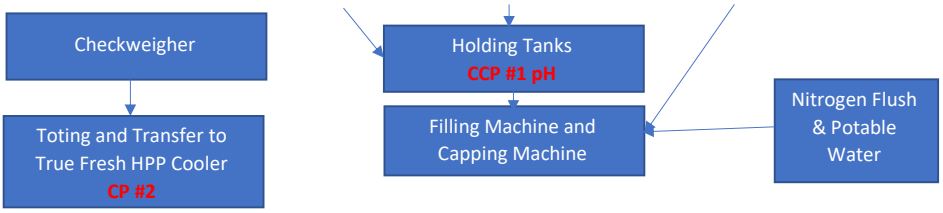
True Fresh HPP and dedicated manufacturing area for baby food can operate 24 hours/7 days a week, includes sanitation and based on production schedule. The site operates under strict cGMP and BRC policies and practices along with pre-requisite programs (e.g. pest control, maintenance). There is a dedicated team assigned for the production of baby food with specific training and supervision. Sanitation will be conducted during allergen changeovers and up to 48 hour continuous production.

Food Safety Plan Version Control

Date	Document Changes	Approved By
8/1/18	New – Product Launch	Richard Gonzalez
8/27/18	Post-Launch Reassessment – updated flow chart, hazard analysis and master summary details to align with overall hazards and monitoring controls	Richard Gonzalez
9/25/18	Allergen matrix changed – removed Almond and Cashews from hazard analysis. Final amends per team review	Richard Gonzalez
6/6/19	Updated process flow and hazard analysis for production being conducted in the True Fresh HPP facility in its designated location with shared storage	Maryam Nojoumi
9/18/19	Updated process flow & addition of likelihood x severity for CODEX compliance	Malynn Porayanee

PROCESS FLOW CHART





FURTHER PROCESSING COMPLETED AT TRUE FRESH BUENA PARK FACILITY

TRUE FRESH PRODUCTION
PRODUCT: ONCE UPON A FARM BABY FOOD POUCHES
Site: 6535-B Caballero Boulevard Buena Park, CA 90620

HAZARD ANALYSIS

Ingredient / Processing Step	Identify potential food safety hazards introduced controlled or enhanced at this step		Do any potential food safety hazards require a preventive control?		Justify your decision for previous column (Severity x Likelihood Risk Assessment)	What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *e.g. Process including CCPs, Allergen, Sanitation, Supply-chain, other Preventive Control*	Is the preventive control applied at this step? Process, Allergen, Sanitation, Supply Chain	
	Hazard Type	Hazard	Yes	No			Yes	No
Receiving Packaging Material (Pouches on Rails, Caps	Biological	None			Records on file for, letter of guarantees and food contact safety SL=1			
	Chemical	Allergens – Coconut	Yes		Pouches need to have correct allergen declaration SL=15 (controlled at a later step)	Allergen Preventive Control – Storage, Segregation and Labeling (applied at a later step)		X
		Chemical Migration		No	Records on file for material migration validation, letter of guarantees and food contact safety SL=4			

	Physical	Foreign Material	Yes		Incoming pouches and caps could be damaged and introduce foreign material SL=3	Supply Chain Preventive Control – approved supplier and inspection upon receipt (Pre-Requisite Programs)		X
Receiving Raw Materials - Ambient	**Biological**	E.Coli EHEC Listeria mono. Salmonella Clostridium Botulinum	Yes		Incoming Ingredients may be contaminated with foodborne pathogens from the supplier SL=20 (controlled at a later step)	Supply Chain Preventive Control – (applied at a prior facility/step by brand owner) Process Preventive Control – HPP (applied at a later step)		X
	Chemical	Allergens – Coconut	Yes		Some Incoming ingredients contain Allergens SL=20 (controlled at a later step)	Allergen Preventive Control – Storage, Segregation and Labeling (applied at a later step)		X
	Physical	Foreign Material	Yes		Incoming Ingredient may be contaminated with foreign material from the supplier SL=6	Supply Chain Preventive Control – (applied at a prior facility/step by brand owner) Process Preventive Control – Metal Detection (applied at a later step)		X
Receiving Raw Materials – Refrigerated (Produce, Juice	**Biological**	E.Coli EHEC Listeria mono Salmonella Clostridium Botulinum	Yes		Incoming Ingredients may be contaminated with foodborne pathogens from the supplier SL=20 (controlled at a later step)	Supply Chain Preventive Control – (applied at a prior facility/step by brand owner) Process Preventive Control – HPP (applied at a later step, HPP process)		X
	Chemical	Allergen - Coconut	YES		Some Incoming ingredients contain allergens SL=20 (later step)	Allergen Preventive Control – Storage, Segregation and Labeling (applied at a later step)		X

	Physical	Foreign Material	YES		Incoming Ingredient may be contaminated with foreign material from the supplier SL=6	Supply Chain Preventive Control – (applied at a prior facility/step by brand owner) Process Preventive Control – Metal Detection (applied at a later step)		X
Receiving Raw Materials - Frozen	**Biological**	E.Coli EHEC Listeria mono Salmonella Clostridium Botulinum	Yes		Incoming Ingredients may be contaminated with foodborne pathogens from the supplier SL=20 (later step)	Supply Chain Preventive Control – approved suppliers (applied at a prior step/facility by brand owner) Process Preventive Control – HPP (applied at a later step)		X
	Chemical	Allergen - Coconut	YES		Some Incoming ingredients contain allergens SL=20 (later step)	Allergen Preventive Control – Storage, Segregation and Labeling (applied at a later step)		X
	Physical	Foreign Material	YES		Incoming Ingredient may be contaminated with foreign material from the supplier SL=6	Supply Chain Preventive Control – approved suppliers Process Preventive Control – Metal Detection (applied at a later step)		X
Storage of Packaging	**Biological**	None						
	Chemical	None						
	Physical	None						
Storage of Ingredients - Ambient	**Biological**	None			Ingredient is fully sealed and GMP's apply SL=1	GMP's - overall cleanliness and appropriate storage		
	Chemical	Allergens – Coconut	YES		Inadequate storing of allergens could cause cross-contamination SL=20 (later step)	Allergen Preventive Control plan managed through GMP's – closed and separated storage		X

	Physical	None			Ingredient is fully sealed and GMP's apply SL=6			
Storage of Ingredients - Refrigerated	**Biological**	E.coli EHEC Listeria mono. Salmonella	YES		Product must be held at refrigerated temperature to minimize growth and Environment must be clean and free of pathogens SL=15 (additional controls at a later step)	Cooler temperature is monitored via GMP checks. Sanitation Preventive Control includes basic GMP hygiene of facility		X
	Chemical	Allergens – Coconut	YES		Inadequate storing of allergens could cause cross-contamination SL=5 (no other allergens stored in that area)	Allergen Preventive Control plan managed through GMP's – closed and separated storage, clean procedure for spills		X
	Physical	None			Ingredient is fully sealed and GMP's apply SL=1			
Storage of Ingredients - Frozen	**Biological**	E.coli EHEC Listeria mono. Salmonella	YES		Product must be held at frozen or refrigerated temperature to minimize growth SL=15 (additional controls at a later step)	Cooler temperature is monitored via GMP checks.		X
	Chemical	None						

	Physical	Foreign Material – Bulk Totes			Most Ingredient is fully sealed, the bulk totes have just lids and GMP's are followed to ensure correctly covered SL=9 further inspection will be conducted	GMP's and further inspection before use		
Tempering of Frozen Raw Materials	**Biological**	E.coli EHEC Listeria mono. Salmonella		No	Growth of biological pathogens could occur if present and product is improperly tempered SL=5 (entire facility is chilled, not possible for ambient tempering)	Air monitoring of product in Cooler used for Tempering Frozen Raw Materials and GMP's as Pre-Requisite for hygienic controls		
	Chemical	None						
	Physical	None			Product is kept fully sealed in original packaging or in closed totes during tempering SL=9 further inspection will be conducted			
Transferring Packaging to Production Room	**Biological**	None			Packaging is protected and GMP's apply SL=1			
	Chemical	None			Packaging is protected and GMP's apply SL=1			

	Physical	None			Packaging is protected and GMP's apply SL=1			
Transferring Raw Material to Production Room	**Biological**	None			Product is transferred in its original packaging and conducted air monitored refrigerated temperature controls rooms/transfer area SL=6			
	Chemical	None			Ingredient is fully sealed and GMP's apply SL=1			
	Physical	None			Ingredient is fully sealed and GMP's apply SL=1			
Handling & Weighing of Raw Materials -Deboxing, Debagging, Weighing	**Biological**	Salmonella Listeria mono Staph Aureus	YES		Ingredients are handled and exposed to the environment and employee handling SL=20 (HPP at later step)	GMP's and Sanitation Pre-Requisite Process Preventative Control applied at later step (e.g. HPP)		X
	Chemical	Allergens – Coconut	YES		Inadequate handling of allergens could cause cross-contact /contamination SL=5 only coconut allergen handled in room	Allergen Preventive Control plan managed through GMP's and SOP's– closed and separated storage, clean procedure for spills		X

	Physical	Foreign Material - Metal	YES		Foreign Material can contaminate the product if not properly handled SL=20 (applied at later step)	Process Preventive Control – Metal Detection (applied at a later step) GMP's – good handling practices		X
Potable Water	**Biological**	Waterborne Pathogens		NO	Municipal City water is used and test results on file SL=1			
	Chemical	Heavy Metals and other Contaminants		NO	Municipal City water is used and test results on file SL=1			
	Physical	None						
Manual Peracetic Wash, Cut & Trimming of Produce	**Biological**	E.coli EHEC Salmonella Listeria mono	YES		Ingredients are handled and exposed to the environment Raw Materials may contain pathogens SL=20 peracetic acid wash and additional HPP at a later step	GMP's and Sanitation Pre-Requisite Process Preventative Control applied at later step (e.g. HPP)		X
	Chemical	Chemical Concentration	YES		Chemical concentration of wash water must be a correct to prevent recontamination SL=16 checked at this step	Process Preventive Control - Chemical Concentration checks	**X CP#1**	
	Physical	Foreign Material - Metal	YES		Foreign Material can contaminate the	Process Preventive Control – Metal Detection (applied at a later step)		X

					product if not properly handled SL=20 (later step)	GMP's – good handling practices & knife check policy Metal Detection (applied at later step)		
Flume Tank Peracetic Acid Wash	**Biological**	E.coli EHEC Listeria mono. Salmonella	YES		Ingredients are handled and exposed to the environment Raw Materials may contain pathogens SL=20 (later step)	GMP's and Sanitation Pre-Requisite Process Preventative Control applied at later step (e.g. HPP)		X
	Chemical	Chemical Concentration	YES		Chemical concentration of wash water must be a correct to prevent recontamination SL=16 checked at this step	Process Preventive Control - Chemical Concentration checks	**X CP#1**	
	Physical	Foreign Material - Metal, Plastic	YES		Foreign Material can contaminate the product due to equipment or handling SL=20(later step)	Process Preventive Control – Metal Detection (applied at a later step) Other: GMP's – good handling practices and Maintenance		X
Flume Conveyor Transfer into Pre-sizing Grind	**Biological**	Listeria mono. Salmonella	YES		Ingredients are handled and exposed to the environment SL=20(later step)	GMP's and Sanitation Pre-Requisite Process Preventative Control applied at later step (e.g. HPP)		X
	Chemical	None						
	Physical	Foreign Material - Plastic		NO	Conveyor Belt and overhead in good condition and monitored during Pre-Op to ensure no risk			

Manual Transfer into Pre-Sizing Grind	**Biological**	Listeria mono. Salmonella	YES		Ingredients are handled and exposed to the environment SL=20(later step)	GMP's and Sanitation Pre-Requisite Process Preventative Control applied at later step (e.g. HPP)		X
	Chemical	None						
	Physical	Foreign Material		NO	Product is manual carried a short distance and GMP's are followed to protect the product SL=6			
Pre Sizing - Grind	**Biological**	Listeria mono. Salmonella	YES		Ingredients are handled and exposed to the environment SL=20(later step)	GMP's and Sanitation Pre-Requisite Process Preventative Control applied at later step (e.g. HPP)		X
	Chemical	Allergens	YES		Inadequate cleaning of equipment to prevent allergens cross-contact /contamination SL=20	Sanitation Preventive Control Plan Allergen Preventive Control Plan	**X** **PC#2**	
	Physical	Foreign Material - Metal	YES		Foreign Material can contaminate the product due to equipment metal on metal contact SL=20(later step)	Process Preventive Control – Metal Detection (applied at a later step)		X
Ribbon Blender – High Shear Grind/ additional ingredients and RO Water	**Biological**	Listeria mono. Salmonella	YES		Ingredients are handled and exposed to the environment SL=20(later step)	GMP's and Sanitation Pre-Requisite Process Preventative Control applied at later step (e.g. HPP)		X
	Chemical - YES	Allergens	YES		Inadequate cleaning of equipment to	Sanitation Preventive Control Plan Allergen Preventive Control Plan	**X** **PC#2**	

					prevent allergens cross-contact /contamination SL=20			
	Physical - NO	Foreign Material - Metal	YES		Foreign Material can contaminate the product if not properly handled, metal on metal contact SL=20(later step)	Process Preventive Control – Metal Detection (applied at a later step) Other: GMP's – good handling practices and Maintenance		X
Preparation of Reverse Osmosis Water	**Biological**	Waterborne Pathogens		NO	Water is municipal and potable and maintained in fully enclosed tank SL=3			
	Chemical	None			Water is municipal sourced SL=3			
	Physical - NO	None						
High Shear Mixer – (e.g. grinding, pulping)	**Biological**	Listeria mono. Salmonella	YES		Ingredients are handled and exposed to the environment SL=20(later step)	GMP's and Sanitation Pre-Requisite Process Preventative Control applied at later step (e.g. HPP)		X
	Chemical	Allergens	YES		Inadequate cleaning of equipment to prevent allergens cross-contact /contamination SL=20	Sanitation Preventive Control Plan Allergen Preventive Control Plan	**X** **PC#2**	

	Physical	Foreign Material - Metal	YES		Foreign Material can contaminate the product due to equipment metal on metal contact SL=20(later step)	Process Preventive Control – Metal Detection (applied at a later step)		X
Holding Tanks	**Biological**	Listeria mono. Salmonella	YES		Ingredients are handled and exposed to the environment Growth of pathogens in the holding tank SL=20(later step)	GMP's and Sanitation Pre-Requisite Tanks are held in a temperature control environment Process Preventative Control applied at later step (e.g. HPP)		X
		Clostridium Botulinum	YES		C.Bot if present in product could cause illness due to inadequate pH control which HPP does not inactivate spores SL=20	Process Preventive Control – pH control of finished product before filling	**X** **CCP#1**	
	Chemical	Allergens	YES		Inadequate cleaning of equipment to prevent allergens cross-contact /contamination SL=20	Sanitation Preventive Control Plan Allergen Preventive Control Plan	**X** **PC#2**	
	Physical	Foreign Material - Metal	YES		Foreign Material can contaminate the product if not properly handled SL=20 (later step)	Process Preventive Control – Metal Detection (applied at a later step) Other: GMP's – good handling practices and Maintenance		X

Pouch Filling and Capping	**Biological**	Listeria mono. Salmonella	YES		Filling machine could be contaminated with pathogens Capper is part of filling machine, no biological risk of cap SL=20 (later step)	GMP's and Sanitation Pre-Requisite Process Preventative Control applied at later step (e.g. HPP)		X
	Chemical	Allergens – Coconut	YES		Inadequate cleaning of equipment to prevent allergens cross-contact /contamination SL=20 for non-coconut skus	Sanitation Preventive Control Plan Allergen Preventive Control Plan	**X** **PC#2**	
	Physical	Foreign Material - Metal	YES		Foreign material such as metal could enter the product through the filling process Any Damaged/Pieces of Capper plastic, would be caught at multiple inspection points SL=12 (later step but not as likely due to the size of the fitment)	Process Preventive Control – Metal Detection (applied at a later step) GMP Inspection		X
Loading Pouches and Date Coding	**Biological**	None			Pouches are approved for Food Contact and further HPP SL=6			
	Chemical	Allergens – Coconut	YES		Incorrect pouch being loaded on the rails with undeclared allergens	Allergen Preventive Control plan – Label Verification	**X** **PC#1**	

					SL=25 verified at this step to be properly labeled			
	Physical	None			Pouches are on secured rails with no exposure of opening SL=1			
Nitrogen Flush of Pouch and Water Clean of Cap	**Biological**	None			Municipal Water is potable and Nitrogen Gas is food grade filtered SL=1			
	Chemical	None			Nitrogen Gas is food grade contact with Specification on file SL=1			
	Physical	None			Nitrogen Gas is food grade contact with Specification on file SL=1			
Conveying	**Biological**	None			Pouch is fully sealed GMP's and Sanitation as Pre-Requisite SL=1			
	Chemical	None						
	Physical	None			Pouch is fully sealed SL=1			
Checkweigher	**Biological**				Pouch is fully closed SL=1			
	Chemical				Pouch is fully closed SL=1			
	Physical				Pouch is fully closed SL=1			

Metal Detector	**Biological**				Pouch is fully closed SL=1			
	Chemical				Pouch is fully closed SL=1			
	Physical	Foreign Material - Metal	X		Metal that may have been introduced through the process from equipment SL=20 applied at this step	Process Preventive Control – Metal Detection	**X CCP #2**	
Toting and Transfer to True Fresh HPP Cooler	**Biological**	E.coli EHEC Listeria mono. Salmonella		X	Raw materials may have contained pathogens and/or product exposed due to the environment. Growth of pathogens prior to HPP processing must be controlled via temperature SL=15 temperature controls required but further HPP at later step	Temperature of Pouches		**X CP #2**
						Process Preventive Control (applied at a later step)		X
	Chemical	None			Pouches are fully sealed during transfer to cooler SL=1			
	Physical	None			Pouches are fully sealed during transfer to cooler SL=1			

Process Preventive Controls

Commented [dw1]: h

CCP #1

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Holding Tank	Biological Pathogens Clostridium Botulinum	≤4.5	pH of the Finished Product	Calibrated pH meter	Every Tank before Filler	Qualified Individual	Investigate root cause and determine if pH adjustment possible If pH adjustment, The CCP will be under control once pH is adjusted, no further action is taken. If pH is unable to be achieved and/or does not meet specifications; product will be placed on Hold and dispositioned by OUF.	Review of Batch Records with pH checks by PCQI Daily pH Meter Calibration Logs	pH Control /CCP Monitoring Form pH Meter Calibration Log Corrective Action Records Verification records (within 7 days of production by PCQI)

CCP #2

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal Detector	Foreign Material – Metal	Foreign Material >7mm (See Operating Limits)	Calibrated Metal Detector	Using metal detectable cards/rods containing: 2.0mm Ferrous 2.5mm Non-Fe 4.0mm Stainless Steel (316) See SOP for further details	Start-up Every 30minute +/- 15minute End of Run/ Shut down	Qualified Individual	Pouches rejected are examined for foreign material. If found, product will be inspected for foreign material and root cause and corrective action identified. Product may require being placed on hold. If metal detector becomes inoperable or found to be not functioning. 1.The line will shut down 2. Product held from last good check. 3. Metal Detector recalibrated 4. Product is re-ran through metal detector.	Review Metal Detector Log Checks by PCQI Daily Calibration Check Annual Calibration of Metal Detector by 3rd party service provider	Metal Detector Log Checks Corrective Action Records Verification records (within 7 days of production by PCQI)

Control Point #1

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Washing - Flume Tank or Sink	E.coli EHEC Listeria mono. Salmonella	65-80ppm Operating Limit 65-75ppm	Concentration of Peracetic Acid Wash Water	Titration	Start of each Batch	Qualified Individual	If concentration is below 65, additional chemical added. Hold product and contact OUF for distribution from last acceptable batch. If concentration is above 80, product is discarded from last good check. If no product was washed, additional water added as needed to meet correct concentration	Washing Control Log Reviewed by PCQI	Wash Control Log Corrective Action Records Verification records (within 7 days of production by PCQI)

Control Point #2

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Toting and Transfer to True Fresh HPP Cooler	Growth of Biological Pathogens E.coli EHEC Listeria mono. Salmonella Staph aureus	Product Temperature at equal or less than 49°F	Product Temperature 2 Pouches	Calibrated Thermometer	Start of Run Every 30 Minutes +/-15 Minutes End of Run/ Shut down	Production Technician-Qualified Individual	If Product is 50°F or higher, product will placed on temporary hold, then sent immediately to freezer and monitored and documented until it achieves <45°F Maximum of 4 hours to chill to 45°F or less Product will be then sent to the Cooler for True Fresh HPP processing	Finished Product Monitoring Record Logs by PCQI Weekly verification of probes	Finished Product Control Record Corrective Action Records Verification records (within 7 days of production by PCQI)

Allergen Preventive Controls

Commented [dw2]: h

PC #1

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Loading Pouches and Date Coding	Chemical: Allergens- Coconut	Correct Pouch on the Line with the Correct Allergen Declaration	Full Box of Pouches on Rail	Visual inspection of the pouch and matches specification	Start of Filler and Every 30 Minutes +/- 15 Minutes End of Run/ Shut down	Production Technician or Qualified Individual	If incorrect pouches were selected, they must be removed from the packaging area/filler and returned to inventory. If product was incorrectly packed, product must be placed on Hold and Destroy.	Finished Product Control Log (CCP#3 Record)	Pouch Allergen Verification Logs Corrective Action records Approved Pouch and Specification

Sanitation/Allergen Preventive Controls

PC #2

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Pre sizing Urschel 1 to Guala pack Filling Machine and Capping	Biological – Listeria mono. Salmonella (Environment) Allergen cross-contact and cross-contamination	Visual clean	Pre-Operational check of Equipment and Facility	Visual inspection of Equipment and Facility for cleanliness	Pre-OP Start of Shift After Cleaning and Sanitation	Qualified Individual	If visually dirty, equipment or area is recleaned, re-sanitized and re-inspected for visual cleanliness until it passes. If unable to obtain cleanliness, the equipment and/or area is put on hold.	Pre-Operational Log and Allergen Change Over/Scheduling Controls	Pre-Operational Log Allergen Change-Over Corrective Action records

Appendix – Hazard Analysis Risk Assessment Table

	Severity of Consequences				
Likelihood of Occurrence	1. Minor Injuries [No lost time]	2. Significant Injury [up to 7 Days]	3. Serious Injury [7 Day Injury]	4. Major Injury	5. Fatality
1. Very unlikely [hasn't occurred before]	1	2	3	4	5
2 - Slight [rarely occurs]	2	4	6	8	10
3 - Feasible [possible, but not common]	3	6	9	12	15
4 - Likely [has before, will again]	4	8	12	16	20
5 - Very Likely [occurs frequently]	5	10	15	20	25
Risk Rating: Likelihood * Severity	Minimal 1-2	Low 3-9	Medium 10-15	High 16-20	Extreme 25