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Process Preventive Controls: PPC-1


Process Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal Detection	Contamination of product with Metal Fragments	Metal detector present and operating correctly: able to reject metal detector test strips (Ferrous, Non-ferrous, Stainless Steel)	Rejection of testing probes.	Calibrate/ Challenge metal detector with the following test samples: <u>E9</u> : Ferrous (1.6mm), Non-Ferrous (1.6mm) and Stainless Steel (2mm). <u>E137</u> : Ferrous (1.6mm), Non-Ferrous (2.2mm) and Stainless Steel (2.5mm). <u>E176</u> : For dry product Ferrous (2.0mm), Non-Ferrous (2.2mm) and Stainless Steel (2.5mm). For frozen Ferrous (2.0mm), Non-Ferrous (4.0mm) and Stainless Steel (3.5mm).	At the beginning of the shift, before starting packaging process. At the beginning and end of packaging process per product. And after 1 hour of continuous packaging of the same product type.	Packaging Supervisor	If metal is found in the product or metal detector fails to reject test samples, all product analyzed until the last good check must be re-analyzed for metal presence or discarded. Activate Non-conforming product and equipment program. Evaluate root cause, establish preventive measures. No product that is injurious to health enters commerce.	Review of monitoring records within 7 working days.	Finished Product Packaging Log CAPA Report

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Allergen Preventive Control Preliminary Steps:

1. Ingredient Allergen Profile:

Ingredient	Supplier/Brand	Allergens in Ingredient Formulation									Allergens in Precautionary statement
		Egg	Milk	Soy	Wheat	Tree Nut (Almond)	Peanut	Fish	Sesame	Shellfish (Market Name)	
Semolina Flour	Falcon Distributon/Durakota				x						None
Wheat Flour	Falcon Distribution/Bay State				x						None
Egg	Sparboe Foods	x									None
Garlic Powder	Restaurant Depot/Badia										None
Spinach Powder	Dehydrates, Inc										None
Parsley Flakes	Woodland Foods										None
Annatto powder	Prime Ingredients										None
Milk Powder	KLIM		x	x							None
Parmesan Cheese	Cheese Merchants		x								None
Olive Oil	Badia										None
Egg Yolk	Papetti's Easy Eggs	x									None
Salt	Morton										None
Black Pepper	Badia										None
Potato Granule	Emsland										None
Baking Powder	Clabber Girl										None

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Lupin Flour	Lupina										None
Fava Bean Protein	Top health ingredients										None
Tapioca Starch	Ciranda										None
Xanthan Gum	Bobs red mill										None

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2. Allergen Label Declaration

Product	Ingredients	Allergen Statement	Label ID
Egg Capellini	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Annatto powder.	Contains: Wheat, Egg.	Dry: CADM-0001 (Dry Bulk: 10lb) CADM-0002 (Dry Pack: 12/10oz) Frozen: CAFM-0001 (Frozen Pack: 8/12oz) CAFM-0002 (Frozen Bulk: 10lb) CAFM-0003 (Frozen Bulk: 6lb)
Egg Fettuccine Egg Tagliatelle	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Annatto powder.	Contains: Wheat, Egg.	Dry: FTDM-0001 (Dry Bulk: 10Lb) FTDM-0004 (Dry Pack: 12/10oz) Dry Tagliatelle: FTDM-0005 (Dry Bulk: 10Lb) FTDM-0007 (Dry Pack: 12/9oz) FTDP-0002 (8/12oz) Frozen: FTFM-0001 (Fresh Pack: 8/12oz) FTFM-0003 (Fresh Bulk: 10Lb) FTFM-0007 (Fresh Bulk: 6Lb) Frozen Tagliatelle: FTFM-0006 (Fresh Bulk: 10Lb) Co-pack: FTDC-0010 (14/8oz) FTDC-0012 (12/8oz) FTDC-0013 (32/8oz) FTDC-0014 (24/8oz)
NCL-Egg Tagliatelle	Dough: Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Egg Yolk; Pasteurized whole eggs (whole eggs, less than 2% Sodium Silicoaluminate added as an anti-caking agent); Salt; Olive Oil; Annatto powder	Contains: Wheat, Egg.	Frozen: FTFM-0010 (Frozen Bulk: 6lb)



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Product	Ingredients	Allergen Statement	Label ID
Fettuccine Spinach	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Spinach powder.	Contains: Wheat, Egg.	Dry: FTDM-0002 (Dry Bulk: 10Lb) FTDM-0006 (Dry Pack: 12/9oz) FTDM-0008 (Dry Pack: 30 /4 oz) Frozen: FTFM-0002 (Frozen Pack: 8/12oz) FTFM-0004 (Frozen Bulk: 10Lb) FTFM-0008 (Frozen Bulk: 6Lb)
Fettuccine Whole Wheat Tagliatelle Whole Wheat	Whole Wheat Flour, Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate).	Contains: Wheat, Egg.	Dry: FTDM-0003 (Dry Bulk: 10Lb) Tagliatelle Dry: FTDP-0001 (Dry Pack: 8/12oz)
Egg Pappardelle	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Annatto powder.	Contains: Wheat, Egg.	Dry: PPDM-0001 (Dry Bulk: 10Lb) PPDM-0004 (Dry Pack: 12/9oz) PPDM-0005 (Dry Pack: 12/12oz) PPDM-0006 (Dry Pack: 12/10oz) PPDM-0007 (Dry Pack: 20/6oz) PPDP-0002 (Dry Pack: 8/12oz) Frozen: PPFM-0001 (Frozen Pack: 8/12oz) PPFM-0002 (Frozen Bulk: 10Lb) PPFM-0005 (Frozen Bulk: 6Lb) PPFM-0008 (Frozen Bulk: 3Lb)
NCL-Egg Pappardelle	Dough: Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Egg Yolk; Pasteurized whole eggs (whole eggs, less than 2% Sodium Silicoaluminate added as an anti-caking agent); Salt; Olive Oil; Annatto powder	Contains: Wheat, Egg.	Frozen: PPFM-0007 (Frozen Bulk: 6Lb)



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Product	Ingredients	Allergen Statement	Label ID
Pappardelle Spinach	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Spinach powder.	Contains: Wheat, Egg.	Dry: PPDM-0002 (Dry Bulk: 10Lb) Frozen: PPFM-0003 (Frozen Bulk: 10Lb) PPFM-0006 (Frozen Bulk: 6Lb)
Pappardelle Garlic & Parsley	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Garlic Powder; Parsley flakes.	Contains: Wheat, Egg.	Dry: PPDM-0003 (Dry Pack: 12/10oz) PPDP-0001 (Dry Pack: 8/12oz)
Egg Linguine Egg Taglierini	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Annatto powder.	Contains: Wheat, Egg.	Taglierini Dry: LGDM-0004 (Dry Bulk: 10Lb) LGDM-0005 (Dry Pack: 12/10oz) LGDM-0007 (Dry Pack: 20 x 6oz) LGDP-0001 (Dry Pack: 8/12oz) Frozen Taglierini: LGFM-0006 (Fresh Pack: 8/12oz) LGFM-0007 (Fresh Bulk: 10Lb) LGFM-0010 (Fresh Bulk: 6Lb)
NCL-Scialatielli	Dough: Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Milk Powder (Whole milk, soy lecithin, Vitamin C [Sodium Ascorbate], Iron [Ferric Pyrophosphate], Zinc Sulfate, Vitamin A Acetate, Vitamin D3 [Cholecalciferol]); Parmesan Cheese (Parmesan Cheese [Pasteurized part-skim cow's milk, cheese cultures, salt, enzymes]; Powdered cellulose added to prevent caking; Natamycin [a natural mold inhibitor]); Pasteurized whole eggs (whole eggs, less than 2% Sodium Silicoaluminate added as an anti-caking agent); Olive Oil; Salt; Parsley; Black Pepper.	Contains: Wheat, Soy, Egg, Milk.	Frozen: FTFM-0011 (Fresh Bulk: 6Lb)



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Product	Ingredients	Allergen Statement	Label ID
NCL-Chitarra	Dough: Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Egg Yolk; Pasteurized whole eggs (whole eggs, less than 2% Sodium Silicoaluminate added as an anti-caking agent); Salt; Olive Oil; Annatto powder	Contains: Wheat, Egg.	Frozen: LGFM-0015 (Fresh Bulk: 6Lb)
Rotini, Elbow, Penne, Ziti, Gnocchi Sardi, Shells, Cavatappi.	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Annatto powder.	Contains: Wheat, Egg.	Dry GNDM-0001 (Dry Bulk) ELDR-0001 (Dry Bulk) RIDM-0001 (Dry Packs) Frozen: RIFM-0001 (Frozen Pack) RIFM-0003 (Frozen Bulk) RIFM-0004 (Frozen Bulk) RIFM-0005 (Frozen Pack) SHFM-0001 (Frozen Bulk) CVFM-0002 (Frozen Bulk)
Potato Gnocchi	Potato Granules (Potatoes, emulsifier mono- and diglycerides of fatty acids - based on rape seed oil, antioxidant sodium metabisulphite); Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Salt; Pasteurized whole eggs (whole eggs, less than 2% Sodium Silicoaluminate added as an anti-caking agent); Baking Powder (Cornstarch, Sodium Bicarbonate, Sodium Aluminum Sulfate, Monocalcium Phosphate).	Contains: Wheat, Egg.	Frozen: GNFM-0001 (Frozen Bulk 12/1Lb) GNFM-0003 (Frozen Bulk 4/3Lb)
Whole Wheat Linguine	Whole Wheat Flour, Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate).	Contains: Wheat, Egg.	Dry: LGDM-0001 (Dry Bulk: 10lb) LGDM-0003 (Dry Pack: 12/10oz) Frozen: LGFM-0004 (Frozen Bulk: 10lb) LGFM-0011 (Frozen Bulk: 6lb)



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Product	Ingredients	Allergen Statement	Label ID
Spinach Linguine Spinach Taglierini	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Spinach powder.	Contains: Wheat, Egg.	Dry: LGDM-0002 (Dry Bulk: 10lb) Frozen: LGFM-0001 (Frozen Pack: 8/12oz) LGFM-0008 (Frozen Bulk: 10lb)
Garlic and Parsley Linguine	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Garlic Powder; Parsley flakes.	Contains: Wheat, Egg.	Frozen: LGFM-0002 (Frozen pack: 8/12oz) LGFM-0009 (Frozen Bulk: 10lb) LGFM-0013 (Frozen Bulk: 6lb)
Linguini Neri	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silicoaluminate); Squid Ink (Cuttlerfish ink, salt, sodium carboxymethyl cellulose).	Contains: Wheat, Egg.	Frozen: LGFM-0003 (Frozen Bulk: 6lb) LGFM-0012 (Frozen Pack: 8/12oz)
Mie Noodle	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Annatto powder.	Contains: Wheat.	Dry: NODM-0001 (Dry Pack: 12/12oz)
Lasagna Sheets	Semolina Flour (milled wheat, enriched with niacin, iron, thiamine, mononitrate, riboflavin, folic acid); Water; Pasteurized whole eggs (whole eggs, sodium silico-aluminate); Annatto powder.	Contains: Wheat, Egg.	Frozen: LAFM-0001
Lupin Pasta (Kaizen)	Lupin Flour, Fava Bean Protein, Tapioca Starch, Xanthan Gum	None	Dry Dry Pack: 8 oz


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3. Allergen Scheduling and Cleaning Implications

Product Name	Prod Line	Intentional Allergens								
		Wheat	Egg	Milk	Soy	Fish (Name)	Crust Shellfish	Treenut (Almond)	Peanuts	Sesame
Egg Nested Pasta	Nested Pasta Line	x	x							
Spinach Nested Pasta	Nested Pasta Line	x	x							
Whole Wheat Nested Pasta	Nested Pasta Line	x	x							
Garlic and Parley Nested Pasta	Nested Pasta Line	x	x							
Mie Noodles	Nested Pasta Line	x								
NCL – Egg Nested Pasta	Nested Pasta Line	x	x							
NCL – Scialatielli	Nested Pasta Line	x	x	x	x					
Squid Ink Nested Pasta	E142 Castiglioni Extruder	x	x							
Gnocchi Sardi, Elbow, Rotini, Rigatoni, Ziti, Penne, Shells, Cavatappi.	E142 Castiglioni Extruder	x	x							
Potato Gnocchi	Gnocchi Machine	x	x							
Pre-cooked lasagna	Pre-cooking tunnel	x	x							
Lupin Pasta (Kaizen)	E142 Castiglioni Extruder									


Scheduling Implications: Mie Noodles or Lupin Pasta must be processed only after line has been thoroughly cleaned with “Controlled Wet” Procedure, to avoid allergen cross-contact. Lasagna must be processed only after pre-cooking tunnel has been thoroughly cleaned and water used to pre-cooked other products has been drained. Scialatielli (egg & dairy nested pasta) must be processed after any other nested pasta, following a “Controlled Wet” Procedure, to avoid allergen cross-contact.

-Allergen Cleaning Implications: a full allergen clean-up is required before the production of Mie Noodles, after Scialatielli (egg & dairy nested pasta), and before the pre-cooking step of lasagna sheets. Protein swabbing procedure is used to verify effectiveness of cleaning procedure.

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Allergen Preventive Control: APC-1 and APC-2

Process Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Primary and Secondary Packaging and Labeling	Undeclared Allergens	All Finished product label must declare allergens present in product	Verify Allergen declaration in finished product label vs Finished product Allergen Register.	Visual verification or label allergen declaration vs register.	At the beginning of packaging run, at roll change or at any product change procedure in the packaging line.	Packaging Supervisor	<p>If label is incorrect, segregate product, inspect back to the last good check, relabel product.</p> <p>Activate Non-conforming product and equipment program.</p> <p>Evaluate root cause, establish preventive measures.</p> <p>No product that is injurious to health enters commerce.</p>	<p>Review of monitoring records within 7 working days.</p>	<p>Finished Product Packaging Log</p> <p>Finished Product Allergen Register</p> <p>CAPA Report</p>

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Sanitation Preventive Control 1: SPC-1

Objective: address *Salmonella* and *S.aureus* growth as a potential hazard, in pasta/flour remaining in production line and surroundings. (Dry Cleaning Procedure for Nested Pasta Line)

Purpose: remove all pasta and flour residues from food contact surfaces and surroundings in the Nested Pasta Production Line.

Frequency: Daily, at the end of the production shift.

Procedure:

1. Remove packaging material, utensils from the area.
2. Disassemble dies from the equipment and transfer to washing room to wash, rinse, sanitize and dry.
3. Using a brush and spatula, scrape pasta dough remaining attached to surfaces of the equipment.
4. Using a vacuum machine, remove all loosen particles from equipment surfaces, carefully making sure that dough does not remain accumulated in areas difficult to reach including the extruder.
5. Using a brush and vacuum machine sweep all surrounding areas of the equipment and line, to remove dough/ flour residues.
6. Once cleaning procedure has been conducted, the equipment should be visually free of any dough/flour residues.


Monitoring: Daily, a Pre-Operational inspection is conducted daily to verify cleanliness of equipment and surrounding areas. Inspection results are recorded.

Corrections: if residues of dough are found on the equipment or surroundings, equipment must be cleaned following each step of this procedure and employee in charge of cleaning and sanitation procedure must be notified to prevent recurrence.

Records: Daily Pre-Operational Inspection.

Verification:

- Plant Manager reviews and signs the Pre-Operational Inspection within 7 working days.
- Environmental Monitoring Program.

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Allergen Sanitation Preventive Control 2: ASPC-2

Objective: prevent allergen cross-contact between products containing egg/milk and soy in their formulation and products that do not contain eggs/milk and soy.

Purpose: remove all remaining of egg/milk and soy from the nested pasta manufacturing line through a controlled wet cleaning procedure using steam in the nested pasta line.

Frequency: Weekly at the end of the production shift on Fridays AND/OR before a Mie Noodle, Lupin Pasta or after a Scialatielli production run.

Procedure: (Nested Pasta Equipment and Line wet cleaning procedure)

1. Remove packaging material, utensils from the area.
2. Disassemble dies from the equipment and transfer to washing room to wash, rinse, sanitize and dry.
3. Using a brush and spatula, scrape pasta dough remaining attached to surfaces of the equipment.
4. Using a vacuum machine, remove all loosen particles from equipment surfaces, carefully making sure that dough does not remain accumulated in areas difficult to reach including the extruder.
5. Using a brush and vacuum machine sweep all surrounding areas of the equipment and line, to remove dough/ flour residues.
6. Once dry cleaning procedure has been conducted, using the steam portable cleaning unit, clean thoroughly every food contact surface of the equipment including mixer, extruder, and conveying belt, trays.
7. All surfaces must be left with no visual residues of dough.
8. Once cleaning procedure has been conducted, before using the line for Mie Noodle, Lupin Pasta or after processing Scialatielli production a protein swab analysis will be conducted on the line to verify effectiveness of cleaning procedure.
9. A negative result must be obtained on each surface tested before releasing the equipment for Mie Noodle, Lupin Pasta or any other nested pasta if Scialatielli was the last production.
10. Monitoring: Protein swab results will be documented in Production Allergen Run Log.

Corrections: if swab results are positive, or the wet cleaning procedure has not been conducted the equipment must be cleaned following the previously explained wet cleaning procedure and be tested until a negative result is obtained on all surfaces.

Corrective Action: if a full allergen wet cleaning procedure or protein swabbing verification procedure was not conducted before running Mie Noodles, Lupin Pasta or before running egg based nested pasta after running Scialatielli, and product was processed, hold all product produced since the last wet cleaning procedure/protein swabbing verification, evaluate product and determine appropriate disposition following Non-conforming product and equipment program guidelines. Identify root cause, implement corrective actions and conduct training as needed. Record Corrective and preventive actions.

Records: Production Allergen Run Log.

Verification: Supervisor reviews and signs the Production Allergen Run Log within 7 working days.