

# FOOD SAFETY PLAN FOR Gluten Free Pasta PASTA (BULK/RETAIL)

PRODUCT(S) Gluten Free Pasta	<b>ISSUE DATE:</b> 5/11/22
PLANT NAME: Rallenti Pasta Company LLC: Building 7	<b>UPDATE</b> : 10/31/22
ADDRESS: 12239 NE MARX ST, PORTLAND, OR 97230	

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## **Background Information**

#### **Company Overview and Food Safety Team**

Rallenti Pasta Company, LLC serves as a co-manufacturer for multiple clients producing a variety of gluten free pasta shapes. Product is made 7 days a week in one 8 hour shift including start of day and end of day sanitation. Cleaning and sanitizing of all processing equipment is standardized via Standard Sanitation Operating Procedures and verified via daily cleaning checklists. All finished products contain no allergens with the exception of insertable cheese flavoring packets introduced during the packaging step. Municipal water, which is treated and tested per EPA requirements by the city, is used throughout the facility. As the end product is not a ready to eat product (the consumer performs a kill step with boiling the pasta) the facility is low risk, however Rallenti has designated hygienic zoning to separate production from administrative areas and Semolina packaging rooms quarantined in the warehouse area of the building. Employees are trained on the company's Good Manufacturing Practices and wear smocks and hairnets when working in hygienic zones.

#### **Food Safety Team**

Name	Position	Training
Dan Carmody*	QA Director	FSPCA Class
Adam Berger	Owner	In house training
Ryan Kennedy	Production Manager	In house training
Jen Currie	Pasta Production	In house training

<sup>\*</sup>Preventive Controls Qualified Individual

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# **Product Description, Distribution, Consumers & Intended Use**

	Distribution, Consumers & Interlueu Use
Product Name(s)	Pasta - See "Clients List" (pg.5) for shapes and ingredient statements per each client
Product Description, including Important Food Safety Characteristics	Dried Lupin Bean pasta Dried Rice Flour pasta Dried Lupin Bean and Chickpea pasta Dried Fava Bean pasta Dried Organic Beet and Tomato Penne Dried Organic Broccoli and Sweet Corn Penne Dried Organic Pumpkin and Carrot Penne Fresh Gluten Free Pasta
Ingredients	Lupin Bean Flour Sunflower Flour Tapioca Starch Xanthan Gum Coarse Pearled Sorghum Flour White Rice Flour Fava Bean Flour Chickpea Flour fiberSMART soluble fiber Whole Grain White Sorghum Flour Kaizen Mix Corn Flour Pumpkin Powder Pumpkin Puree* Carrot Puree* Carrot Powder Beet Puree* Tomato Powder Beet Puree* Sweet Corn Puree* Green Spirulina Pea Protein Cara Gum Konjac TruBlock Core Sealed insertable Gluten Free Cheddar Flavoring packet *received and store refrigerated prior to production use
Packaging Used	Twin sealed retail cartons packed in corrugated master cases, bulk bags packed in corrugated master cases, MAP trays with lidding film packed into corrugated master cases, sealed gusset bags

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	packed into corrugated master cases	
Intended Use	The product is not ready to eat. End users will add pasta to boiling water for 6-9 minutes, or until desired texture, prior to consumption.  Sold for foodservice applications	
Intended Consumers	General Public	
Shelf Life	1-2 years, at the discretion of the client	
Labeling Instructions	Add pasta to boiling water for 6-8 minutes, or until desired texture, prior to consumption	
Storage & Distribution	Dried Pasta: Room Temperature Fresh Pasta: Stored and Distributed frozen	
Approved: Print Name:	Signature:Adam Berger, Owner Date: 5/11/2022	

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# **Client List**

Client Name	Products	Packaging	Ingredients
New Seasons Market	Penne, Radiatori, Fettuccine (fresh)	Retail 10oz MAP trays in 12/1 Master Cases	White Rice Flour, Fava Bean Flour, Whole Grain White Sorghum Flour, Xanthan Gum
Montelupo	Radiatori, Penne	Retail 16oz Cartons in 6/1 Master Case	White Rice Flour, Fava Bean Flour, Whole Grain White Sorghum Flour, Xanthan Gum
Lupii	Elbow Macaroni, Penne	Retail 8oz Cartons in 6/1 Master Cases	Lupin Flour, Chickpea Flour, Tapioca Starch, Xanthan Gum
Alexis Foods	Penne, Radiatori	Penne: 10# bags in corrugated Master  Radiatori: 5# bags in corrugated Master	White Rice Flour, Fava Bean Flour, Whole Grain White Sorghum Flour, Xanthan Gum
Wholesome Provisions	Penne, Rotini, Elbow Macaroni, Orzo,	8oz bags in 20/1 Master Cases (16/1 for Rotini)	Lupin Flour, Sunflower Flour, Soluble Tapioca Fiber, Xanthan Gum
Perfect Keto	Yellow Cheddar Mac & Cheese White Cheddar Mac & Cheese	Retail 6oz Cartons in 6/1 Master Cases	Lupin Flour, Sunflower Flour, Soluble Tapioca Fiber, Xanthan Gum
Aviate	Rotini, Orzo	Rotini: Retail 8oz Gusset Bags	Fusilli: Lupin Flour, Sunflower Flour, Xanthan Gum, Soluble Tapioca Fiber Natural Wheat Flavoring Orzo: Lupin Flour,

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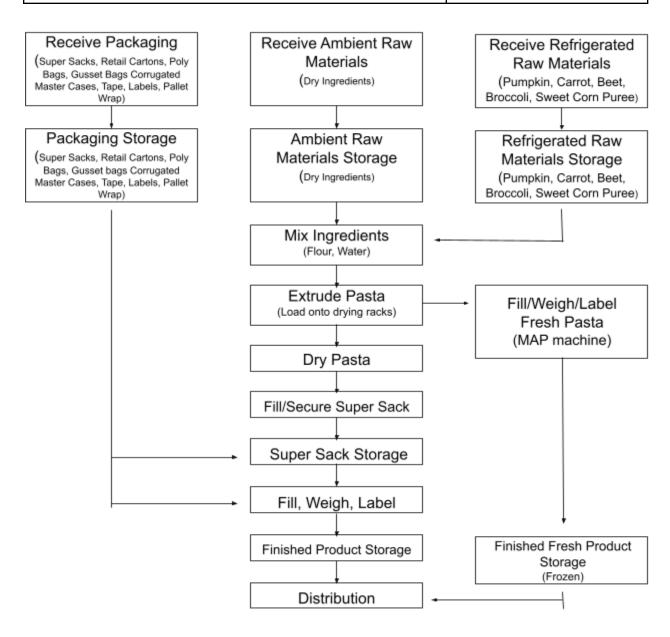
			Sunflower Flour, Xanthan Gum, Soluble Tapioca Fiber Popcorn Flavoring
Voodles	Pumpkin & Carrot Penne, Beet & Tomato Penne, Broccoli & Sweet Corn Penne	Retail Gusset 6oz bag in 6/1 Master Case	Pumpkin & Carrot :Coarse Pearled Sorghum Flour, Whole Grain Sorghum Flour, Corn Flour, Pumpkin Powder, Pumpkin Puree, Carrot Puree, Carrot Powder, Pea Protein, Xanthan Gum, Cara Gum 200, Konjac, TruBlock Core Beet & Tomato: Coarse Pearled Sorghum Flour, Whole Grain Sorghum Flour, Corn Flour, Beet Puree, Carrot Powder, Tomato Powder, Pea Protein, Xanthan Gum, Cara Gum 200, Konjac, TruBlock Core Broccoli & Sweet Corn: Coarse Pearled Sorghum Flour, Whole Grain Sorghum Flour, Yellow Corn Flour, Broccoli Puree, Carrot Powder, Sweet Corn Puree, Green Spirulina, Pea

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			Protein, Xanthan Gum, Cara Gum 200, Konjac, TruBlock Core
Kaizen	Fusilli, Orzo, Radiatori	Retail Cartons in 40/1 Master Case	Lupin Flour, Fava Bean Protein, Tapioca Starch, Xanthan Gum

# Flow Diagram

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Verified by: \_\_\_\_\_ 5/11/2022

# **Process Description**

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#### **Receiving Ingredients and Packaging**

Ingredients and raw materials are purchased from reputable verified suppliers that comply with internationally recognized food safety and quality systems. For each ingredient, the same brand is used consistently to minimize variation. Ingredients are stored according to the manufacturers' recommendations when specified.

 Receiving Packaging: Corrugated master cases, food grade poly bags, super sacks, tape, pallet wrap, and blank labels are purchased in bulk. Retail Cartons and Gusset Bags are reviewed for conformance with product allergens requirements and ingredients prior to storage.

#### • Receiving Ambient Raw Materials:

- Lupin Platform Lupin Bean Flour: Received in 50# bags. COAs requested per each lot
- o Lupina Lupin Bean Flour: Received in 50# bags. COAs requested per each lot
- o Inveja Lupin FLour: Received in 50# bags. COAs requested per each lot
- o Ciranda Tapioca Starch: Received in 50# bags. COAs requested per each lot
- o Artesa Chickpea Flour: Received in 50# bags. COAs requested per each lot
- o Tic Gums Xanthan Gum: Received in 50# bags. COAs requested per each lot
- Jungbunzlaur Xanthan Gum: Received in 50# bags. COAs requested per each lot
- New Life Market Coarse Pearled Sorghum Flour. Received in 50# bags. COAs requested per each lot
- New Life Market Whole Grain White Sorghum Flour. Received in 50# bags.
   COAs requested per each lot
- o Riceland White Rice Flour. Received in 50# bags. COAs requested per each lot
- Suntein Sunflower Flour. Received in 50# bags. COAs requested per each lot
- Prairie Fava Fava Bean Flour: Received in 50# bags. COAs requested per each lot
- fiberSMART Soluble Tapioca Fiber: Received in 50# bags. COAs request per each lot
- Grain Millers Corn Flour. Received in 50# bags. COAs requested per each lot
- Food to Live Green Spirulina Powder. Received in 50# bags. COAs request per each lot
- Naturz Organics Pea Protein: Received in 50# bags. COAs requested per each lot
- Van Drunen Farms Pumpkin Powder: Received in 50# bags. COAs requested per each lot
- Van Drunen Farms Carrot Powder. Received in 50# bags. COAs requested per each lot
- Van Drunen Farms Tomato Powder. Received in 50# bags. COAs requested per each lot

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- o Ingredion Cara Gum 200: Received in 50# bags. COAs requested per each lot
- o Ingredion Konjac HV: Received in 50# bags. COAs requested per each lot
- Tastes Natural TruBlock Core: Received in 50# bags. COAs requested per each lot
- Gamay Foods Gluten Free Cheddar Seasoning Packets: Received in 500/1 30# boxes. COAs requested per each lot
- Gamay Foods Gluten Free White Cheddar Seasoning Packets: Received in 500/1 30# boxes. COAs requested per each lot
- o Kaizen Pasta Mix: Received in 50# bags. COAs requested per each lot

#### • Receiving Refrigerated Raw Materials

- Stahlbush Farms: 30# pails. COAs requested per each lot
  - Pumpkin Puree
  - Carrot Puree
  - Beet Puree
  - Broccoli Puree
  - Sweet Corn Puree

#### **Storing Ingredients and Packaging**

- Packaging Storage: Retail cartons, corrugated master cases, food grade poly bags, super sacks, tape, pallet wrap, and blank labels are stored in the "Gluten Free" section of the Building 7 warehouse. Retail Cartons and food grade poly bags are in sealed containers to protect from physical hazards. Packaging materials are used First-In-First-Out.
- Ambient Raw Materials Storage: Flours and Dry Ingredients are stored in the "Gluten Free" dry storage section of the Building 7 warehouse, segregated from wheat containing ingredients. Ingredients are used First-In-First-Out. All raw materials in storage are completely covered to avoid any cross contact or potential physical hazards. Punctured bags are segregated and put on hold to determine disposition.
- Refrigerated Raw Materials Storage: All purees come thawed from 3rd Party Storage and are stored in reach in refrigerators. Temperatures cannot exceed 39 degrees for longer than 4 hours. Temperatures are checked periodically throughout the day.

**Mix Ingredients:** Flour(s), dry ingredients, and water are scaled into containers and are loaded into the upper hopper of the pasta extruder. Once ingredients are homogenized into a dough mixture the operator pulls a lever to turn over the upper hopper and load the dough into the extruding hopper.

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**Extrude Pasta:** Dough mixture passes through the extruding barrel and die cuts into the specified shape listed on the Production Work Order. The Pasta Production Operator catches and spreads the pasta shapes onto drying racks in even layers before stacking on rack carts.

**Fill/Weigh/Label Fresh Pasta:** Prior to packaging the product the Packaging Lead verifies the shape, lot, and best by date of the pasta on the Production Work Order. The Packaging Lead then verifies the allergen statement, lot code, and best by accuracy of the Retail Carton and/or Master Case label. Once verification is complete pasta is scaled onto trays and set aside to cool down. Operators will check the temperature of the pasta using an infrared thermometer. Once temperatures fall between 59 and 70 degrees F the operator will load two trays at a time and seal the lidding film onto the trays. A retail sleeve will be placed around the tray and finished products will be stored in a refrigerator.

**Dry Product:** Once racks are stacked to the appropriate height limit of the pasta dryer, the Operator loads the racks into the pasta dryers. They set the parameters of the dryer (time, temperature) dependent on the shape of the pasta. Pasta is stored and dried for 12-16 hours. Dryers automatically shut off once the specified duration is complete.

**Fill Super Sack:** At the beginning of the shift on the following day the Operator unloads the racks from the dryers and fills a super sack, attaching the Production Work Order.

**Store Super Sack:** For pastas that still need to be packaged, super sacks are stored First-In-First-Out in the gluten free production room, adjacent to the Packaging zone.

**Fill/Weigh/Label:** Prior to packaging the product the Packaging Lead verifies the shape, lot, and best by date of the pasta on the Production Work Order. The Packaging Lead then verifies the allergen statement, lot code, and best by accuracy of the Retail Carton and/or Master Case label. Once verification is complete, pasta is loaded into the hopper of the weigh fill machine to portion the pasta at the specified weight listed on the retail carton or master case label and load into the specified container.

- Retail Cartons are loaded onto a conveyor and pass through a glue twin sealer to adhere the carton flaps. Cartons drop onto a second conveyor where a laser prints the lot code and best by date on the bottom of the package. Cartons are loaded into a master case, pass through a tape sealer and labeled before loaded onto a pallet.
- Bulk bags in master cases are passed through a tape sealer and labeled before being loaded onto a pallet.
- Although all of the pasta produced is allergen free there are two cheddar packets that are inserted into retail cartons prior to the weigh/fill step. After handling these packets

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the packaging team will triple clean all tables and shelving used during the packaging run.

**Storage:** Finished product pallets are wrapped and stored into the "Gluten Free" finished goods section of the warehouse. Pallets are arranged First-In-First-Out.

**Finished Fresh Pasta Storage**: Once finished products are below 40 degrees F they will be transferred to a freezer for storage prior to pickup from a 3rd party warehouse.

**Distribution:** Product is shipped in ambient temperature trucks for dried pasta and refrigerated (below 40 degrees F) trucks for fresh pasta, free of debris.

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### **Hazard Analysis**

Hazard identification considers those that may be present in the food because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

- **B** = Biological hazards including bacteria, viruses, parasites, and environmental pathogens
- **C** = Chemical (including radiological) hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives
- **P** = Physical hazards include potentially harmful extraneous matter that may cause choking, injury, or other adverse health effects

(1) Ingredient/ Processing Step		(2) entify <b>potential</b> food safety hazards introduced, controlled or	(3) Do any potential food safety hazards require a		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize	(6) Is to preve con applications of this series.	he entive trol ed at
		step	· \	entati /e trol?		prevent the food safety hazard? Process including		
			Yes	No		CCPs, Allergen, Sanitation, Supply-chain, other preventive control	Yes	No
Receive	В	None						
<sup>'</sup> Packaging	С	Undeclared allergens - wheat	Х		Labeled Retail Cartons must declare allergens present in the product and print errors have/may occur	Allergen control: label review for allergen information upon receipt	X	
	Р	None						
Receive Ambient Raw Materials	В	Vegetative pathogens such as <i>B.</i> cereus <i>S.</i> aureus and <i>Salmonella</i>	X		Pathogens listed were identified to pose an elevated risk in rice and lupin flours. These hazards must be controlled when the	Supply Chain Control: Approved supplier and COAs provided for each lot for analysis prior to use in production area	X	

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		and coliforms, yeast and mold		flour and dry ingredients are milled and packaged			
	С						
	Р	Presence of extraneous materials: external contamination from rainwater, bird droppings, vermin/rodents , or flying insects, foreign materials, metal	X	Presence of extraneous matters can result in damaged final product or equipment	Process Control: Inbound Shipment Inspection Form performed by trained personnel	X	
Receive Refrigerated Raw Materials	В	Presence of pathogens, <i>L. monocytogene</i> s,coliforms, <i>Salmonella</i> , and <i>E. coli</i>	X	Pathogens listed were identified to pose an elevated risk in vegetable purees. These hazards must be controlled when the ingredients are processed, stored, and in transit	Supply Chain Control: Approved supplier and COAs provided for each lot for analysis prior to use in production area  Process Control: Trained personnel will check the temperature of the inbound truck and probe check the temperature of the purees and verify on the Inbound Shipment Inspection Form	X	
	С	None					
	Р	Presence of extraneous materials: external contamination from rainwater, bird droppings,	X	Presence of extraneous matters can result in damaged final product or equipment	Process Control: Inbound Shipment Inspection Form performed by trained personnel.	X	

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		vermin/rodents , or flying insects, foreign materials, metal					
Storage -	В	None					
Packaging and Ambient	С	None					
Raw Materials	Р	None					
Refrigerated Raw Materials Storage	В	Microbiological spoilage	X	Temperature abuse pose an elevated risk to the growth of spoilage microorganisms on vegetable purees	Process Control: All frozen purees are stored in reach-in refrigerators at or below 39°F. Temperatures are monitored and routinely verified on the QA checklist	X	
	С	None					
	P	None					
Mix	В	None					
'Ingredients	С	None					
	Р	Metal	X	Extruder has metal on metal contact	Process Control: Operator visually inspect extruder and verifies on Production Work Order	х	
Extrude Product	В	Vegetative pathogens such as <i>S. aureus</i> and <i>Salmonella</i>	Х	Unclean equipment can increase the risk of pathogens and bacteria to form and cross contaminate fresh product	Sanitation Control: Basic Sanitation Procedure (SSOP 4) to prevent recontamination	х	
	С	None					
	Р	None					

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Fill/Weigh/ Label Fresh Pasta	В	Microbiological spoilage such as yeast and mold	x	Pasta exceeding temperatures of 70°F prior to packaging can increase the risk of mold forming spores in an aerobic sealed package (MAP)  Process Control:  Operator scales pasta First-In-First-Out and records the temperature via infrared thermometer and verifies on the packaging work order prior to sealing trays	х	
	С	None				
	Р	Metal		Although pre-op checks of metal on metal contact are verified prior to mixing and extruding product there is still the risk of metal being introduced to the product during the production of pasta  Process Control: Finished sealed trays pass through a metal detector prior to storage. Any finished products detected to have metal will be tossed and recorded on the packaging work order	X	
Dry Product	В	None				
•	С	None				
	Р	None				
Fill Super Sack	В	Bacterial growth of <i>B. cereus</i> and/or other mycotoxins due to lack of time / temperature control	×	Improperly dried pasta with a moisture content over 13% can elevate the risk of bacteria, spoilage-microorganis ms, and pathogens to form on pasta. Since moisture tracking cannot be measured while pasta is in the dryer preventive controls must take place after the drying process and before packaging and/or distribution  Process Control:  Moisture Log for all dried product prior to release for packaging and/or distribution	X	

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1	_	ī				
	С	None				
	Р	None				
Store	В	None				
Supersack	С	None				
	Р	None				
Fill/ Weigh/	В	None				
<sup>'</sup> Label	С	None				
	Р	Metal	×	Although pre-op checks of metal on metal contact are verified prior to mixing and extruding product there is still the risk of metal being introduced to the production of pasta products detected to have metal will be tossed and recorded on the packaging work order	×	
Finished	В	None				
Goods Storage	С	None				
Storage	Р	None				
Distribution	В	None				
	С	None				
	Р	None				

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### **Process Preventive Control**

roc	-	s Preventive Control
Records	punoqui	Shipment Inspection Form Quality Control Form Corrective Actions Log
Verification	Review of	Inbound Shipment Inspection F Inspection F Inspection Form, Quality Control Form, and Corrective Actions Log Corrective within 7 working Actions Log days
Corrective Action	If the inspection	of inbound raw materials does materials does not meet the trained personnel are not permitted to schipment. Quality Control Forms are to be filled out and the incident is to be escalated to the Quality Assurance Director to reach out to the Quality assurance defermine next steps of disposition
	Who	personnel
Monitoring	Frequency	Every inbound a personnel supplier
Moni	How	Visual examination of supplier's truck prior to unloading raw materials
	What	Off-odors, cross Visual contact of raw materials, rainwater, prior to bird/vermin/rode unloading raw nt droppings, foregin materials foregin metal. Punctured packaging
Critical Limits	No visual signs	of external contamination from rainwater, bird droppings, vermin/rodents, or flying inspects, foreign materials, metal. Punctured Packaging
Hazard(s)	Ţ	matters
Process Control	Receive	Ambient Raw Marerials

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### **SOP 2: Labeling Incoming Raw Materials**



# SOP 2: Labeling Incoming Raw Materials Organic: Document 2 Rev. 9.3.21

Frequency: With every inbounding delivery

Operators: Production Manager/Qualified Receiving Team Member

Equipment: Inbounding Equipment Inspection Checklist

#### Procedure

- 1. Upon delivery, inspect truck
  - Automatic Rejection: off odors, out of spec product, punctured/damaged packaging, unsegregated (organic v conventional) ingredients
- 2. Verify product against P.O.
- 3. Store product in designated "Organic" location, separate from Conventional
  - If unable to completely separate product store organic ingredients above conventional ingredients
- 4. Complete Inbound Shipment Inspection Checklist and submit for filing

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# Sample Inbound Shipment Inspection Sheet

Date:		Rallenti Pasta Doc. 2/	Created 9.3.21		
Date.	Raw Materials Receive Product verified via Inspect Truck? Internal Temperature Internal Product Temperature	P.O.? of Truck (for re	y / n y / n rigerated ing	gredients)	
	Any off odor	s?	y / n		
	Product out	of spec?	y / n	-	end truck back
		ckaging? If yes, Lot Code			
		Amt/Units			_
	Organic ingredients	segregated?	y / n		<del></del>
	Driver Name				
	Product stored in de	signated area?	y / n		
	Organic ingredients	stored seperate	from conver	ntional?	y / n
Notes:	Initial	ls			
<b>Updates</b> Added Or	rganic Designation	Date 7/28/22	By Dan Carmod		ALLENTI -

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#### **Process Preventive Control**

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Records	Production	Work Order	Maintenance Log	Quality Control	Forms	Corrective	Actions Log																					
Verification	Review of	Maintenance Log, Quality	Control Forms, and Corrective	Actions Log within 7 working	days																							
Corrective Action	Halt all production	activities and escalate to Quality	Assurance and Production	Management. Identify the	affected areas and determine a root	cause for the	occurence. Contact equipment	manufacture for	guidance on now to fix the issue and	prevent	reoccurence. Fill	out a maintenance form and	segregate	equipment from	production until	problem is lixed.	Prace previous	production days	using a Quality	Control Form.	Product will remain	on noid until	proper disposition	is agreed upon	(dispose, metal defection)			
	Who	Production																										
ning	Frequency	At the beginning Production	produciton shift																									
Monitoring	How	Visual	and checklist	Production Work Order																								
	What	Visual signs of	chipping or scoring on	metal food	surfaces on the	eauipment																						
Critical Limits	No visual signs	of scraping, chipping, or	scoring of metal food contact	surfaces																								
Hazard(s)	Extruder has	metal on metal contact																										
Process Control	Mix Ingredients																											

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# Sample Production Work Order

	roductio			
Production Date:	_		/Shape:	
Product Lot:	_	Batche	es:	
Fresh / [	ried		Conventional	/ Organic
Ingredients	weight #		Brand	Lot Code
		$\neg$		
	1	$\neg$		
	1	$\neg$		
	1	$\neg$		
Total	#	$\dashv$	L	
Pre-Op Check				
Equipment clean/sanitized?	Υ /		Die Purged?	Y / N
Missing pieces of equipment?	Y /	ı		
			# Purged	
Broken Equipment?		'		
If running organic, have drying rack been cleaned/sanitized?		1		
Operator intials	Т			
Manager initials	+			
Notes:				
				OALLENTI
Updates	Date	By		RALLENTI
Added Organic Designation	7/28/22	Dan Car	mody	

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# Sample Maintenance Request Form

Main	tenance Requ	uest Form	
Date:			
Building: Semolina / Gluten Free /	Warehouse		
Equipment to Repair:			
Problem:			
Assigned To:			
Date Completed:		Time Spent:	
Completed By:			
Remarks:			
Manager Initials:			
manager initials.	Rallenti Pasta updated (	06/26/2022	

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# Sample QC Form

Date:	Item:	Lot #	
Problem:			
Item on hold?	Vos. / No.		
QA Manager Folio			
——————————————————————————————————————			

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## **Process Preventive Control**

	_	S Fleventive Control
Records	Moisture Log	Quality Control Forms Corrective Actions Log
Verification	Review of	Mosture Log and Quality Confrol Coms within 7 working days
Corrective Action	Any dried pasta	with a moisture contact exceeding 13% will be placed on QC hold and a Quality Control Form will be submitted to the Quality Assurance Director. An investigation will be performed to determine the root cause of the moisture content breaching the critical limit. Disposition will be determined (rework, dispose, lab test to verify product is out of spec).
	Who	Quality Assurance Director Production Manager Trained Personnel
ning	Frequency	After each lot of pasta has been dried overnight, prior to release for packaging
Monitoring	How	HE 53 Moisture Analyzer
	What	Moisture Content of dried pasta pre- packaging
Critical Limits	Moisture	content at or below 13% Operating Limit: 12%
Hazard(s)	Bacterial growth	of B. cereus and/or other and/or other to lack of time/femperature control
Process Control	Fill Super Sack	

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# Sample Moisture Log

Moisture Log						
Test Date	Pasta Shape	Lot Code	Retail/Bulk?	Moisture Test Weight	Moisture %	Test Duration
·						

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# Allergen Preventive Control

Records	Allergen Verification Listing Allergem Label Verification Log Corrective Actions Log Verification Records
Verification	Review of Label Verification, Corrective Action Corrective Mad Verification Records within 7 working days
Corrective Action	If label is incorrect reject the cartons and contact supplier for next steps of disposition (return, dispose). If not dispose). If not presonnel at receipt of shipment provide retraining as needed
	Who Quality Assurance Director Production Manager Trained Personnel
ning	Frequency Before release to packaging
Monitoring	Visual check of carton label to match product formula
	What Allergen Label Verification Listing and product allergen declaration on retail cartons matches product
Criterion	All finished product packaging must deckaging must allergars the allergars present in the formula per Allergan Label Verification Listing
Hazard(s)	Allergens
Process Control	Receive Packaging

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# Ingredient Allergen Identification

Ingredient An		Allergens in Ingredient Formulation						Allergen		
Raw Material Name	Supplier	Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shellfish	Precautionary
Lupin Bean Flour	Lupin Platform									None
Inveja Lupin Bean Flour	CK Lupin									None
Irwin Valley Lupin Bean Flour	Lupina									None
Xanthan Gum 200 EC	Tic Gums									None
Coarse Pearled Sorghum Flour	NuLife Market									None
Whole Grain White Sorghum Flour	NuLife Market									None
White Rice Flour	Riceland									None
Sunflower Flour	Suntein									None
Fava Bean Flour	Prairie Fava									None
Soluble Tapioca Flour	fiberSMAR T									None
Tapioca Starch	Ciranda									None
Corn Flour	Grain Millers									None
Green Spirulina Flour	Food To Live									None
	Allergens in Ingredient Formulation									

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Name		Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shellfish	Precautionary Labeling
Pea Protein	Naturz Organics									None
Pumpkin Powder	Van Drunen Farms									None
Carrot Powder	Van Drunen Farms									None
Tomato Powder	Van Drunen Farms									None
CaraGum 200	Ingredion									None
TruBlock Core	Tastes Natural									None
Konjac HV	Ingredion									None
GF Whitre Cheddar Seasoning Packets	Gamay Foods		X							None
Gluten Free Cheddar Seasoning Packets	Gamay Foods		х							None
Pumpkin Puree	Stahlbush Farms									None
Carrot Puree	Stahlbush Farms									None
Beet Puree	Stahlbush Farms									None
Broccoli Puree	Stahlbush Farms									None
Sweet Corn Puree	Stahlbush Farms									None
Kaizen Pasta Mix	Bridgewell									None

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# Allergen Preventive Control

Records	Allergen Listing Allergem Label Verification Log Work Order Corrective Actions Log Verification Records	
Verification	Newley of the Packaging Work Order, Corrective Actions Log, and Verification rercords within 7 working days	
Corrective Action	allergeal Carron allergean Allergean Verification Listing packaging is halted for escalation to management. Food Safety Team will investigate the root cause and make decision on disposition (contact supplier, return or dispose of packaging). Re- training of Allergen Verification during the Receiving Packaging step	
	Trained Personnel	
oring	Before start of packaging	
Monitoring	Nisual check Visual check of carton label to Allergen Label Verification Listing, verified on Packing Work Order	
	What Werification Verification Verification Droduct allergen declaration on retail cartons matches product	
Criterion	All minshed packaging must declare the allergens present in the formula parkaging products are verified to have accurate allergen statements statements step is to ensure the correct packaging is used for the product	
Hazard(s)	Allergens	
Process Control	Till Vveigru Label	

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# Allergen Verification Listing

Client Name	Shapes	Retail	Bulk	Super Sack	Allergens
New Seasons	Penne, Radiatori, Fettuccine	Х			N/A
Montelupo	Radiatori, Fusilli, Penne, Macaroni	Х			N/A
Perfect Keto	Yellow Cheddar Mac & Cheese, White Cheddar Mac & Cheese	Х			Milk
Lupii	Elbow Macaroni, Penne, Fusilli	Х			N/A
Wholesome Provisions	Penne, Rotini, Elbow Macaroni, Orzo	Х			N/A
Aviate	Fusilli, Orzo	X			N/A
Voodles	Pumpkin & Carrot Penne, Beet & Tomato Penne, Broccoli & Sweet Corn Penne	Х			N/A
Kaizen	Fusilli, Rice, Radiatori, Ziti	Х			N/A
Alexis Foods	Penne, Radiatori		х		N/A
Provvista	Penne, Radiatori		Х		N/A

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#### **Sanitation Preventive Control**



#### SOP 4: Basic Sanitation Procedure

Organic: Document 4 Rev. 5.25.2022

Frequency: After every production shift Operators: All production team members

Equipment: 3 compartment sink, chlorine test strips, Clorox Commercial Solutions Green Works solution, clean water, bleach, triple cleaning pails (green, blue, red), towels, isopropyl

#### Procedure

- 1. In the 3 compartment sink fill:
  - One sink with hot water mixed with Clorox Commercial Solutions Green Works Soap Solution
  - b. One sink with warm-to-hot clean water
  - c. One sink with cold water mixed with solution bleach
    - i. Use chlorine test strips to verify solution is between 100-200ppm
    - If solution is below 100ppm add more bleach at 2 fl oz at a time, retest until solution is within range
    - If solution is above 200ppm dilute with more cold water, retest until solution is within range
- 2. Wash, rinse, and sanitize all bowls and small production tools in the 3 compartment sink
- 3. Disassemble the Extruder
  - a. Triple clean mixing arms and auger in 3 compartment sink, air dry overnight
  - Sanitize mixing arms and auger with isopropyl prior to reassembly
- Reassemble Extruder
  - Wash, rinse, and sanitize the inside and outside of Extruder using triple cleaning pails and towels
  - b. Rinse with clean warm water
  - c. Sanitize with isopropyl
- 5. Triple clean all work tables and food contact surfaces
- 6. Sweep and Mop production floor

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# Hygienic Zoning Building 4: Gluten Free Ingredient & Finished Goods Storage, Production & Packaging



The office, break room, and bathrooms are considered non-manufacturing zones. The Gluten Free Production & Packaging area is considered HYGIENE ZONE 1 and is the primary pathogen control area. Employee lockers and chef coat storage area as well as the gluten free ingredient and finished goods storage areas are considered HYGIENE ZONE 2 and require basic good manufacturing practices.

**Purpose:** Hygienic zoning in the production area is important to minimize the potential of re-contamination with environmental pathogens as well as physical and chemical hazards **Frequency:** During production hours

**Procedure:** Employees entering the Ingredient and Packaging Storage Area and the Employee Lockers and Chef Coat Storage areas must (in order listed)

- 1. Wear a hairnet completely covering their hair and ears
- 2. Wear a beard net if they have facial hair
- 3. Wash their hands at the handwash sink

Employees entering the Production Area must follow the three steps above and also put on a clean smock or chef coat prior to washing their hands and entering the work area.

Maintenance workers and visitors are to wear hairness and beard nets (if applicable) when entering Hygiene Zones 1 & 2.

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Packaging employees who work in Building 4 (Gluten Free) use separate doors to enter the designated "Semolina" sections of the building and are prohibited from entering any gluten free areas unless they wash their hands, change their chef coat, and reapply a new hairnet.

**Monitoring:** The Production Manager visually observes the presence of the chef coats correctly worn by employees before start up, after lunch break, and every two hours. The Director of Quality Assurance also does hourly quality checks and can correct team members if they are not appropriately dressed for production or packaging.

**Corrections:** Employee is instructed to gown properly

**Records:** Quality Assurance Checklist, Environmental Monitoring Program and lab results.

**Verification:** EMP and checklist review within 7 working days.

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#### **Environmental Monitoring for Sanitation Preventive Control Verification**

**Purpose**: Environmental monitoring is conducted to verify the effectiveness of sanitation and hygienic zoning procedures in the Production, Dish, and Packaging areas to control environmental pathogens such as L. monocytogenes.

**Sample Identification**: based on observation when sampling, "worst case" areas are sampled (standing water, floor drains, table legs, castors on extruding machines, major traffic areas, etc). Record the specific location sampled.

**Sampling Procedure**: Once a month, sponge swabs are collected before the start of production (to avoid any bias of results). Samples are shipped to a laboratory using the sampling kit provided by the laboratory. Samples are refrigerated until a lab tech picks them up from the facility.

The following number of samples are collected each time:

- 3 in the production area
- 1 in the dish area
- 1 in the packaging area
- 1 in a highly trafficked area or an area based on observed conditions (Investigation Sample)

**Laboratory:** Biogen Laboratory Developments, LLC (36740 E. Historic Columbia River Hwy Corbett, OR 97019) conducts the analysis using FDA BAM procedures. Analysis is started within 48 hours of sampling.

**Test conducted**: For routine samples, the contract lab composites sponges from the same area following Rallenti Pasta's recommended procedures to run as one test of Listeria species. Investigation samples must be run individually.

#### Interpretation of Results

Action for a negative result - Continue routine operations

#### Corrective action for a positive result:

1. If a composite is positive, the positive areas are re-sampled within a day of notification and prior to implementing intensive sanitation procedures. Additional samples (depending on the size of the area) are taken in other potential problem areas in an

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attempt to identify a site of contamination. All samples are run individually, without compositing.

- 2. Intensive sanitation procedures are implemented after sampling is complete.
- 3. Production can continue after sanitation is complete and product can be shipped.
- 4. If all re-samples are negative, resume the normal sampling frequency.
- 5. If one or more re-samples are positive, perform corrective action investigation to resolve the issue. Implement a hold and a finished product testing procedure per Corrective Action protocol.

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# **Supply Chain Preventive Controls**

# **Approved Suppliers for Ingredients Requiring a Supply Chain Applied Control**

Ingredient (requiring a supply-chain control)	Approved Supplier	Hazard(s) requiring supply-chain applied control	Date of approval	Verification method	Verification records
Lupin Bean Flour	Irwin Valley	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	Request ed	COAs for every lot requested and reviewed prior to entering production facility	COAs kept in ingredient supplier folder
Lupin Bean Flour	CK Lupin	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	7/25/22	Certificate of Registration with USDA (FSVP) FSSC 22000 certificate	Certificates kept in Supplier Verification Folder
Lupin Bean Flour	Lupin Platform	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	Request ed	COAs for every lot requested and reviewed prior to entering production facility	COAs kept in ingredient supplier folder
Chickpea Flour	Artesa	Vegetative and spore forming pathogens such as Salmonella, pathogenic E.	Request ed	COAs for every lot requested and reviewed	COAs kept in ingredient supplier folder

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		coli, L. monocytogenes and C. botulinum		prior to entering production facility	
Tapioca Starch	Ciranda	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	7/26/22	Certificate of Registration with BSI Group (BRC Global Standard for Food Safety exp 4.15.23  Record of Compliance with FSVP under FDA guidance	Certificates kept in Supplier Verification Folder
Coarse Pearled Sorghum Flour Whole Grain White Sorghum Flour	NuLife Market	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	Request ed	COAs for every lot requested and reviewed prior to entering production facility	COAs kept in ingredient supplier folder
White Rice Flour	Riceland	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	6/13/202 0	SQF Certificate and AUdit Report (Received a 94 Rating on 1/14/2021)	Certificates kept in Supplier Verification Folder
Sunflower Flour	Suntein	Vegetative and spore forming pathogens such as Salmonella, pathogenic E.	2/4/2022	BRC Certificate (Received A Grade and score of	Certificates kept in Supplier Verification Folder

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		coli, L. monocytogenes and C. botulinum		97.41% on 9/17/21)	
Fava Bean Flour	Prairie Fava	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	1/10/202	Statement of Commitment from NSF	Certificates kept in Supplier Verification Folder
Soluble Tapioca Fiber	fiberSMART	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	2/18/202 2	BRC Audit Report and Certificate (Received A Grade on 11/23/21, re-audit date 11/23/22)	Certificates kept in Supplier Verification Folder
Corn Flour	Grain Millers	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	12/29/20 21	NSF Certificate of Conformity (Grade AA received 5/09/2022)	Certificates kept in Supplier Verification Folder
Green Spirulina Powder	Food To Live	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	2/4/2022	COAs for every lot requested and reviewed prior to entering production facility	COAs kept in ingredient supplier folder

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Pea Protein	Naturz Organics	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	Request ed	COAs for every lot requested and reviewed prior to entering production facility	COAs kept in ingredient supplier folder
Pumpkin Powder Carrot Powder Tomato Powder	Van Drunen Farms	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	12/29/20 21	Copy of BRC certificate (Grade AA) (10/28/21)	Certificates kept in Supplier Verification Folder
Pumpkin Puree  Carrot Puree  Beet Puree  Broccoli Puree  Sweet Corn Puree	Stahlbush Farms	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	1/11/2022	Copy of Certificate of Registration with SQF through NSF (9/25/2021)	Certificate kept in Supplier Verification Folder
Xanthan Gum Konjac CaraGum	Ingredion	Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	12/29/20 21	Copy of Certificate of compliance with Food Safety System Certification (FSSC 22000)	Certificate kept in Supplier Verification Folder
Kaizen Pasta Mix	Bridgewell	Vegetative and spore forming	9/6/22	Copy of Certificate	Certificate kept in

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pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum	for meeting the requirement s for the SQF Food Safety Code for Food Manufacturi ng, Edition 9	Supplier Verification Folder
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#### Receiving Procedure for Ingredients Requiring a Supply-Chain Control

**Purpose:** Ensure that all ingredients requiring a supply-chain-applied preventive control are received from approved suppliers with appropriate preventive controls in place.

Frequency: Each Delivery

Who: Trained employees and managers

#### **Procedure:**

- Perform the steps outlined in the "Inbound Shipment Inspection Form" verifying that ingredients were supplied by approved vendors by the bill of lading or invoice with manufacturer's name
- 2. Document quantity received and by which approved manufacturer

**Corrections:** If product is not from the approved supplier

- 1. Receiving employee places product on hold and notifies QA
- 2. QA reviews status and
  - a. Rejects load, or
  - b. Attaches the receiving record documentation of verification activity applied for use of ingredient from temporary supplier, allowing release for use

Records: Inbound Shipment Inspection Form, Bill of Lading, Invoice

**Verification**: Inbound Shipment Inspection Form review within 7 working days

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# **Determination of Verification Procedures All ingredients**

Hazards requiring a supply-chain control: Hazard analysis determined that Vegetative and spore forming pathogens such as Salmonella, pathogenic E. coli, L. monocytogenes and C. botulinum are hazards requiring a supply-chain-applied controls in the milling, processing, pasteurizing, packaging, and storing of ingredients. We do not have a kill step for pasta as it is performed by the end user.

**Preventive controls applied by suppliers:** Suppliers must have process controls to mitigate the growth of vegetative and spore forming pathogens from harvest to end-product storage.

#### **Verification procedures:**

- A copy of a 3rd party audit or audit score, requested annually
  - Includes audit date, auditor qualifications, audit procedures and results for reviewal
  - COAs per each lot to verify the safety of the ingredient
  - FSVP for domestic suppliers who purchase ingredients internationally

**Records:** Copy of the audit report and, where necessary, verification of corrective actions taken by the supplier are maintained on file by the Food Safety Team Leader