



UNITED SAFETY AGENTS  
**F S V P**  
COMPLIANCE PLAN

P&L IMPORTS LLC

*Name of FSVP Importer*

PASTIFICIO LUCIO GAROFALO S.P.A.

*Name of Foreign Supplier*

TAGLIATELLE NEST

*Name of Product*

NOVEMBER 11, 2021

*Date of Initial Verification / Reverification*

NOVEMBER 12, 2022

*Date of FSVP Plan Expiration*

VERIFICATION COMPLETE | APPROVED | CLOSE MONITORING SUGGESTED

*Status of Review*

NUMBER 01

*Version*



– Confidential –



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## OVERVIEW of FSVP PLAN

Title 21 of the Code of Federal Regulations requires that “. . . for each food you import; you must develop, maintain, and follow an FSVP [Foreign Supplier Verification Program] that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act. . .” for each product (and each foreign supplier of each product) that our client imports, United Safety Agents (USA) has been engaged to undertake and successfully complete all requisite actions on our client’s behalf; to analyze, verify, build and maintain this FSVP plan, that our client will now use to keep in compliance with FSVP regulations.

## INSTRUCTIONS

Please review this FSVP plan in its entirety and sign where indicated. 21 C.F.R., §1.510 requires that this FSVP plan be kept on file for a minimum of two years after its use is discontinued. All records must be legible and stored to prevent deterioration or loss. If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly. Off-site storage of records, including records maintained by other entities in accordance with §1.504, §1.505, or §1.506, is permitted if such records can be retrieved and provided on-site within 24 hours of FDA’s request for review. Electronic records are considered to be on-site if they are accessible from an on-site location. Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter. **Please contact United Safety Agents immediately to report a change in a foreign supplier’s process or status**, in the case of an FDA inspection, or with any questions that you may have by email: [info@unitedsafetyagents.com](mailto:info@unitedsafetyagents.com), by fax: +1 (888) 557-2649, or by telephone: +1 (888) 551-7403.

## TERMS & DEFINITIONS

**FSVP Importer (Importer):** The importer, is the U.S. owner or consignee of an article of food that is being offered for import into the United States. **U.S. owner or consignee** means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

**Foreign Supplier (Supplier):** The foreign supplier or supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States.

**Qualified Individual (QI):** Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart.

**Verified &/or Approved:** Verified & approved means only that actions were taken to fulfill regulatory obligations. It does NOT mean that the subject product of this FSVP plan is ready for consumption in its current state.

## RULES of USE

This document is considered privileged, proprietary, and confidential. It may not be reproduced in whole, or part, nor may it be shared with any third party – including a customer – without the prior written consent of United Safety Agents. All FSVP plans and are bound under the terms of the Agreement which has been made between your company and United Safety Agents. Please see <https://www.unitedsafetyagents.com/rulesofuse> for more information.

## FOREIGN SUPPLIER VERIFICATION PROCEDURES

21 C.F.R., §1.506 (a), (a)(2), (b), and (c) require that written procedures are established and followed to ensure that food is imported from approved suppliers only and that these procedures provide adequate assurance that the hazards requiring a control in the imported food have been significantly minimized or prevented. 21 C.F.R., §1.506 (d) requires that “. . . Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, [an FSVP Importer] must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food [an FSVP Importer] obtain[s] from the foreign supplier is produced in accordance with paragraph (c) of this section. Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (e.g., when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under §1.505.” As an FSVP Agent or Qualified Individual, USA's FDA-mandated goal is to verify that a product's innate physical, chemical and biological hazards are being controlled in a manner that is at least equivalent to the FDA's domestic standards. In order to accomplish this goal, documentation of a foreign supplier's processes, procedures and control methods will be required. Understanding that all foods may not share identical hazards - their control(s) also not being identical - USA utilizes a variety of foreign supplier verification activities to verify that a food's hazards have been significantly minimized or prevented. USA's determination of appropriate supplier verification activities is based on an evaluation of a specific food, its relevant hazards, and its corresponding foreign supplier. The following activities may be used to satisfy the requirements of 21 C.F.R., §1.506 (a), (a)(2), (b), (c), and (d):



A foreign supplier's Hazard Analysis and Critical Control Point (*HACCP*) plan may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's HACCP plan will be included within this FSVP plan.



An onsite audit of a foreign supplier's facility may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's onsite audit report will be included within this FSVP plan.



Sampling and testing of a food may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's reviewed sampling and testing results will be included within this FSVP plan.



A foreign supplier's relevant food safety record(s) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's relevant food safety record(s) will be included within this FSVP plan.

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## FOREIGN SUPPLIER VERIFICATION PROCEDURES

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Certifying documents for a foreign supplier's Qualified Individual(s) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the certifying documents for a foreign supplier's Qualified Individual(s) will be included within this FSVP plan.



A food's nutritional label(ing) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the food's nutritional label(ing) will be included within this FSVP plan.



Completion of the FSVP Importer's Supplier Assessment Questionnaire and/or the FSVP Importer's Allergen and Intolerance Questionnaire may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the completed Questionnaire(s) will be included within this FSVP plan.



Documentation that a foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination, and that the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of all substantiating documents will be included within this FSVP plan.



Documentation that a foreign supplier meets the definition of a qualified facility (*as defined by §117.3 or §507.3*) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of all substantiating documents will be included within this FSVP plan.



The FSVP Importer may rely upon performance of activities by other entities. If the FSVP Importer relies upon supplier verification activities conducted by another entity, the FSVP Importer will review and assess the results of these activities. Notation and documentation of the FSVP Importer's review and assessment will be recorded in this FSVP plan, including documenting that the determination of appropriate verification activities was made by a Qualified Individual.



When the FSVP Importer determines that a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the FSVP Importer will require a copy of the foreign supplier's annual on-site audit results. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's annual on-site audit results will be included within this FSVP plan. After initial verification, the FSVP Importer will require that the foreign supplier provide copies of their annual on-site results at least annually thereafter.

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## FOREIGN SUPPLIER VERIFICATION PROCEDURES

*Continued from previous page.*



It may be required that the FSVP Importer conduct or obtain documentation of other (not previously mentioned) appropriate supplier verification activity(s) based on the foreign supplier's performance and the risk associated with the food. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the supplier verification activity(s) will be included within this FSVP plan.

### FREQUENCY of VERIFICATION PROCEDURES

All above noted foreign supplier verification procedures and activities will be conducted and/or re-conducted at a frequency appropriate to the relevant procedure/activity and the corresponding hazard profile for the relevant food. Please refer to document-specific notes found on pg. 11, Ongoing Document Requirements found on pg. 12, Additional Recommendations found on pg. 21, and Verification Timeline found on pg. 23 for information about the frequency of verification procedures.

### USE of APPROVED SUPPLIERS ONLY

Food and/or food-related products should only be imported from foreign suppliers that have been verified to the standards of FSVP. Prior to importation, all steps necessary to successfully verify that a foreign supplier's food safety processes and procedures meet the requirements of FSVP (*and other applicable regulations*), must be undertaken. Once complete, the product specific FSVP plan - created by United Safety Agents - will denote a supplier's status on the Title Page of each plan. Importation may occur if the following three parameters are met: 1) the FSVP plan's status does not read "Denied" or other wording denoting that product is not currently approved for import; 2) the date of importation will fall within one calendar year (*365 days*) from the plan's noted "Review End" date, and 3) there are no outstanding issues or changes in the supplier's processes and/or procedures since the noted "Review End" date.

### CORRECTIVE ACTIONS

The FSVP Importer will take prompt corrective actions if it determines that a foreign supplier does not produce food consistent with the written assurance, and in compliance with applicable processes and procedures that provide same level of protection as FDA requirements. If the FSVP Importer determines by means other than verification activities that a foreign supplier does not produce food in compliance with applicable processes and procedures that provide the same level of protection as FDA requirements, it will conduct an investigation to determine whether the FSVP should be modified accordingly. Such corrective actions are dependent upon the specific circumstances of the deviation but could include: the complete discontinued use of the foreign supplier, or the discontinued use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed.

### IDENTIFICATION of FSVP IMPORTER

The FSVP Importer will ensure that, for each line entry, the following information is provided to U.S. Customs and Border Protection: 01) FSVP Importer's Business Name; 02) FSVP Importer's Electronic Mail Address; and 03) The FSVP Importer's FDA acceptable UFI (*Unique Facility Identifier*) such as a DUNS number.

Supplier: Pastificio Lucio Garofalo S.p.A.

Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC)

Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

## UNITED STATES CODE of FEDERAL REGULATIONS

*The following are or may be applicable to this product/supplier, FSVP Importer should confirm & comply independently.*

- 101.** §101.1–101.108. Food Labeling.
- 106.** §106.1–106.160. Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, & Notifications.
- 110.** §110.3–110.110. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.
- 111.** §111.1–111.610. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.
- 112.** §112.1–112.213. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.
- 113.** §113.3–113.100. Thermally Processed Low-Acid Foods Pkged in Hermetically Sealed Containers.
- 114.** §114.3–114.100. Acidified Foods.
- 117.** §117.1–117.475. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.
- 120.** §120.1–120.25. Hazard Analysis and Critical Control Point (HACCP) Systems.
- 121.** §121.1–121.401. Mitigation Strategies to Protect Food Against Intentional Adulteration.
- 123.** §123.3–123.28. Fish and Fishery Products.
- 129.** §129.1–129.80. Processing/Bottle Drinking Water.
- 131.** §131.3–131.206. Milk and Cream.
- 133.** §133.3–133.196. Cheeses & Related Products.
- 135.** §135.3–135.160. Frozen Desserts.
- 136.** §136.3–136.180. Bakery Products.
- 137.** §137.105–137.350. Cereal Flours.
- 139.** §139.110–139.180. Macaroni & Noodle Products.
- 145.** §145.3–145.190. Canned Fruits.
- 146.** §146.3–146.187. Canned Fruit Juices.
- 150.** §150.110–150.160. Fruit Butters, Jellies, Preserves, and Related Products.
- 152.** §152.126. Fruit Pies.
- 155.** §155.3–155.201. Canned Vegetables.
- 156.** §156.3–156.145. Vegetable Juices.
- 158.** §158.3–158.170. Frozen Vegetables.
- 160.** §160.100–160.190. Eggs and Egg Products.
- 161.** §161.30–161.190. Fish and Shellfish.
- 163.** §163.5–163.155. Cacao Products.
- 164.** §164.110–164.150. Tree Nut and Peanut Products.
- 165.** §165.3–165.110. Beverages.
- 166.** §166.40–166.110. Margarine.
- 168.** §168.110–168.180. Sweeteners and Table Sirups.
- 169.** §169.3–169.182. Food Dressings and Flavorings.
- 170.** §170.3–170.285. Food Additives.
- 179.** §179.21–179.45. Irradiation in the Production, Processing and Handling of Food.
- 190.** §190.6. Dietary Supplements.
- 501.** §501.1–501.110. Animal Food Labeling.
- 507.** §507.1–507.215. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.
- 570.** §570.3–570.280. Food Additives.
- 579.** §579.12–579.40. Irradiation in the Production, Processing, & Handling of Animal & Pet Food.

*Note: List is not exhaustive. Other regulations may be applicable.*

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI, Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**21 C.F.R. § 1.500 – § 1.514**

The following section(s) of the FSVP regulation is/are or may be particularly relevant to this product/supplier.

- §1.500.** What Definitions Apply to This Subpart?
- §1.501.** To What Foods Do the Requirements in This Subpart Apply?
- §1.502.** What Foreign Supplier Verification Program (FSVP) Must I Have?
- §1.503.** Who Must Develop My FSVP and Perform FSVP Activities?
- §1.504.** What Hazard Analysis Must I Conduct?
- §1.505.** What Evaluation for F. Supplier Approval & Verification Must I Conduct?
- §1.506.** What Foreign Supplier Verification and Related Activities Must I Conduct?
- §1.507.** What Requirements Apply When I Import Food That Cannot Be Consumed Without the Hazards Being Controlled or for Which the Hazards Are Controlled After Importation?
- §1.508.** What Corrective Actions Must I Take Under My Foreign Supplier Verification Program?
- §1.509.** How Must the Importer Be Identified at Entry?
- §1.510.** How Must I Maintain Records of My FSVP?
- §1.511.** What FSVP Must I Have If I Am Importing A Food Subject to Certain Requirements in the Dietary Supplement Current Good Manufacturing Practice Regulation?
- §1.512.** What FSVP May I Have If I Am A Very Small Importer or I Am Importing Certain Food from Certain Small Foreign Suppliers?
- §1.513.** What FSVP May I Have If I'm Importing Certain Food from A Country with An Officially Recognized Food Safety System?
- §1.514.** What Are Some Consequences of Failing to Comply with the Requirements of FSVP?

**NOTES & COMMENTS**

FSVP 21 CFR §1.500–§1.514

This product falls – at least in part – under the jurisdiction of the United States Food and Drug Administration (FDA), and does not qualify for an exemption in Title 21, Code of Federal Regulations, Chapter I, Sub-chapter A, Part 1, Subpart L, §1.501. As the FSVP Importer's Qualified Individual (as the term is defined in §1.503) United Safety Agents – through the actions of this FSVP Plan's identified "Agent(s)" – has performed all actions required by FSVP and has presented this FSVP Plan for the review of this product's FSVP Importer. Please refer to pages 27 through 35 for substantiation of the FSVP QI's / PCQI's qualifications and certifications.

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**ATTESTATION of REVIEW & ASSESSMENT**

21 C.F.R., §1.506, (d)(3) provides that “You may rely on a determination of appropriate foreign supplier verification activities . . . made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities. . . . You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.” **Please review this FSVP plan in its entirety and document your review below.**

I, \_\_\_\_\_ type name certify that I reviewed this FSVP plan on \_\_\_\_\_ today's date and found its contents to be acceptable.

Reviewer's Name: \_\_\_\_\_

Reviewer's Signature: \_\_\_\_\_

Reviewer's Title: \_\_\_\_\_

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI, Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

## DESIGNATION of ROLES & SUMMARY of REVIEW

### FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: P&L Imports LLC FDA FEI: \_\_\_\_\_

Physical Address: 10051 E Dynamite Blvd. Suite 160 DUNS No.: 11-723-0310

City: Scottsdale State: Arizona, 85262-5242 Country: United States

Mailing Address: 10051 E Dynamite Blvd. Suite 160

City: Scottsdale State: Arizona, 85262-5242 Country: United States

Phone Number: +1 (480) 493-5304 Email Address: info@pandlimports.com

Name of Representative(s): Mr. Chris Mohrweis Title: Operations Manager

### FOREIGN SUPPLIER &/OR MANUFACTURER as defined by §1.500

Company Name: Pastificio Lucio Garofalo S.p.A. FDA FFR: 12507415488

Manufacturing Address: Via Dei Pastai 42 FDA FEI: 3003845382

City: Gragnano Province/Territory: Naples, 80054 Country: Italy

Office Address: Via Dei Pastai 42

City: Gragnano Province/Territory: Naples, 80054 Country: Italy

Phone Number: +39 081 801 1002 Email Address: info@pastagarofalo.it

Name of Representative(s): Mr. Sergio de Gennaro Title: PCQI

### QUALIFIED INDIVIDUAL(s) & AGENT(s)

Agent/QI Name: Claudio Innocenti Signature: 

Title: Partner & Preventive Controls Qualified Individual. Date: Nov 11, 2021

Agent/QI Name: William J. Barber Signature: 

Title: Preventive Controls Qualified Individual. Date: Nov. 11, 2021

### SUMMARY of REVIEW

Details of Product(s)	Is foreign supplier expected to implement controls for			Comments
	Biological Hazards	Chemical Hazards	Physical Hazards	
Tagliatelle Nest. Product must be cooked prior to consumption and is considered to be it in Ready-to-Cook form.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Undetermined	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Undetermined	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Undetermined	Verified. — — See Addendum.
	<input checked="" type="checkbox"/> FSVP Importer	<input type="checkbox"/> FSVP Importer	<input type="checkbox"/> FSVP Importer	
	<input type="checkbox"/> Disclosure	<input type="checkbox"/> Disclosure	<input type="checkbox"/> Disclosure	
	<input checked="" type="checkbox"/> Customer	<input type="checkbox"/> Customer	<input type="checkbox"/> Customer	

Preventive Control or Disclosure Rqd.: Per §117, §507, §111 and/or §1.507, Notice is required when FSVP Importer or FSVP Importer's customer will be responsible for controlling hazards. See "Hazard Analysis & Determination" section(s) and "Addendum" section for additional information. ■ Required ■ Recommended ■ Confirm efficacy of previously applied control(s)

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

## REGISTER of SUBSTANTIATING DOCUMENTS



### HAZARD ANALYSIS

Requested  Required  Received  Reviewed

NOTES Pastificio Lucio Garofalo S.p.A.'s HACCP Plan / Food Safety Plan received.

Dated: April 24, 2021.

Plan Contains: Company Overview, Product Description, Flow Diagram, Process Narrative, Hazard Analysis, Process Preventive Controls, Food Allergen Preventive Controls, Sanitation Preventive Controls, and Supply-chain-applied Preventive Controls Program.

Prepared By: Sergio de Gennaro (PCQI).

CCP(s): 9 Total CCPS.



### ON-SITE AUDIT

Requested  Required  Received  Reviewed

NOTES Pastificio Lucio Garofalo S.p.A.'s BRC Audit Report received.

Dated: November 12, 2020

Re-audit Due Date: January 16, 2022.

Audit Grade: AA+

Number of Minor Non-conformities: 2. With corresponding corrective measures.

Previous Audit Grade: AA+

Note: On-site audit report was not relied upon to approve this foreign supplier.



### SAMPLING OR TESTING RESULTS

Requested  Required  Received  Reviewed

NOTES Ingredient Testing Plan received from supplier.

Dated: July 30, 2018.

Tested typically conducted for: Heavy metals, Pesticides, Mycotoxins, and Soybean trace.

Laboratory: No laboratory identified.

Note: Testing Plan is not a Certificate of Analysis.

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Note: We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified biological and chemical hazards (preferably by an ISO 17025-accredited laboratory).



### OTHER FOOD SAFETY RECORDS

Requested  Required  Received  Reviewed

NOTES Completed Foreign Supplier FSVP Questionnaire received.

Dated: October 11, 2021

Completed by: Sergio De Gennaro

Pastificio Lucio Garofalo S.p.A.'s Recall Plan received.

FSVP Attestation of Conformance received.

Re: Garofalo Tagliatelle Nest.



### PRODUCT LABELING

Requested  Required  Received  Reviewed

NOTES Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to mean that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101.. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all regulations prior to import.

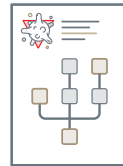
**VERIFICATION FREQUENCY for UPDATED DOCUMENTS**

21 C.F.R., §1.505, §1.506, and §1.510 require that all FSVP records be updated and maintained. Depending on USA’s review and determination of the supplier’s compliance history and food safety program, receipt of the following food safety documents are recommended according to their individually-marked time interval.



**FACILITY FOOD SAFETY PLAN**

- if a change or update occurs
- annual basis (*regardless of change*)
- other: \_\_\_\_\_



**RECALL PLAN**

- if a change or update occurs
- annual basis (*regardless of change*)
- other: \_\_\_\_\_



**HACCP PLAN / HARPC PLAN**

- if a change or update occurs
- annual basis (*regardless of change*)
- other: \_\_\_\_\_



**PRODUCT LABEL**

- if a change or update occurs
- annual basis (*regardless of change*)
- other: \_\_\_\_\_



**ON-SITE AUDIT RESULTS**

- if a change or update occurs
- annual basis (*regardless of change*)
- other: \_\_\_\_\_



**QUALIFICATIONS**

- if a change or update occurs
- annual basis (*regardless of change*)
- other: \_\_\_\_\_



**LABORATORY TESTING RESULTS**

- if positive results are returned
- if recall or import refusal occurs
- if inspection occurs
- on an annual basis
- on a per-batch/shipment basis
- Chemical     Biological
- other: \_\_\_\_\_



**IMPLEMENTATION RECORDS**

- if recall or import refusal occurs
- if inspection occurs
- on an annual basis
- on a per-batch/shipment basis
- other: \_\_\_\_\_



**FDA REGISTRATION**

- if a change or update occurs
- bi-annual basis (*regardless of change*)



**FSVP QUESTIONNAIRE**

- if a change or update occurs
- annual basis (*regardless of change*)
- other: \_\_\_\_\_



**FACILITY LICENSE**

- if a change or update occurs
- annual basis (*regardless of change*)
- not applicable



**NOTES**

All documents used for FSVP verification and approval must be re-acquired at least one every three years or sooner, per above.

[unitedsafetyagents.com/documents](https://unitedsafetyagents.com/documents)



Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

### FDA COMPLIANCE ACTIONS & REGULATORY HISTORY

21 CFR part 1, subpart L, §1.505(a)(1)(iii)(A)(C), and elsewhere requires that a foreign supplier’s compliance history be evaluated, including whether the foreign supplier is the subject of an FDA Warning Letter(s), Import Alert(s), or other FDA compliance action(s) related to food safety. The following constitutes the results of this evaluation.

### RESULTS of EVALUATION

Date of Action	Description of Action
Year of 2014	46 x IMPORT REFUSALS Product Code: Vary. Includes Pasta. Refusal Charges: Vary. Includes: MISBRANDING and ADULTERATION Shipment ID: Vary.
March 20, 2019	FDA FACILITY INSPECTION Inspection Id: 1084534 Project Area: Foodborne Biological Hazards Classification: VAI. (Voluntary Action Indicated). Details: Issues with Process Controls Monitoring Frequency and Process Controls Corrective Action Proced: Estab Implement.
	NOTE: We suggest that P&L Imports inquire about supplier's corrective measures and obtain all relevant documents including copy of full EIR for review.
	FDA Data Dashboard search results indicate that supplier's compliance history does not include FDA Warning Letters, Import Alerts, or other applicable compliance actions.
Covers: Pastificio Lucio Garofalo S.p.A. FEI: 3003845382 Date: Nov. 11, 2021	

Note: Results may not be exhaustive. FSVP Importer should conduct independent inquiry.

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**REVISION LOG for FSVP PLAN**

Version No.	Date of Change	Description of Revision
No. 01	Nov. 11, 2021	Product underwent initial FSVP verification.

**ANALYSIS & DETERMINATION of BIOLOGICAL HAZARDS**

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input checked="" type="checkbox"/> <i>Bacillus cereus</i> <input type="checkbox"/> <i>Clostridium botulinum</i> <input type="checkbox"/> <i>C. perfringens</i> <input type="checkbox"/> <i>Brucella spp.</i> <input type="checkbox"/> <i>Campylobacter spp.</i> <input type="checkbox"/> <i>Pathogenic E. coli</i> <input checked="" type="checkbox"/> <i>Salmonella spp.</i> <input checked="" type="checkbox"/> <i>S. aureus</i> <input type="checkbox"/> <i>L. monocytogenes</i> <input type="checkbox"/> <i>Trichinella spiralis</i> <input type="checkbox"/> <i>Giardia lamblia</i> <input type="checkbox"/> <i>Shigella spp.</i> <input type="checkbox"/> <i>Other</i>	1	3	<p>Biological hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – the application of a heat and/or chemical kill-step, implementing and following raw material supplier approval procedures, subjecting raw material(s) and/or finished product(s) to laboratory testing, and/or through the utilization of a number of other appropriate control measures.</p> <p>———— SUPPLIER CONTROL MEASURES ————</p> <p>01. Supplier utilizes (low moisture levels in product to control hazards posed by biological agents.                      Details: Drying process takes 4-6 hours for the short shape lines and 7-14 hours for the long shapes lines and for the specialties one. The product moisture fall down from 30% to less than 12.5%, according the Italian regulation on pasta. At this content the aw value is lower than 0.60 and this is the key for the product stability for so long time.</p> <p>02. Supplier certifies that laboratory testing is conducted to control hazards posed by biological agents.                      Details: Regulation (CE) 1881/2006.                      Total Viable Count.                      S. Aureus.                      Total Coliforms.                      Mould and yeast.                      Testing Frequency: 4 years.                      Note: Frequency is low. We recommend testing frequency be increased.</p> <p>03. Product is not in ready to eat form and must be fully cooked prior to consumption.</p> <p>04. Product is positively released.</p> <p>————NOTE————</p> <p>We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified biological and chemical hazards (preferably by an ISO 17025-accredited laboratory).</p>	<p>Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified biological hazards.</p> <p>USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified biological hazards.</p> <p>Product must be cooked prior to consumption and is considered to be in Ready-to-Cook form.</p> <p>----- HAZARD PROFILE -----                      ----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables)                      Category: Pasta Products.                      Category No.: 18.                      Subcategory: Dried pasta (not ready-to-eat).                      Storage: Shelf-Stable.</p>

**Legend for Hazard Analysis & Determination**

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.  
 C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.  
 P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.  
**Probability (P):** Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))  
**Severity (S):** Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))  
**P. & S. Assessment Scale:** 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.  
**Hazard(s) Controlled:** Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

**Source**

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**ANALYSIS & DETERMINATION of CHEMICAL HAZARDS**

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input type="checkbox"/> <i>Drug residues</i> <input type="checkbox"/> <i>Heavy metals</i> <input type="checkbox"/> <i>Industrial chemicals</i> <input type="checkbox"/> <i>Pesticides</i> <input checked="" type="checkbox"/> <i>Mycotoxins/Toxins</i> <input type="checkbox"/> <i>Radiological</i> <input type="checkbox"/> <i>Unapproved colors &amp; additives</i> <input type="checkbox"/> <i>Chemical hazards due to mis-formulation</i> <input type="checkbox"/> <i>Other</i>	1	2	<p>Chemical hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – implementing and following appropriate raw material supplier approval procedures, and/or subjecting raw material(s) and/or finished product(s) to laboratory testing.</p> <p>_____ SUPPLIER CONTROL MEASURES _____</p> <p>01. Supplier utilizes raw material inspection and approval procedures to control for hazards posed by chemical agents prior to production.</p> <p>02. Supplier utilizes laboratory testing to verify that product is free from chemical hazards prior to release. Details: Regulation (CE) 1881/2006.            OTA &lt; 3.0 ppb.            DON &lt; 750 ppb.            ZEA &lt; 75 ppb.            Afla B1 &lt; 2.0ppb.            Afla tot &lt; 4.0 ppb.            Frequency: Yearly by mill.            Corrective Actions: Product recall, supplier suspension.</p> <p>_____ NOTE _____</p> <p>We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified biological and chemical hazards (preferably by an ISO 17025-accredited laboratory).</p> <p>USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards.</p>	<p>Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified chemical hazards.</p> <p>USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards.</p>

**Legend for Hazard Analysis & Determination**

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.  
 C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.  
 P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.  
**Probability (P):** Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))  
**Severity (S):** Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))  
**P. & S. Assessment Scale:** 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.  
**Hazard(s) Controlled:** Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

**Source**

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

----- HAZARD PROFILE -----  
 ----- SOURCE -----  
 Appendix 1 (Hazards Tables)  
 Category: Pasta Products.  
 Category No.: 18.  
 Subcategory: Dried pasta (not ready-to-eat).  
 Storage: Shelf-Stable.

**ANALYSIS & DETERMINATION of ALLERGENIC HAZARDS**

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input checked="" type="checkbox"/> <b>Undeclared allergens - Incorrect label</b> <input checked="" type="checkbox"/> <b>Undeclared allergens - Cross-contact</b>  <b>ALLERGENS</b> <input type="checkbox"/> <b>Milk</b> <input type="checkbox"/> <b>Eggs</b> <input type="checkbox"/> <b>Fish</b> <input type="checkbox"/> <b>Shellfish (Crustacean)</b> <input type="checkbox"/> <b>Tree nuts</b> <input type="checkbox"/> <b>Peanuts</b> <input checked="" type="checkbox"/> <b>Wheat</b> <input type="checkbox"/> <b>Soybeans</b> <input type="checkbox"/> <b>Sesame*</b>	3	3	<p>Allergens themselves can not be directly controlled. However, the presence of allergens – or a given allergen – can be controlled. The presence of allergenic hazards can be effectively controlled through the utilization of a number of control measures, including – but not limited to – staff training for common food allergens, avoiding cross-contact, and proper food labeling. These may be effective methods to ensure that allergens are not ingested by a person who will be experience a negative reaction.</p> <p>_____ SUPPLIER CONTROL MEASURES _____</p> <p>01. Supplier certifies that:                      A) WHEAT is handled on site and present in product.                      B) a documented allergen control program is in use.                      C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination.                      D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area.</p> <p>_____NOTE_____</p> <p>Label states "Ingredients: Organic Durum Wheat Semolina". We recommend that supplier print the name of present allergens in a manner that more fully complies with the Food Allergen Labeling and Consumer Protection Act. For example "Product contains WHEAT."</p> <p>----- Labeling Requirements -----</p> <ul style="list-style-type: none"> <li>- Food Allergen Labeling and Consumer Protection Act -</li> <li>- Nutritional information (not appliance to bulk).</li> <li>- Name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5).</li> <li>- Quantity of contents (21 CFR 101.7).</li> <li>- Statement of identity (21 CFR 101.3).</li> <li>- Presence of artificial flavoring, artificial coloring, or chemical preservative ( 21 CFR 101.22).</li> <li>- Ingredient statement if the product has two or more ingredients (21 CFR 101.4).</li> <li>- Presence of major food allergens (21 U.S.C. 343(w)).</li> <li>- Percent juice ( 21 CFR 101.30), when applicable.</li> </ul>	<p>Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control the hazard posed by allergenic adulteration.</p> <p>Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to meant that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&amp;C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all applicable regulations prior to import.</p> <p>----- HAZARD PROFILE -----</p> <p>----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables)                      Category: Pasta Products.                      Category No.: 18.                      Subcategory: Dried pasta (not ready-to-eat).                      Storage: Shelf-Stable.</p>

**Legend for Hazard Analysis & Determination**

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.  
 C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.  
 P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.  
**Probability (P):** Assesses the probability that the hazard will occur in the absence of controls. (§1.505, (c))  
**Severity (S):** Assesses the severity of the illness or injury if the hazard were to occur. (§1.505, (c))  
**P. & S. Assessment Scale:** 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.  
**Hazard(s) Controlled:** Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

**Source**

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)  
 \*Per Food Allergy Safety, Treatment, Education and Research Act, food packages will need to reflect allergen labeling for sesame beginning on January 1, 2023.

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**ANALYSIS & DETERMINATION of ENVIRONMENTAL HAZARDS**

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input type="checkbox"/> <b>Recontamination with environmental pathogens.</b> <input checked="" type="checkbox"/> <b>Bacterial pathogen survival of a lethal treatment.</b> <input type="checkbox"/> <b>Bacterial growth and/or toxin formation due to lack of time / temperature control.</b> <input type="checkbox"/> <b>Recontamination due to lack of container integrity.</b> <input type="checkbox"/> <b>Bacterial growth and/or toxin formation due to poor formulation control.</b> <input type="checkbox"/> <b>Bacterial growth and/or toxin formation due to reduced oxygen packaging.</b> <input type="checkbox"/> <b>Other</b>	1	2	<p>Hazards posed by ineffective processes or environmental pathways can be controlled by the utilization of Current Good Manufacturing Practices, positively releasing finished product, avoiding cross-contamination, carefully monitoring production process, subjecting raw material(s) and/or finished product(s) to laboratory testing, and/or through the utilization of a number of other appropriate control measures.</p> <p style="text-align: center;">----- SUPPLIER CONTROL MEASURES -----</p> <p>01. Hazard posed by recontamination with environmental pathogens is controlled through Current Good Manufacturing Practices.</p> <p>02. Supplier has implemented a cleaning program and environmental monitoring for microbiological and biological hazards.</p> <p>03. All product is positively released and hermetically sealed within plastic.</p> <p style="text-align: center;">----- NOTE -----</p> <p>We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified biological and chemical hazards (preferably by an ISO 17025-accredited laboratory).</p>	<p>Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified environmental hazards.</p> <p>Due to the long time-tables associated with international freight shipping, USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified environmental hazards.</p> <p>Product must be cooked prior to consumption and is considered to be it in Ready-to-Cook form.</p>
				<p style="text-align: center;">----- HAZARD PROFILE -----            ----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables)            Category: Pasta Products.            Category No.: 18.            Subcategory: Dried pasta (not ready-to-eat).            Storage: Shelf-Stable.</p>

**Legend for Hazard Analysis & Determination**

**M&B:** Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.  
**C:** Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.  
**P:** Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.  
**Probability (P):** Assesses the probability that the hazard will occur in the absence of controls. (§1.505, (c))  
**Severity (S):** Assesses the severity of the illness or injury if the hazard were to occur. (§1.505, (c))  
**P. & S. Assessment Scale:** 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.  
**Hazard(s) Controlled:** Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

**Source**

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**ANALYSIS & DETERMINATION of PHYSICAL HAZARDS**

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input checked="" type="checkbox"/> <b>Metal</b> <input type="checkbox"/> <b>Glass</b> <input type="checkbox"/> <b>Extraneous Matter</b> <input type="checkbox"/> <b>Plastics</b> <input type="checkbox"/> <b>Stones</b> <input type="checkbox"/> <b>Wood</b> <input type="checkbox"/> <b>Natural Component of Food</b> <input type="checkbox"/> <b>Other</b>	1	2	<p>Physical hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – the utilization of an operational and calibrated metal detector during and/or after the production process, sieving raw material and/or finished product, optical sorting machinery, visual inspection, appropriate and consistent raw material supplier approval methods, and/or through the utilization of a number of other appropriate control measures.</p> <p>———— SUPPLIER CONTROL MEASURES ————</p> <p>01. Supplier utilizes an operational and calibrated metal detector to control hazards posed by physical agents.  Metal Detector's Critical Limits  Ferrous: 1.5 mm.  Non Ferrous: 2.0 mm.  Stainless Steel: 2.5 mm.</p> <p>Verification: The QC manager verify the automatic logs related to the metal detection, including the working data and the testing results.</p> <p>Corrective Action: In case of failing the product packed after the latest complete control is on hold and re-tested through a metal detector</p> <p>02. Supplier sieves incoming ingredients.</p> <p>03. Supplier utilizes a Supply-chain-applied Preventive Controls Program that aligns with CGMPs.</p>	<p>Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control physical hazards.</p> <p>----- HAZARD PROFILE -----  ----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables)  Category: Pasta Products.  Category No.: 18.  Subcategory: Dried pasta (not ready-to-eat).  Storage: Shelf-Stable.</p>

**Legend for Hazard Analysis & Determination**

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.  
C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.  
P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.  
**Probability (P):** Assesses the probability that the hazard will occur in the absence of controls. (§1.505, (c))  
**Severity (S):** Assesses the severity of the illness or injury if the hazard were to occur. (§1.505, (c))  
**P. & S. Assessment Scale:** 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.  
**Hazard(s) Controlled:** Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

**Source**

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

## ASSESSMENT of FOREIGN SUPPLIER

### 1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: Pastificio Lucio Garofalo S.p.A.

1.2. Supplier address: via dei pastai, 42 – 80054 Gragnano (NA) Italy

1.3. Products manufactured/supplied: Macaroni Products, Dried macaroni products.

1.4. Is the supplier certified to a food safety standard and audited regularly?  Yes  No  N/A

*GFSI Standard:* GFSI certification (BRC, IFS, ISO 22000). BRC IOP.

1.5. Is the standard GFSI benchmarked/recognized?  Yes  No  Other (see Addendum)

1.6. Has the supplier provided specifications?  Yes  No

1.7. Has the supplier completed a Supplier Assessment and an Allergen Questionnaire?  Yes  No

1.8. Have the supplier's specifications and/or completed questionnaires been evaluated by USA's PCQI(s)?

Yes  No *PCQI(s):* C. Innocenti (PCQI Member, USA LLC)

### 2.0 SUPPLIER PROCEDURES, PROCESSES & PRACTICES

2.1. Does supplier follow current GMPs?  Yes  No

2.2. Does the supplier have SOP in place for each procedure in the production & release of product?  Yes  No  N/A

2.3. Does the supplier have allergen controls in place to prevent cross-contamination?  Yes  No  N/A

### 3.0 SUPPLIER PERFORMANCE HISTORY

3.1. Does the supplier have a HACCP/PC plan for each product manufactured for the importer?  Yes  No  N/A

3.2. Has the supplier's HACCP/PC plan been reviewed and approved by USA's PCQI(s)?  Yes  No

*PCQI(s):* C. Innocenti (PCQI Member, USA LLC)

3.3. To the best of USA's knowledge, has the supplier been the subject of a public FDA Alert/Warning Letter?

Yes  No  N/A *Description:* No. Import Alert & Warning Letter search-results.

which were conducted on – or about – the Review End date, have been attached to this FSVP Plan.

3.4. Has the supplier supplied a product that needed to be recalled for a food safety reason?  Yes  No  N/A

*Description:* No, as of this FSVP Plan's Review End date, USA has no knowledge

of any recall undertaken by supplier.

*Continued onto next page.*

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**ASSESSMENT of FOREIGN SUPPLIER**

**3.0 SUPPLIER PERFORMANCE HISTORY** *(Continued)*

3.5. Has the supplier supplied out of specification product excluding quality issues?  Yes  No  N/A

3.6. Has importer conducted microbiological testing for all lots imported from the supplier?  Yes  No  N/A

3.7. Has any lot tested positive for chemical, physical or biological hazards?  Yes  No  N/A

Description of the incident and the corrective actions taken by the supplier: No, as of this FSVP Plan's Review End date, USA has no knowledge of any lot/batch testing positive for any FDA-identified hazard(s).

3.8. Has the supplier provided timely and adequate responses to all requests and issues related to food safety?

Yes  No

Description: Yes, supplier (either directly, or through the FSVP Importer) has provided timely and adequate responses to our inquiries and requests.

**4.0 SUPPLIER APPROVAL**

4.1. Have USA's PCQI(s) identified and evaluated the known and reasonably foreseeable hazards for each product imported from the supplier and are there preventive controls in place to adequately control the hazards?

Yes  No

PCQI(s): C. Innocenti (PCQI Member, USA LLC)

4.2. After reviewing all hazards and the supplier's performance, have USA's PCQI(s) determined appropriate verification activities that will be conducted and documented on an ongoing basis to verify the preventive controls are effectively controlling the hazard(s)?  Yes  No

PCQI(s): C. Innocenti (PCQI Member, USA LLC)

4.3. **Is the foreign supplier approved for import into the United States under this FSVP plan?**  Yes  No

Comments: Supplier has been verified and their products have been approved for importation.

Additional Recommendations:

USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified hazards.

Supplier follows CGMPs and utilizes an established food safety program. Products supplied by this supplier have been verified and are approved for import. Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis (or sooner if necessary). This FSVP will expire one year from its above the above noted "Review End" date.

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

## REVIEW of GENERAL FOOD SAFETY PROGRAM

### Claims Made Against Product

Product is claimed to be Organic.

NOTE: No substantiation of this claim has been provided.

### Overview of Foreign Supplier's Commercial Operation

Pastificio Lucio Garofalo is a small business (a business with fewer than 500 full-time equivalent employees) pasta manufacturer. The product variety includes more than 100 different pasta shapes and the possible addition of vitamin and minerals (Enriched Macaroni Product) and vegetable (Tricolor pasta).

FDA Registration Number: 12507415488

DUNS Number 630998235

U.P.C. Company Prefix: 085164

Product is made 7 days a week, 24 hours a day. The site has 8 different production lines, 4 dedicated to short shapes (penne, fusilli or similar), 3 dedicated to long shapes (as spaghetti or vermicelli), 1 dedicated to specialties (lasagna sheets and nested noodles). 14 different packing lines are present.

### Testing Program & Accreditation

An internal laboratory is present to check the chemical and microbiological parameters on raw material (durum wheat semolina) and on the finished product (dry pasta). Water comes from an internal well, partially softened and sterilized by UV lamp. An integrated pest control plan is in place.

### Supplier & Product Allergen Information

We recommend that supplier print the name of present allergens in a manner that more fully complies with the Food Allergen Labeling and Consumer Protection Act. For example "Product contains WHEAT."

Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to mean that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all applicable regulations prior to import.

### Packaging Type & Shipping / Handling Requirements

Plastic bag (Polypropylene or Polyethylene made) thermally sealed, never hermetic in order to permit the pack breathing.

Supplier certifies that packaging is accredited for food use. Ambient shipping and handling requirements.

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**REVIEW of GENERAL FOOD SAFETY PROGRAM**

**Supplier GFSI Status & Historical Performance**

Supplier appears to be following CGMPs and utilizes an established food safety program. Products supplied by this supplier have been verified and are approved for import.

**Close Supplier Monitoring**

Yes. Due to suppliers poor FDA compliance history and recent VAI Facility Inspection, we recommend that close supplier monitoring be instituted.

**General Comments & Verification Timeline**

Products supplied by this supplier have been verified and are approved for import. Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis (or sooner if necessary). This FSVP will expire one year from its above the above noted "Review End" date.

NOTE

We respectfully request:

We respectfully request that Pastificio Lucio Garofalo S.p.A. provide current testing results for all FDA-identified biological and chemical hazards.

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**ADDENDUM**

NOTE

Labeling Requirements

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 requires food manufacturers to label food products that contain an ingredient that is or contains protein from a major food allergen in one of two ways.

The first option for food manufacturers is to include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major allergen does not appear elsewhere in the ingredient statement. For example: Vanilla Waffers Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring) salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono-and diglycerides (emulsifier)

The second option is to place the word "Contains" followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in type size that is no smaller than the type size used for the list of ingredients. For example: Contains Wheat, Milk, Egg, and Soy

Food Allergen Labeling and Consumer Protection Act

- Nutritional information (not appliance to bulk).
- Name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5).
- Quantity of contents (21 CFR 101.7).
- Statement of identity (21 CFR 101.3).
- Presence of artificial flavoring, artificial coloring, or chemical preservative ( 21 CFR 101.22).
- Ingredient statement if the product has two or more ingredients (21 CFR 101.4).
- Presence of major food allergens (21 U.S.C. 343(w)).
- Percent juice ( 21 CFR 101.30), when applicable.

IMPORTANT NOTE: Supplier has Food Allergen Preventive Controls in place. Product's label states "Ingredients: Organic Durum Wheat Semolina". We recommend that supplier print the name of present allergens in a manner that more fully complies with the Food Allergen Labeling and Consumer Protection Act. For example "Product contains WHEAT."

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

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Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

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Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT**

  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

## CERTIFICATE OF TRAINING

is awarded to

**Claudio Innocenti**

in recognition for having successfully completed  
the Food Safety Preventive Controls Alliance course:  
**Foreign Supplier Verification Programs**  
delivered by Lead Instructor

Bob Bauer  
completed on  
05/13/2021

  
Robert Brackett, VP and Director  
Institute for Food Safety and Health  
  
ILLINOIS INSTITUTE OF TECHNOLOGY

  
Gerald Wojtala, Executive Director  
International Food Protection Training Institute  
  
Certificate # 31d8ad94

  
Steve Mandernach, Executive Director  
Association of Food and Drug Officials  


  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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is awarded to

**Claudio Innocenti**

in recognition for having successfully completed  
the Food Safety Preventive Controls Alliance course:  
**FSPCA Preventive Controls for Animal Food**  
delivered by Lead Instructor

Charles Nolan  
completed on  
07/09/2020

  
Robert Brackett, VP and Director  
Institute for Food Safety and Health  
  
ILLINOIS INSTITUTE OF TECHNOLOGY

  
Gerald Wojtala, Executive Director  
International Food Protection Training Institute  
  
INTERNATIONAL  
FOOD PROTECTION  
TRAINING INSTITUTE  
Certificate # 223faa17

  
Susan M. Hays, Executive Director  
Association of American Feed Control Officials  


Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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the Food Safety Preventive Controls Alliance course:  
**Foreign Supplier Verification Programs**  
delivered by Lead Instructor

**Bob Bauer**  
completed on  
09/14/2018

  
Robert Brackett, VP and Director  
Institute for Food Safety and Health

  
Gerald Wojtals, Executive Director  
International Food Protection Training Institute

  
Joseph Corby, Executive Director  
Association of Food and Drug Officials

  
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AND HEALTH  
ILLINOIS INSTITUTE OF TECHNOLOGY

  
ifpti INTERNATIONAL  
FOOD PROTECTION  
TRAINING INSTITUTE

  
AFDO

Certificate # d2e9c287



## Certificate of Training

is awarded to

# Claudio Innocent

in recognition for having successfully completed  
the Produce Safety Alliance course:  
**PSA Grower Training Course**  
Delivered by PSA Lead Trainers and/or PSA Trainers  
**Cara Fraver, Laura McDermott, Yolanda Gonzalez,  
Lindsey Pashow**

  
ASSOCIATION OF FOOD  
& DRUG OFFICIALS  
SINCE 1898

  
Joseph Corby  
Executive Director, AFDO

  
Elizabeth A. Bihn, Ph.D.  
Produce Safety Alliance Director

**Class Number**  
NY-180712-GR  
**Grower ID Number**  
50447  
**Training Date and Location**  
7/12/2018-7/12/2018  
Voorheesville, NY

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

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Bob Bauer  
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05/31/2018

  
Robert Brackett, VP and Director  
Institute for Food Safety and Health  
  
ILLINOIS INSTITUTE OF TECHNOLOGY

  
Gerald Wojtala, Executive Director  
International Food Protection Training Institute  
  
INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

  
Joseph Corby, Executive Director  
Association of Food and Drug Officials  


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completed on  
09/14/2017

  
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Institute for Food Safety and Health  
  
ILLINOIS INSTITUTE OF TECHNOLOGY

  
Gerald Wojtala, Executive Director  
International Food Protection Training Institute  
  
INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

  
Joseph Corby, Executive Director  
Association of Food and Drug Officials  


Certificate # d2e9c287

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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the Food Safety Preventive Controls Alliance course:  
**FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD**  
delivered by Lead Instructor  
Amanda Evans  
completed on  
07/25/2017

 Robert Brackett, VP and Director Institute for Food Safety and Health	 Gerald Wojtals, Executive Director International Food Protection Training Institute	 Joseph Corby, Executive Director Association of Food and Drug Officials
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 IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH <small>ILLINOIS INSTITUTE OF TECHNOLOGY</small>	 ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE	 AFDO
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Certificate # 2d697331

Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT**

  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

## CERTIFICATE OF TRAINING

is awarded to

### WILLIAM BARBER

in recognition for having successfully completed  
the Food Safety Preventive Controls Alliance course:  
**FSPCA Preventive Controls for Human Food**  
delivered by Lead Instructor  
Mirasol Mohal  
completed on  
06/05/2019

  
Robert Brackett, VP and Director  
Institute for Food Safety and Health  
  
ILLINOIS INSTITUTE OF TECHNOLOGY

  
Gerald Wojtals, Executive Director  
International Food Protection Training Institute  
  
Certificate # ed6f0b58

  
Steve Mandernach, Executive Director  
Association of Food and Drug Officials  


  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

## CERTIFICATE OF TRAINING

is awarded to

### William Barber

in recognition for having successfully completed  
the Food Safety Preventive Controls Alliance course:  
**Foreign Supplier Verification Programs**  
delivered by Lead Instructor  
tina coil  
completed on  
06/13/2017

  
Robert Brackett, VP and Director  
Institute for Food Safety and Health  
  
ILLINOIS INSTITUTE OF TECHNOLOGY

  
Gerald Wojtals, Executive Director  
International Food Protection Training Institute  
  
Certificate # 917b0241

  
Joseph Corby, Executive Director  
Association of Food and Drug Officials  


Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT**



This is to certify that

**William Barber**

Has been awarded the

**Level 4 Award in HACCP Management for  
Food Manufacturing  
500/6523/3**

**PASS**

*Date of Award  
10 November 2016*



Richard Burton  
Head of Qualifications



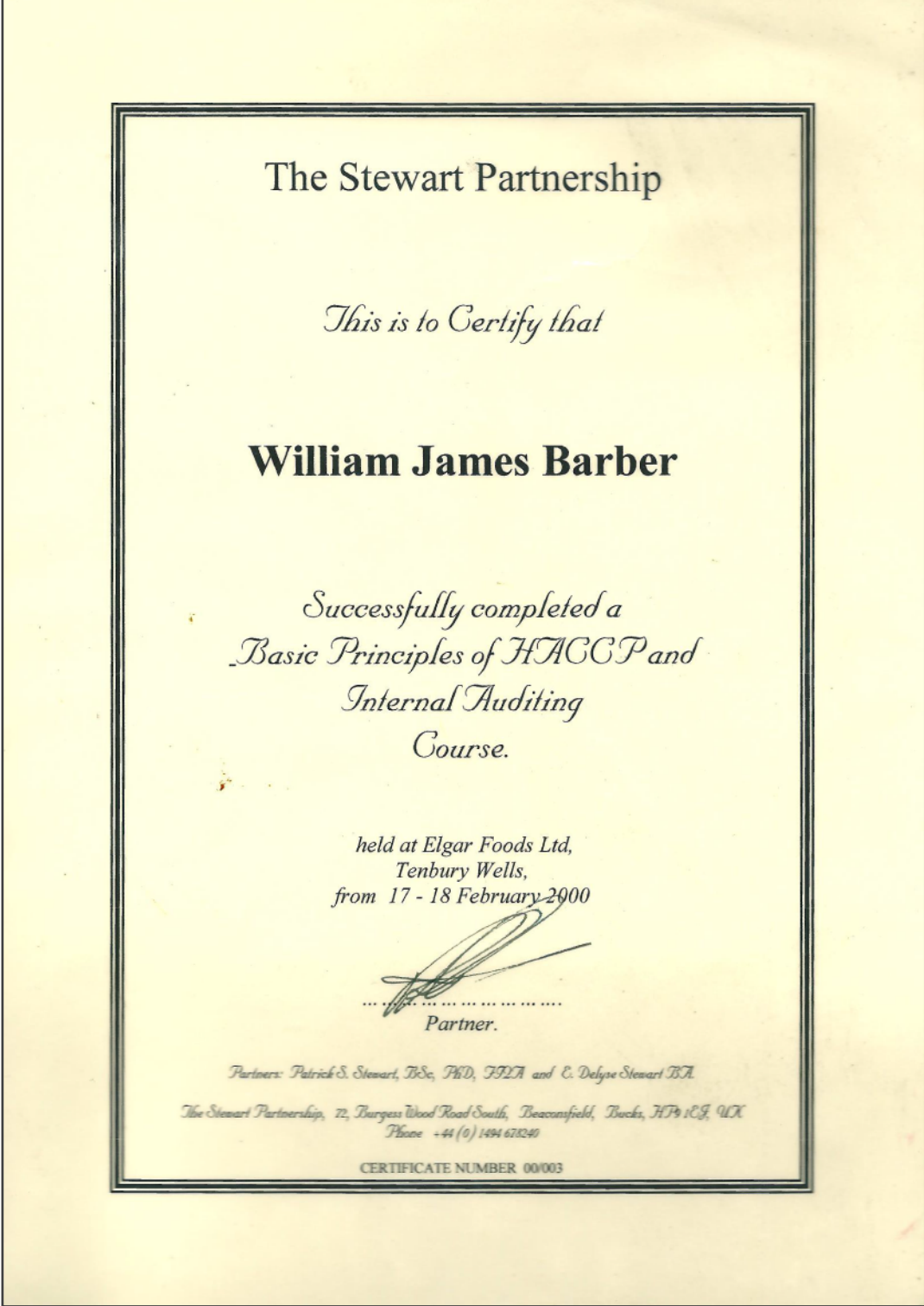
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Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021


**CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT**



Supplier: Pastificio Lucio Garofalo S.p.A. Product: Tagliatelle Nest

Agent(s): Claudio Innocenti (PCQI, Member, USA LLC) Review Start: Oct. 18, 2021 Review End: Nov. 11, 2021

**CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT**



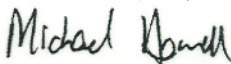
**NATIONAL VOCATIONAL QUALIFICATION**


**LEVEL 3 NVQ IN FOOD AND DRINK MANUFACTURING OPERATIONS  
(Q1054402)**


**IS AWARDED TO  
WILLIAM BARBER**


THE HOLDER HAS A NUMBER OF FORMAL UNIT CREDITS BY WHICH THIS AWARD WAS ACHIEVED


AWARDED    SEPTEMBER 2007    0709/024307A/124203/PXC4025/1/13/03/64

  
M Howell  
Chairman  
The City and Guilds of London Institute

  
C Humphries  
Director-General  
The City and Guilds of London Institute

  
Qualifications and Curriculum Authority





The City and Guilds of London Institute founded 1878 and incorporated by Royal Charter 1900.  
The City & Guilds Group comprises City & Guilds, ILM, City & Guilds NPTC and City & Guilds HAB.

**CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT**



**CERTIFICATE OF UNIT CREDIT TOWARDS  
NATIONAL VOCATIONAL QUALIFICATION  
LEVEL 3 NVQ IN FOOD AND DRINK MANUFACTURING OPERATIONS**

**IS AWARDED TO  
WILLIAM BARBER**

**WHO ATTENDED PERSHORE GROUP OF COLLEGES**

AND WAS SUCCESSFUL IN THE  
FOLLOWING TEN UNITS

CONTROL AND MAINTAIN QUALITY WITHIN MULTI-STAGE MANUFACTURING OPERATIONS	U1024734
RESOLVE PROBLEMS IN MULTI-STAGE MANUFACTURING OPERATIONS	U1024735
MAINTAIN AND IMPROVE HEALTH AND SAFETY WITHIN THE WORKPLACE	U1024736
MAINTAIN AND IMPROVE HYGIENE AND PRODUCT SAFETY WITHIN THE WORKPLACE	U1024737
CONTRIBUTE TO THE ACHIEVEMENT OF ORGANISATIONAL AND PERSONAL GOALS	U1028661
PROVIDE INFORMATION TO SUPPORT DECISION MAKING	U1026144
MONITOR AND MAINTAIN THE HANDLING AND STORAGE OF MATERIALS	U1024742
IMPLEMENT QUALITY ASSURANCE SYSTEMS	U1027820
DEVELOP A FOOD AND DRINK PRODUCT	U1050274

**CONTINUED**

AWARDED SEPTEMBER 2007 0709/024307A/124203/PXC4025/1/13/03/64

M Howell  
Chairman  
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ROT



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The City & Guilds Group comprises City & Guilds, ILM, City & Guilds NPTC and City & Guilds HAB.



**SUBSTANTIATING DOCUMENTS**



**This FSVP plan is based – at least in part – on the following foreign supplier-provided food safety documents. All substantiating documents have been reviewed and assessed by United Safety Agents LLC.**

**Note** All foreign supplier-provided documents are considered to be the property of that foreign supplier and may contain information which is privileged, confidential, and protected. Any reproduction, distribution or other use of these documents without the express written consent of the foreign supplier is prohibited. Enclosed documents are meant for review purposes only and are subject to change without notice. Documents may contain non-binding recommendations and are uncontrolled.

**ATTESTATION of CONFORMANCE**

Per Title 21 of the United States Code of Federal Regulations, Chapter I, Subchapter A, Part 1, Subpart L, §1.502; Pastificio Lucio Garofalo S.p.A., which maintains a manufacturing facility at Via dei pastai, 42, Gragnano, 80054, Naples, Italy; is producing all of the below enumerated product(s): I) at the same location, and on the same production line as previously verified product, II) under the same food safety program and HACCP Plan used to manufacture/process previously verified product, and III) has certified that all of the below enumerated product(s) have identical hazards, and critical controls as those of previously verified product.

FURTHERMORE, I \_\_\_\_\_, hereby certify that this information is true, accurate, and complete to the best of my knowledge and understand that any false statements or deliberate omissions may be grounds for disqualification from successful Foreign Supplier Verification Program (FSVP) approval or, if discovered after FSVP approval takes place, can result in the revocation or termination of United Safety Agent LCC's FSVP Agent coverage of previously approved products, and may result in a product or shipment being rejected from entry into the United States.

**Name of Previously Verified Product-line**

Durum Wheat Semolina Pasta Line.

**List of New Products**

Garofalo Tagliatelle Nest.

*include the full name and size/seasonal variation of each product*

Signed \_\_\_\_\_

Certified by \_\_\_\_\_

Title Operations Manager \_\_\_\_\_

Company \_\_\_\_\_

Date \_\_\_\_\_

<b>PRODUCT:</b>	Macaroni Products	<b>PAGE 1 of 47</b>
<b>PLANT NAME:</b>	Pastificio Lucio Garofalo S.p.A.	<b>ISSUE DATE</b> 05/24/2021
<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b> 12/30/2020



STORICO PASTIFICIO

*Garofalo*

**PASTIFICIO LUCIO GAROFALO S.p.A.**

---

**Food Safety Plan  
for  
MACARONI PRODUCT**

Developed by: Sergio de Gennaro (PCQI)

Issuing Date: August 16, 2017  
revision date May 24, 2021

Approved by: Massimo Menna (CEO - Plant Manager)

Date: May 24, 2021

Food Safety Plan

<b>PRODUCT:</b>	Macaroni Products	<b>PAGE 2 of 47</b>
<b>PLANT NAME:</b>	Pastificio Lucio Garofalo S.p.A.	<b>ISSUE DATE</b> 05/24/2021
<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b> 12/30/2020

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<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b> 12/30/2020

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Food Safety Plan

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<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b> 12/30/2020

## Company Overview

Pastificio Lucio Garofalo is a small business (a business with fewer than 500 full-time equivalent employees) pasta manufacturer. The product variety includes more than 100 different pasta shapes and the possible addition of vitamin and minerals (Enriched Macaroni Product) and vegetable (Tricolor pasta).

FDA Registration Number: 19493040738

DUNS Number 630998235

U.P.C. Company Prefix: 085164

Product is made 7 days a week, 24 hours a day. The site has 9 different production lines, 5 dedicated to short shapes (penne, fusilli or similar), 3 dedicated to long shapes (as spaghetti or vermicelli), 1 dedicated to specialties (lasagna sheets and nested noodles). 16 different packing lines are present.

An internal laboratory is present to check the chemical and microbiological parameters on raw material (durum wheat semolina) and on the finished product (dry pasta). Water comes from an internal well, partially softened and sterilized by UV lamp. An integrated pest control plan is in place.

Members of the Food Safety Team are:

Massimo Menna – C.E.O. – Site Manager

Gianni Schisa – Operation Manager

Sergio De Gennaro – QA Manager – PCQI – Team Leader

Alessio Stellato – PCQI – GMP expert

Germana Amadoro – QC Manager - PCQI

Rosanna Mainardi – QC Manager

Sabato Genovese –Production Manager

Cristofero Palermo – Maintenance Manager

<b>PRODUCT:</b>	Macaroni Products	<b>PAGE 5 of 47</b>
<b>PLANT NAME:</b>	Pastificio Lucio Garofalo S.p.A.	<b>ISSUE DATE</b> 05/24/2021
<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b> 12/30/2020

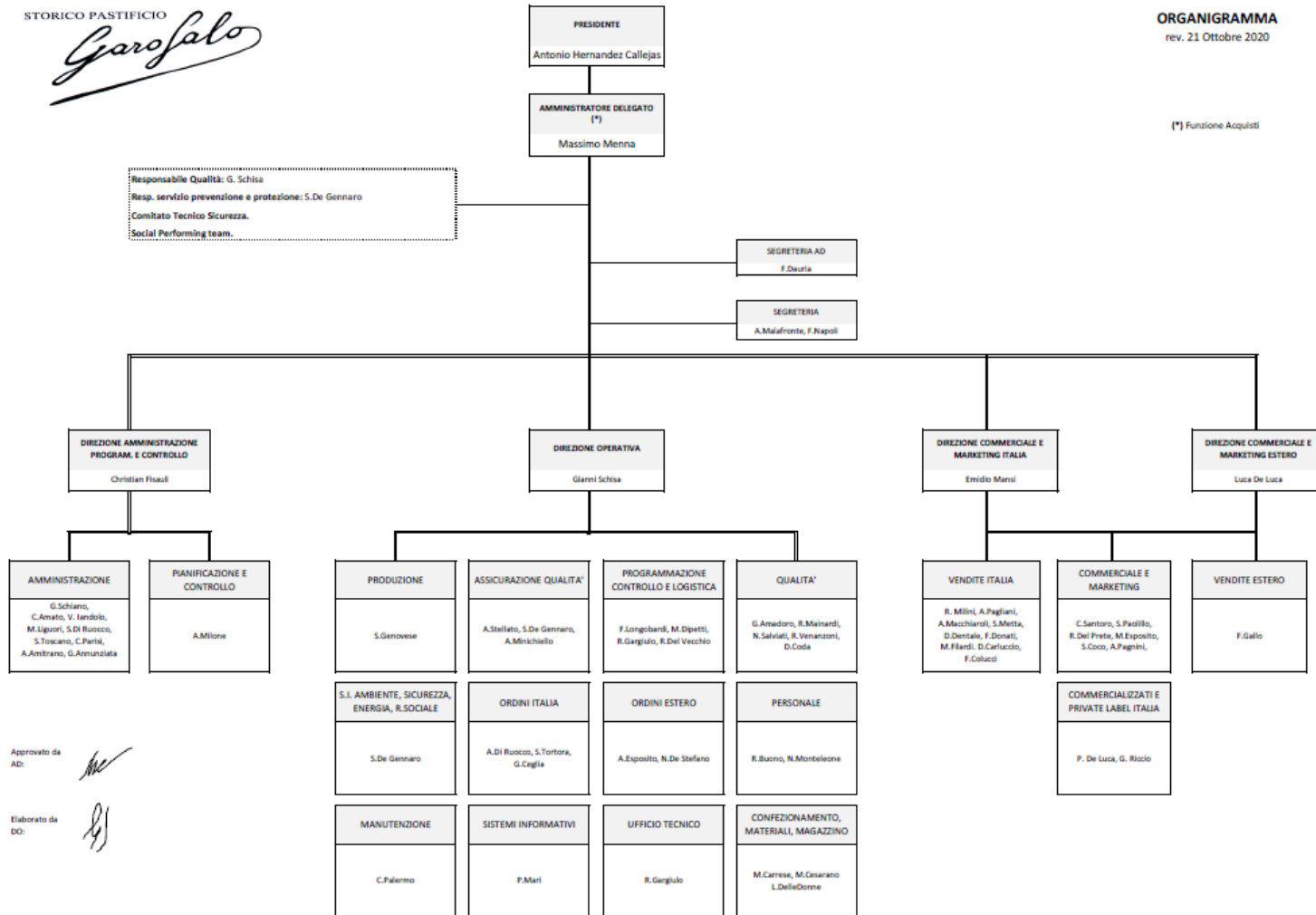
## ORGANIZATION CHART

STORICO PASTIFICIO



**ORGANIGRAMMA**  
rev. 21 Ottobre 2020

(\*) Funzione Acquisti

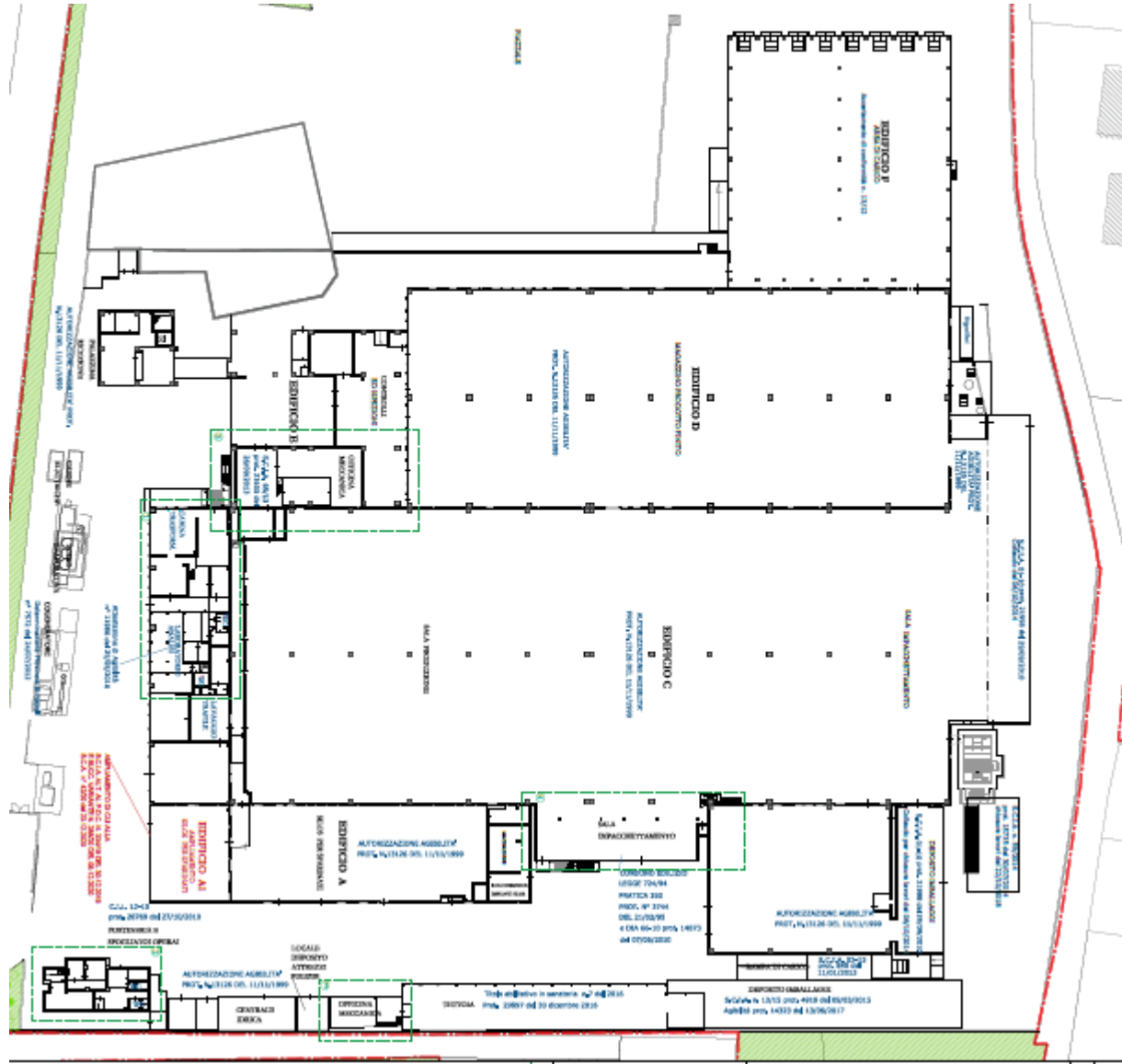


Approvato da AD:

Elaborato da DO:

<b>PRODUCT:</b>	Macaroni Products	<b>PAGE 6 of 47</b>
<b>PLANT NAME:</b>	Pastificio Lucio Garofalo S.p.A.	<b>ISSUE DATE</b> 05/24/2021
<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b> 12/30/2020

### PLANT LAYOUT



### Food Safety Plan

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START/END DATES

CONFIDENTIAL TREATMENT REQUESTED

*Claudio Innocenti*

<b>PRODUCT:</b>	Macaroni Product	<b>PAGE 7 of 47</b>
<b>PLANT NAME:</b>	Pastificio Lucio Garofalo S.p.A.	<b>ISSUE DATE</b> 05/24/2021
<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b> 12/30/2020

## Product Description

<b>Product Name</b>	<b>Macaroni Product</b>
<b>Product Description, including Important Food Safety Characteristics</b>	Traditional Italian Pasta from durum wheat semolina moisture <12.5% $a_w < 0.60$
<b>Ingredients</b>	Durum wheat semolina
<b>Allergens</b>	Contains wheat
<b>Packaging Used</b>	Plastic bag (Polypropylene or Polyethylene made) thermally sealed, never hermetic in order to permit the pack breathing.
<b>Intended Use</b>	The product needs to be cooked in boiling water for a proper rehydration before being eaten.
<b>Intended Consumers</b>	General public, except for coeliac people.
<b>Shelf Life*</b>	36 months
<b>Labeling Instructions*</b>	None
<b>Storage and Distribution*</b>	Ambient temperature.

<b>Product Name</b>	<b>Whole Wheat Macaroni Product</b>
<b>Product Description, including Important Food Safety Characteristics</b>	Traditional Italian Pasta from whole durum wheat flour moisture <12.5% $a_w < 0.60$
<b>Ingredients</b>	Whole durum wheat flour.
<b>Allergens</b>	Contains wheat
<b>Packaging Used</b>	Plastic bag (Polypropylene or Polyethylene made) thermally sealed, never hermetic in order to permit the pack breathing.
<b>Intended Use</b>	The product needs to be cooked in boiling water for a proper rehydration before being eaten.
<b>Intended Consumers</b>	General public, except for coeliac people.
<b>Shelf Life*</b>	36 months
<b>Labeling Instructions*</b>	None
<b>Storage and Distribution*</b>	Ambient temperature.

Food Safety Plan

<b>PRODUCT:</b>	Macaroni Product	<b>PAGE 8 of 47</b>
<b>PLANT NAME:</b>	Pastificio Lucio Garofalo S.p.A.	<b>ISSUE DATE</b> 05/24/2021
<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b> 12/30/2020

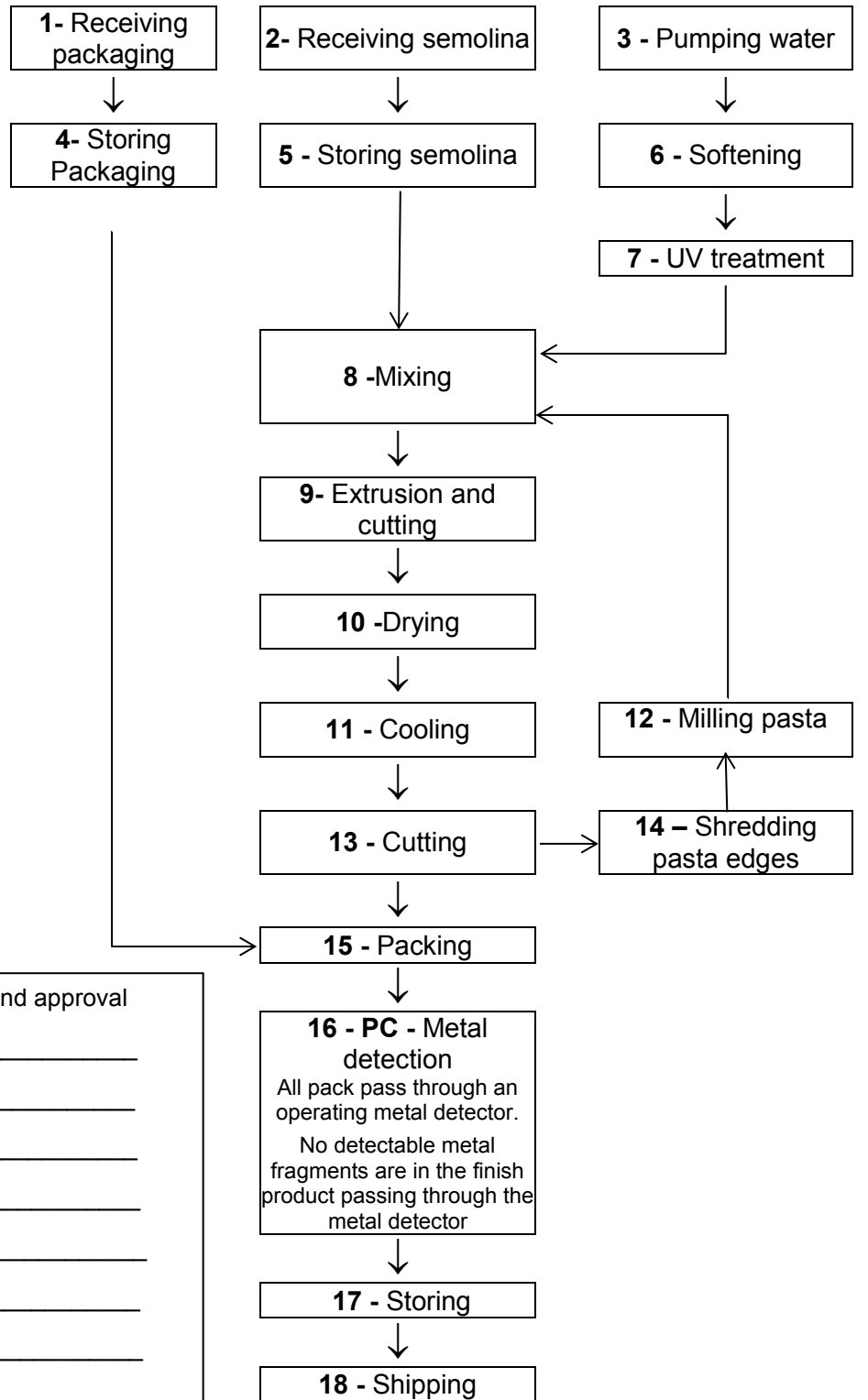
<b>Product Name(s)</b>	<b>Tricolor pasta</b>
<b>Product Description, including Important Food Safety Characteristics</b>	Traditional Italian Pasta flowered with tomato and spinach moisture <12.5% $a_w < 0.60$
<b>Ingredients</b>	Durum wheat semolina, tomato powder, spinach powder.
<b>Allergens</b>	Contains wheat
<b>Packaging Used</b>	Plastic bag (Polypropylene or Polyethylene made) thermally sealed, never hermetic in order to permit the pack breathing.
<b>Intended Use</b>	The product needs to be cooked in boiling water for a proper rehydration before being eaten.
<b>Intended Consumers</b>	General public, except for coeliac people.
<b>Shelf Life*</b>	36 months
<b>Labeling Instructions*</b>	None
<b>Storage and Distribution*</b>	Ambient temperature.

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## Flow Diagram

Macaroni Product



FS team verification and approval

M. Menna \_\_\_\_\_

G. Schisa \_\_\_\_\_

S. De Gennaro \_\_\_\_\_

A. Stellato \_\_\_\_\_

G. Amadoro \_\_\_\_\_

R. Mainardi \_\_\_\_\_

S. Genovese \_\_\_\_\_

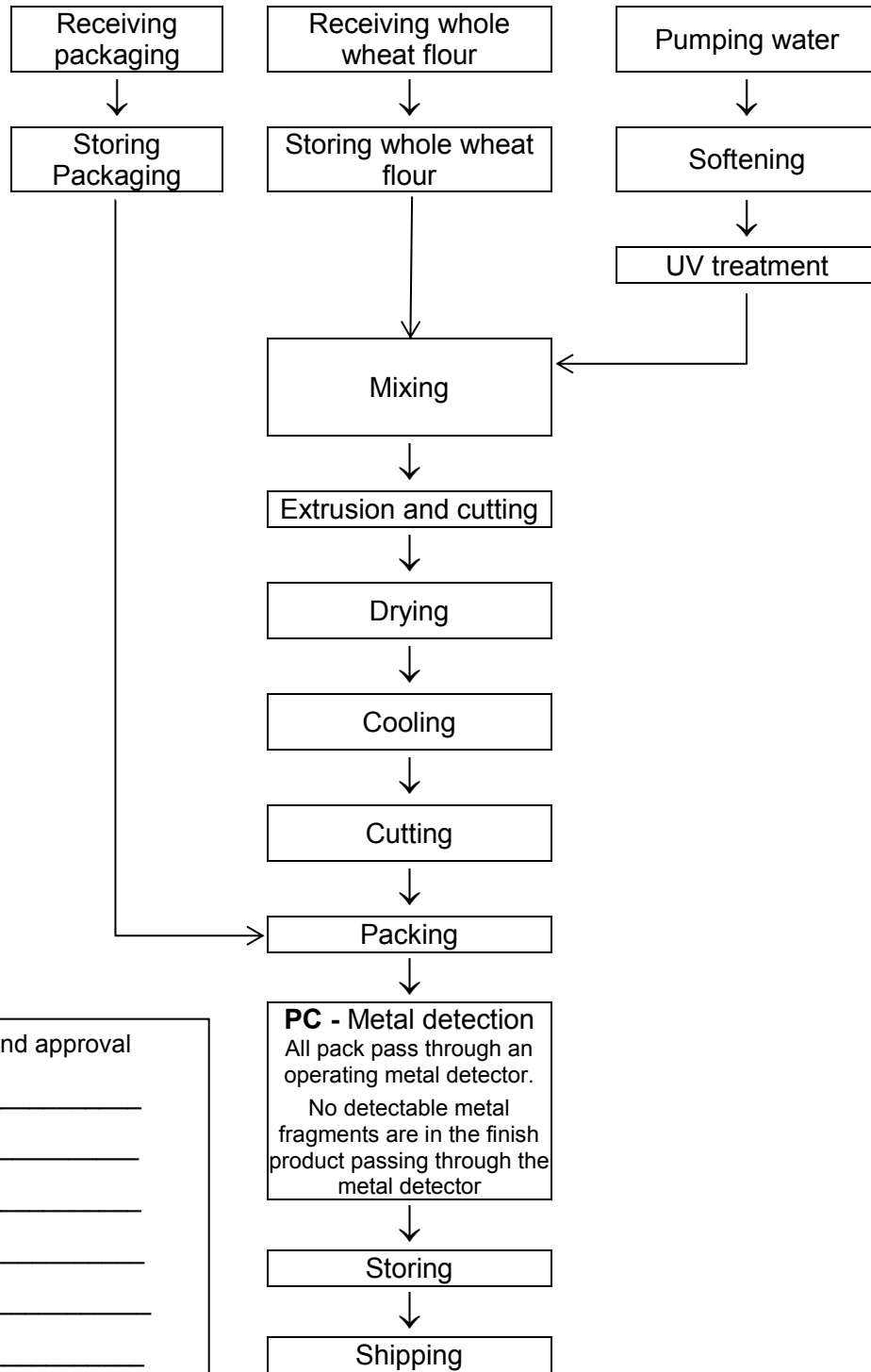
C. Palermo \_\_\_\_\_

May 24, 2021

Food Safety Plan

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Whole-wheat Macaroni product



FS team verification and approval

M. Menna \_\_\_\_\_

G. Schisa \_\_\_\_\_

S. De Gennaro \_\_\_\_\_

A. Stellato \_\_\_\_\_

G. Amadoro \_\_\_\_\_

R. Mainardi \_\_\_\_\_

S. Genovese \_\_\_\_\_

C. Palermo \_\_\_\_\_

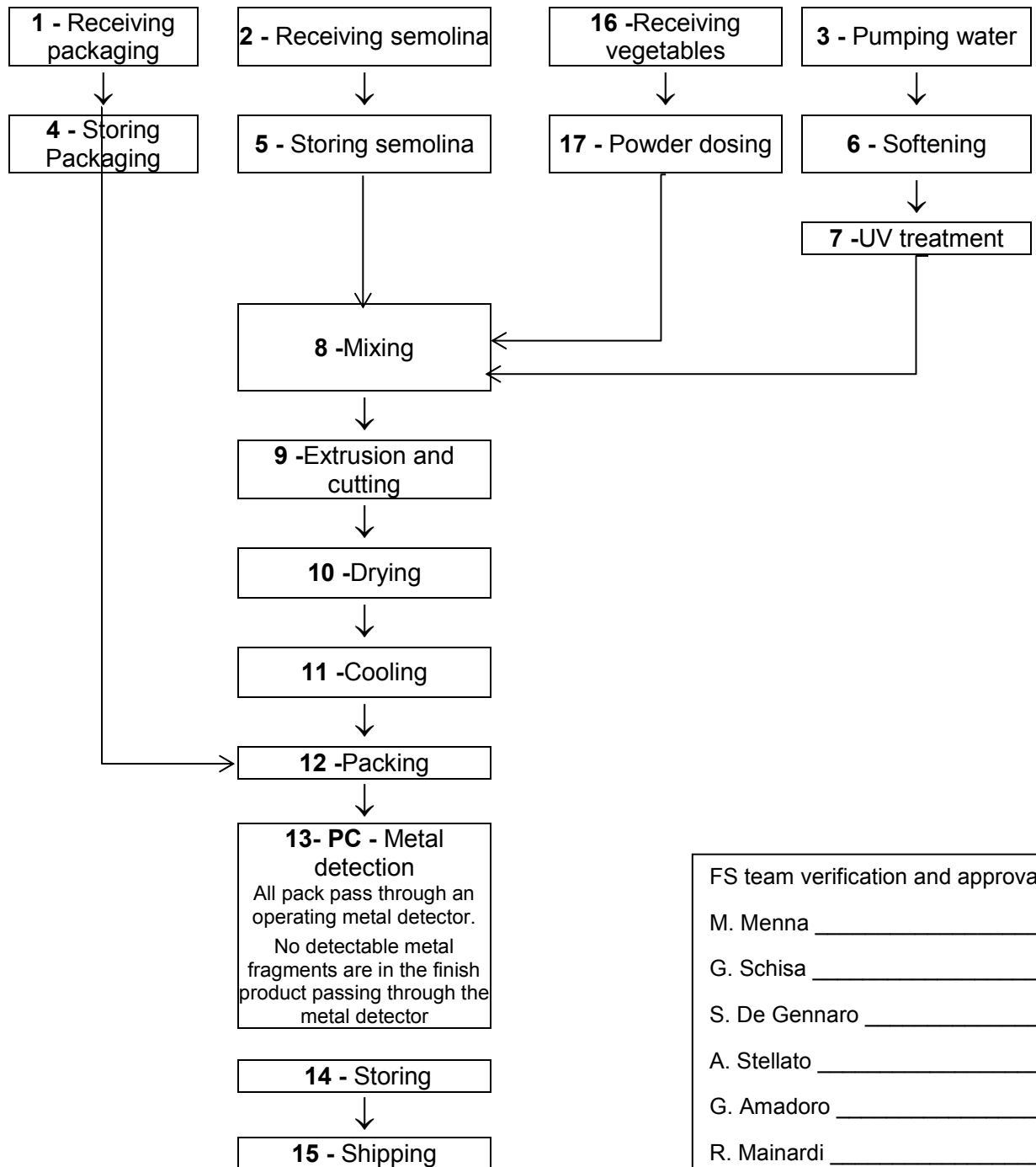
May 24, 2021

**PC - Metal detection**  
 All pack pass through an operating metal detector.  
 No detectable metal fragments are in the finish product passing through the metal detector

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Tricolor Pasta



FS team verification and approval

M. Menna \_\_\_\_\_

G. Schisa \_\_\_\_\_

S. De Gennaro \_\_\_\_\_

A. Stellato \_\_\_\_\_

G. Amadoro \_\_\_\_\_

R. Mainardi \_\_\_\_\_

S. Genovese \_\_\_\_\_

C. Palermo \_\_\_\_\_

May 24, 2021

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## Process Narrative

### Macaroni product and whole-wheat macaroni product

#### Receiving packaging

Polypropylene and polyethylene coils are received individually wrapped into a protective bag. Specifications require food grade material for packaging material that is compatible with ambient storage of macaroni product. Vendors provide a certificate of conformance that packaging materials meet safety and regulatory requirements. Corrugated cardboard boxes are received strapped in bundles.

#### Receiving semolina and whole-wheat flour

Semolina and flour are received in bulk truck of about 30 tons. Specifications require the chemical and microbiological minimum quality standards. Vendors provide a certificate of conformance that semolina and flour materials meet safety and regulatory requirements. The internal lab confirms the ash, moisture, protein and color value for any delivery. Quarterly the internal lab perform a microbiological survey for any mill. Yearly a complete analytical screening confirms the food safety system of any supplier.

#### Pumping water

Processing water comes from an internal well. Its chemical and microbiological quality is monitored quarterly by an external accredited laboratory.

#### Storing packaging

Film coils, corrugated shippers and any minor packaging material (stripe, labels and glue) are stored in a dry storage area and segregated by food material. Boxes are ordered and processed according the production schedule while coils are managed with stock and used on a First-In-First-Out basis.

#### Storing semolina and whole-wheat flour

Semolina and whole-wheat flour are stored in a dedicated silos room. The total capability is around 1500 tons and cover less than 48 production hours. 24 silos are dedicated to the semolina incoming while 15 are dedicated to the line feeding. The raw materials are managed according the quality standards defined with the vendors and can be used individually or according recipes within the following week (usually within the following 36 hours). Any flour pass through magnetic traps and is sieved before the line feeding with a mesh of 800 µm.

#### Softening

Water is softened from a native hardness value over 40 °F to 20-25 °F by an ion exchange resins equipment.

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### UV treatment

Although the native microbiological quality of the water is confirmed by any checks made in the last 10 years, an UV lamp is present on the piping addressing the water in the production area as precautionary measure.

### Mixing

Semolina or whole wheat flour are mixed with water in an approximate rate of 70/30. The dough is processed in about 20 minutes.

### Extrusion and cutting.

The fresh dough passes through a vacuum mixer before incoming the die. At this step it has a moisture content of about 30% and suffers a pressure from 50 to 120 bar at a temperature of about 60°C. It is sieved by a 1-2 mm mesh to intercept any foreign material. The pasta is cut under the die to give the desired shape.

### Drying.

The drying process takes 4-6 hours for the short shape lines and 7-14 hours for the long shapes lines and for the specialties one. The product moisture falls down from 30% to less than 12.5%, according to the Italian regulation on pasta. At this content the  $a_w$  value is lower than 0.60 and this is the key for the product stability for so long time.

### Cooling.

The cooling step takes less than one hour and lets the product go out the line at a temperature lower than 40°C, confirming the vitreous structure of the product and its resistance to the swelling in the cooking before the consumption.

### Cutting.

The spaghetti are automatically cut to about 10 inches of length before the packing operation.

### Shredding pasta.

The spaghetti edges are grinded in elements smaller than 1 cm by an equipment close to line exit. These fragments are pumped in a holding silo.

### Milling pasta.

The spaghetti fragments are milled to grids smaller than 0.6 mm in order to be added once more at the mixing step. The milled pasta passes through magnetic traps, is immediately sieved with a mesh of 800  $\mu\text{m}$  and is stored into a dedicated silo. Once mixed with the semolina is sieved once more. The reworked rate never exceeds the 10%.

### Packing.

The packing operations are totally automatic. Conveyors carry the product to the balance and after the dosage the pasta is closed into a flexible packaging. The bags are never hermetic in order to permit the pack breathing. The bags are closed into cardboard boxes, the boxes are

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carried to a palletizer to build the logistic unit and permit the warehouse handling. A label complying the GS1 standard identifies any logistic unit.

#### **Metal detection.**

Any packing line is equipped with a metal detector. Any device is tested hourly against 1.5 mm Fe object, 1.5 mm no-Fe and 2.0 mm S/S. Food service packs are tested against 2.0mm Fe, 2.0 mm no-Fe, 2.5 mm S/S. An automatic rejection system ensure that contaminated pack cannot be distributed.

#### **Storing.**

The logistic units are stored in a dedicated dry warehouse at ambient temperature. A pest control system is in place in order to detect any possible insect infestation.

#### **Shipping.**

The product is shipped to the USA into containers at ambient temperature, loose on the floor, on pallet or slip-sheet, as agreed with the consignee. The informative system ensure a ready traceability of any product loaded.

#### **Tricolor pasta**

##### **Receiving packaging**

Polypropylene and polyethylene coils are received individually wrapped into a protective bag. Specifications require food grade material for packaging material that is compatible with ambient storage of macaroni product. Vendors provide a certificate of conformance that packaging materials meet safety and regulatory requirements. Corrugated cardboard boxes are received strapped in bundles.

##### **Receiving semolina**

Semolina is received in bulk truck of about 30 tons. Specifications require the chemical and microbiological minimum quality standards. Vendors provide a certificate of conformance that semolina meets safety and regulatory requirements. The internal lab confirms the ash, moisture, protein and color value for any delivery. Quarterly the internal lab perform a microbiological survey for any mill. Yearly a complete analytical screening confirms the food safety system of any supplier.

##### **Receiving vegetables**

Vegetables added to tricolor pasta are Spinach and Tomato. Vegetables are purchased as dry powders, with a moisture content lower than 6%, delivered in sealed plastic bag of 20/25 kg.

##### **Pumping water**

Processing water comes from an internal well. Its chemical and microbiological quality is monitored quarterly by an external accredited laboratory.

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### Storing packaging

Film coils, corrugated shippers and any minor packaging material (stripe, labels and glue) are stored in a dry storage area and segregated by food material. Boxes are ordered and processed according the production schedule while coils are managed with stock and used on a First-In-First-Out basis.

### Storing semolina

Semolina is stored in a dedicated silos room. The total capability is around 950 tons and cover less than 48 production hours. 16 silos are dedicated to the semolina incoming while 11 are dedicated to the line feeding. The raw materials are managed according the quality standards defined with the vendors and can be used individually or according recipes within the following week (usually within the following 36 hours). Any flour pass through magnetic traps and is sieved before the line feeding with a mesh of 800 µm.

### Powder dosing.

The bags of powdered vegetables (tomato and spinach) are opened directly in the feeding hoppers that, by means of augers, introduce them in the right proportion (2% and 1.5%) into the flow of semolina.

### Softening

Water is softened from a native hardness value over 40 °F to 20-25 °F by an ion exchange resins equipment.

### UV treatment

Although the native microbiological quality of the water is confirmed by any checks made in the last 10 years an UV lamp is present on the piping addressing the water in the production area as precautionary measure.

### Mixing

Enriched semolina is mixed with water in an approximate rate of 70/30. The dough is processed in about 20 minutes.

### Extrusion and cutting.

The fresh dough passes through a vacuum mixer before incoming the die. At this step it has a moisture content of about 30% and suffers a pressure from 50 to 120 bar at a temperature of about 60°C. It is sieved by a 1-2 mm mesh to intercept any foreign material. The pasta is cut under the die to give the desired shape.

### Drying.

The drying process takes 4-6 hours for the short shape lines and 7-14 hours for the long shapes lines and for the specialties one. The product moisture fall down from 30% to less than 12.5%, according the Italian regulation on pasta. At this content the  $a_w$  value is lower than 0.60 and this is the key for the product stability for so long time.

### Cooling.

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The cooling step takes less than one hour and let the product go out the line at a temperature lower than 40°C, confirming the vitreous structure of the product and its resistance to the swelling in the cooking before the consumption.

#### **Cutting.**

The spaghetti are automatically cut to about 10 inches of length before the packing operation.

#### **Packing.**

The packing operations are totally automatic. Conveyors carry the product to the balance and after the dosage the pasta is closed into a flexible packaging. The bags are never hermetic in order to permit the pack breathing. The bags are closed into cardboard boxes, the boxes are carried to a palletizer to build the logistic unit and permit the warehouse handling. A label complying the GS1 standard identifies any logistic unit.

#### **Metal detection.**

Any packing line is equipped with a metal detector. Any device is tested hourly against 1.5 mm Fe object, 1.5 mm no-Fe and 2.0 mm S/S. Food service packs are tested against 2.0mm Fe, 2.0 mm no-Fe, 2.5 mm S/S. An automatic rejection system ensure that contaminated pack cannot be distributed.

#### **Storing.**

The logistic units are stored in a dedicated dry warehouse at ambient temperature. A pest control system is in place in order to detect any possible insect infestation.

#### **Shipping.**

The product is shipped to the USA into containers at ambient temperature, loose on the floor, on pallet or slip-sheet, as agreed with the consignee. The informative system ensure a ready traceability of any product loaded.

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## Current Good Manufacturing Practice (cGMP)

### Personnel

#### Disease control.

Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). The Pastificio instructed the personnel to report such health conditions to their supervisors and issued the document “Prescrizioni igieniche per gli ambienti interni”, shared it with the workers and published it in the note board.

#### Cleanliness.

All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

- Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.
- Maintaining adequate personal cleanliness.
- Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
- Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
- Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.
- Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
- Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
- Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
- Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

The Pastificio instructed the personnel, issued the document “Prescrizioni igieniche per gli ambienti interni”, shared it with the workers and published it in the note board.

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### Plant and grounds.

#### Grounds.

The grounds about the food plant under the control of the Pastificio Garofalo is kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include:

- Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.
- Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
- Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
- Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.
- Inspecting the plant to exclude pests, dirt, and filth originating from grounds not under the Pastificio Garofalo control that may be a source of food contamination.

The Pastificio scheduled monthly audit of the ambient and keep full records of the finding and of the eventual corrective action.

#### Plant construction and design.

The plant is suitable in size, construction, and design to facilitate maintenance and sanitary operations for pasta-production purposes.

#### The plant:

- provides adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.
- permits the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material.
- permits the taking of adequate precautions to protect food (tomato paste) installed outdoor in drums by any effective means, including:
  - Using protective coverings.
  - Controlling areas over and around the drums to eliminate harborage for pests.
  - Checking on a regular basis for pests and pest infestation.
- is constructed in such a manner
  - that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair;
  - that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials;
  - that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.
- provides adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned;
- provides shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination

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in case of glass breakage. The Pastificio instructed the personnel, issued the document “Gestione vetro e plastica dura”, shared it with the workers and published it in the note board.

- provides adequate ventilation to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.
- provides, where necessary, adequate screening or other protection against pests.

The Pastificio instructed the personnel, issued the document “Gestione vetro e plastica dura”, shared it with the workers and published it in the note board.

The “procedure Pest control” details any action related to the pest control prevention.

### Sanitary operations.

#### *General maintenance.*

Buildings, fixtures, and other physical facilities of the plant are maintained in a clean and sanitary condition and are kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment are conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

Substances used in cleaning and sanitizing; storage of toxic materials.

Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures are free from undesirable microorganisms and are safe and adequate under the conditions of use.

Compliance with this requirement are verified by the analysis of technical and safety sheets

Only the following toxic materials are used or stored in the Gragnano plant:

- Those required to maintain clean and sanitary conditions;
- Those necessary for use in laboratory testing procedures;
- Those necessary for plant and equipment maintenance and operation;
- Those necessary for use in the plant's operations.

Toxic cleaning compounds, sanitizing agents, and pesticide chemicals are identified, held, and stored in specific areas in order to protect against contamination of food, food-contact surfaces, or food-packaging materials.

#### *Pest control.*

Pests must not be allowed in any area of a food plant.

Detection tools, specific for infesting insects and rodents are installed all over the plant. They are monitored any two weeks by a contractor. Pastificio Garofalo schedules two preventive treatments of the internal areas by heat. The treatment by pesticides could be a corrective action in well defined area or specific activities against flies or beetles in the external ones and will be performed only by a professional contractor.

The “procedure Pest control” details any action related to the pest control prevention.

#### *Sanitation of food-contact surfaces.*

All food-contact surfaces, including utensils and food-contact surfaces of equipment are cleaned as frequently as defined by the “Piano di pulizia”, signed by the professional contractor.

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Food-contact surfaces used for manufacturing/processing, packing pasta are in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they are sanitized and thoroughly dried before subsequent use.

In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces are cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation (as dough mixing), the utensils and food-contact surfaces of the equipment are cleaned and sanitized as necessary with the supervision of the CQ staff to protect against the growth of microorganisms.

Single-service articles (such as blue paper towels) are stored, handled, and disposed of in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

*Sanitation of non-food-contact surfaces.*

Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against contamination of food, food-contact surfaces, and food-packaging materials.

Storage and handling of cleaned portable equipment and utensils.

Cleaned and sanitized portable equipment with food-contact surfaces and utensils are stored in dedicated location in order to protect food-contact surfaces from contamination.

The “Piano di Pulizia” details any action related to Sanitation procedures.

**Sanitary facilities and controls.**

Garofalo plant must be equipped with adequate sanitary facilities and accommodations including:

*Water supply.*

The water supply are adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials are safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, are provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

The water comes from an internal well and is regularly check as defined in the document “Piano della Qualità”.

*Plumbing.*

Plumbing are of adequate size and design and adequately installed and maintained to:

- Carry adequate quantities of water to required locations throughout the plant.
- Properly convey sewage and liquid disposable waste from the plant.
- Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
- Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

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- Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

*Sewage disposal.*

Sewage are disposed of into an adequate sewerage system or disposed of through other adequate means.

*Toilet facilities.*

Garofalo plant provides employees with adequate, readily accessible toilet facilities. Toilet facilities are kept clean and are not a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

*Hand-washing facilities.*

Garofalo plant must provides hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

*Rubbish and offal disposal.*

Rubbish and any offal are so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

Garofalo deliveries daily offal to a professional contractor to forward it to feed and pet food producers.

**Equipment and utensils.**

All plant equipment and utensils used in manufacturing, processing, packing, or holding food are so designed and of such material and workmanship as to be adequately cleanable, and are adequately maintained to protect against allergen cross-contact and contamination.

Equipment and utensils are designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

Equipment are installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

Food-contact surfaces are corrosion-resistant when in contact with food.

Food-contact surfaces are made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

Food-contact surfaces are maintained to protect food from allergen cross-contact (although not present in the plant) and from being contaminated by any source, including unlawful indirect food additives (although not present in the plant).

Seams on food-contact surfaces are smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

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Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, are of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

In the plant there are no freezer and cold storage compartment

Instruments and controls used for measuring, regulating, or recording temperatures, moisture, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food are accurate and precise and adequately maintained, and adequate in number for their designated uses.

Compressed air mechanically introduced into food or used to clean food-contact surfaces or equipment are filtered so that food is not contaminated with unlawful lubricant.

### Processes and controls.

#### *General*

All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with adequate sanitation principles.

Appropriate quality control operations are employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

Overall sanitation of the plant are under the supervision of the Quality Control staff with assigned responsibility for this function.

Adequate precautions are taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

#### *Raw materials and other ingredients.*

Semolina and other ingredients are inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into pasta and is stored under conditions that will protect against against contamination and minimize deterioration. Raw materials are not washed or cleaned as it isn't necessary.

Water used for dissolving tomato and spinach is safe and of adequate sanitary quality. Water is not re-used for washing, rinsing, or conveying food..

Semolina and other ingredients does either not contain levels of microorganisms that may render the food injurious to the health of humans. A pasteurization or an otherwise treatment are not necessary.

Semolina, as susceptible to contamination with aflatoxin or other natural toxins, is checked though the supply chain control to be sure to comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

Semolina, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material complies with applicable FDA regulations for natural or unavoidable defects.

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Semolina, other ingredients, and rework are held in bulk, or in containers designed and constructed so as to protect against contamination and are held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework is identified as such.

In the plant there are no frozen raw materials and other ingredients

Semolina, received and stored in bulk form, is held in dedicated silos so that is protected against contamination.

Semolina, and reworked pasta are food allergens, and are identified and held in a manner that prevents allergen cross-contact.

*Manufacturing operations.*

Equipment and utensils and food containers are maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment are taken apart for thorough cleaning.

Pasta manufacturing, processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

Dry pasta cannot support the rapid growth of undesirable microorganisms and is held at ambient temperatures packing and holding.

Pasta moisture controlling (and consequently aw controlling) is taken to destroy or prevent the growth of undesirable microorganisms under the conditions of manufacture, handling, and distribution and to prevent pasta from being adulterated.

Work-in-process and rework is handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

Packed pasta is protected from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. Semolina, other ingredients, or refuse are never unprotected and they are not handled simultaneously in a receiving, loading, or shipping.

Pasta transported by conveyor are protected against contamination by effective covers.

Equipment, containers, and utensils used to convey, hold, or store semolina and other ingredients, work-in-process, rework, or pasta are constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

Metal detector are installed on any packing line in order to protect against the inclusion of metal or other extraneous material in the pasta.

Pasta, semolina, and other ingredients that are adulterated:

- Are disposed of in a manner that protects against the contamination of other pasta;

Or, if the adulterated food is capable of being reconditioned, it is:

- Reconditioned (if appropriate) using a method that has been proven to be effective;

or

- Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.

Steps such as extruding, cutting, drying, cooling, are performed so as to protect pasta against allergen cross-contact and against contamination. Pasta is protected from contaminants that may drip, drain, or be drawn into the food.

Heat blanching is not required in the preparation of pasta.

Tomato and spinach solutions are prepared and maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

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Packaging, and other operations are performed in such a way that the pasta is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

Dry pasta relies principally on the control of aw for preventing the growth of undesirable microorganisms and therefore is processed to and maintained at a safe moisture level.

Dry pasta is not a food that relies principally on the control of pH for preventing the growth of undesirable microorganisms then pH is not monitored.

Ice is not used in contact with pasta.

#### **Warehousing and distribution.**

Storage and transportation of pasta is under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

#### **Holding and distribution of human food by-products for use as animal food.**

Pasta by-products held for distribution as animal food without additional manufacturing or processing by the Pastificio Garofalo is held under conditions that will protect against contamination, including the following:

- Containers and equipment used to convey or hold pasta byproducts for use as animal food before distribution are designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of pasta by-products for use as animal food;
- Pasta by-products for use as animal food held for distribution is held in a way to protect against contamination from sources such as trash;
- During holding, pasta by-products for use as animal food are accurately identified.

Labeling that identifies the by-product by the common or usual name are affixed to or accompany pasta by-products for use as animal food when distributed.

Shipping containers (e.g., plastic basket) and bulk vehicles used to distribute pasta by-products for use as animal food are examined prior to use to protect against contamination the pasta by-products for use as animal food from the container or vehicle. Pastificio Garofalo is not responsible for transporting the human food by-products for use as animal food itself doesn't arrange with a third party to transport the human food by-products for use as animal food.

#### **Defect action levels.**

Pastificio Garofalo at all times utilizes quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

The mixing of a pasta containing defects at levels that render that food adulterated with another lot of pasta is never performed and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible

<http://www.fda.gov/pchfrule> and [athttp://www.fda.gov](http://www.fda.gov)

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## Hazard Analysis

Hazard identification (column 2) considers known or reasonably foreseeable hazards (i.e., potential hazards) 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 hazards, 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

E = Economically motivated adulteration.

The food safety team completed the reasonability foreseeable hazard identification considering:

- RASFF portal – alert record 2017-2018.
- FRF Fifth Annual report by FDA.
- Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry - by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration – August 2016;
- The Garofalo Food Defence Plan rev 2 dated April 1<sup>st</sup>, 2019 for the EMA hazards
- “Guida di corretta Prassi Igienica e HACCP nella fabbricazione dei prodotti di pastificazione (GMP and HACCP Guideline for pasta manufacturing)” issued by AIDEPI (Italian pasta manufacturer Association) and approved by Ministero della Salute (Italian Health Ministry) on November 2017;
- The chemical, physical and microbiological analysis conducted in the latest ten years on the raw materials and on the final products, according the sampling plan “Piano della Qualità”.

## Macaroni Product

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving packaging	B None						
	C Residue releasing to the product	X		Plastic materials and inks have a history of contamination of foodstuff, although the dry pasta was never involved.	<i>Supply-chain control</i> - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor	X	
	P None						
Receiving semolina	B None						
	C Mycotoxins Aflatoxins DON OTA ZEA HT – H2T	X		Durum wheat semolina has an history of mycotoxins presence	<i>Supply-chain control</i> - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor	X	

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
	Unapproved pesticides	X		Durum wheat semolina has an history of pesticide content (Pirimiphos-methyl) not approved by EPA on wheat (see 40 CFR § 180.409)	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor	X	
	Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	Food allergen preventive control. Formal approval of the label layout and verification at the receiving packaging		X
	Undeclared allergen (soybeans)	X		Cereal products have a history of presence of soybeans trace due to post harvesting operation and storing.	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor	X	
	Heavy metal Lead Cadmium	X		Cereal products have a history of presence of heavy metal trace due to fertilizing practices or environmental pollution.	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor"	X	
	Radio nucleotides		X	there are no cases of radioactivity in the areas where durum wheat is grown, nor are there any confirmed cases in durum wheat products			
	P None						
	E None		X	Analytical checks on the incoming semolina can easily detect any deviation in the raw material profile			
Pumping water	B Environmental pathogens such as <i>Salmonella spp.</i> or pathogenic <i>E. Coli</i>		X	Historical facility data confirm the microbiological quality of the water coming from the internal well. A preventive sanitizer equipment is present at a following step			
	C Metal such as Lead Arsenic or Chromium		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Ingredient/ Processing Step	Unapproved pesticides due to the anthropic activity		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	P None						
	B None						
Storing Packaging	B None						
	C None						
	P None						
Storing semolina	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Softening	B None						
	C None						
	P None						
UV treatment	B None						
	C None						
	P None						
Mixing	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Extrusion and cutting	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P Metallic foreign bodies from the knives	X		Possible metallic foreign matter is detected at the metal detection step	<i>Process control</i> Metal detection		X
Drying	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and		X

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
					verification at the receiving packaging		
	P None						
Cooling	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Cutting	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P Metallic foreign bodies from the knives	X		Possible metallic foreign matter is detected at the metal detection step	<i>Process control</i> Metal detection		X
Shredding pasta edges	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P Metallic foreign bodies from the knives	X		Possible metallic foreign matter is detected at the metal detection step	<i>Process control</i> Metal detection		X
Milling pasta	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P Metallic foreign bodies from the milling equipment	X		Possible metallic foreign matter is detected at the metal detection step	<i>Process control</i> Metal detection		X
Packing	B None						

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Metal detection	B None						
	C None						
	P Metallic foreign bodies presence (7-25 mm)	X		Potential equipment failure against the detection of foreign material present in the packed product, generated by the equipment or introduced by the employees	<i>Process control</i> Metal detection	X	
storing	B Bacillus Cereus Salmonella spp S. Aureus		X	The product reaches temperature >70°C for more than 10 minutes and has an a <sub>w</sub> < 0.6. Historical food sector data confirm the safety profile of the semolina based dry pasta			
	C None						
	P None						
Shipping	B None						
	C None						
	P None						

### Whole wheat Macaroni product

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving packaging	B None						
	C Residue releasing to the product	X		Plastic materials and inks have a history of contamination of foodstuff, although the dry pasta was never involved.	<i>Supply-chain control</i> - Approved supplier and 3 <sup>rd</sup> party supplier audit by a	X	

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
					qualified auditor”		
	P None						
Receiving whole wheat flour	B None						
	C Mycotoxins Aflatoxins DON OTA ZEA HT – H2T	X		Durum wheat semolina has an history of mycotoxins presence	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor”	X	
	Unapproved pesticides	X		Durum wheat semolina has an history of pesticide content (Pirimiphos-methyl) not approved by EPA on wheat (see 40 CFR § 180.409)	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor”	X	
	Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	Food allergen preventive control. Formal approval of the label layout and verification at the receiving packaging		X
	Undeclared allergen (soybeans)	X		Cereal products have a history of presence of soybeans trace due to post harvesting operation and storing.	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor”	X	
	Heavy metal Lead Cadmium	X		Cereal products have a history of presence of heavy metal trace due to fertilizing practices or environmental pollution.	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor”	X	
	Radio nucleotides		X	there are no cases of radioactivity in the areas where durum wheat is grown, nor are there any confirmed cases in durum wheat products			
	P None						
E None		X	Analytical checks on the incoming semolina can easily detect any deviation in the raw material profile				

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?  <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Pumping water	B Environmental pathogens such as <i>Salmonella spp.</i> or pathogenic <i>E. Coli</i>		X	Historical facility data confirm the microbiological quality of the water coming from the internal well. A preventive sanitizer equipment is present at a following step			
	C Metal such as Lead Arsenic or Chromium		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	Unapproved pesticides due to the anthropic activity		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	P None						
Storing Packaging	B None						
	C None						
	P None						
Storing whole wheat flour	B None						
	C Undeclared allergen (wheat)		X	Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Softening	B None						
	C None						
	P None						
UV treatment	B None						
	C None						
	P None						
Mixing	B None						
	C Undeclared allergen (wheat)		X	Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Extrusion and cutting	B None						
	C Undeclared allergen (wheat)		X	Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and		X

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
					verification at the receiving packaging		
	P Metallic foreign bodies from the knives	X		Possible metallic foreign matter is detected at the metal detection step	Process control Metal detection		X
Drying	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	Food allergen preventive control. Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Cooling	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	Food allergen preventive control. Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Cutting	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	Food allergen preventive control. Formal approval of the label layout and verification at the receiving packaging		X
	P Metallic foreign bodies from the knives	X		Possible metallic foreign matter is detected at the metal detection step	Process control Metal detection		X
Packing	B None						
	C None						
	P None						
Metal detection	B None						
	C None						
	P Metallic foreign bodies presence (7-25 mm)	X		Potential equipment failure against the detection of foreign material present in the packed product, generated by the equipment or introduced by the employees	Process control Metal detection	X	
storing	B Bacillus Cereus Salmonella spp S. Aureus		X	The product reaches temperature >70°C for more than 10 minutes and has an a <sub>w</sub> < 0.6.			

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?  <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
				Historical food sector data confirm the safety profile of the semolina based dry pasta			
	C None						
	P None						
Shipping	B None						
	C None						
	P None						

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### Tricolor pasta

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving packaging	B None						
	C Residue releasing to the product	X		Plastic materials and inks have a history of contamination of foodstuff, although the dry pasta was never involved.	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor"	X	
	P None						
Receiving semolina	B None						
	C Mycotoxins						
	Unapproved pesticides	X		Durum wheat semolina has an history of pesticide content (Pirimiphos-methyl) not approved by EPA	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor"	X	
	Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	Food allergen preventive control. Formal approval of the label layout and verification at the receiving packaging		X
	Undeclared allergen (soybeans)	X		Cereal products have a history of presence of soybeans trace due to post harvesting operation and storing.	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor"	X	
	Heavy metal Lead Cadmium	X		Cereal products have a history of presence of heavy metal trace due to fertilizing practices or environmental pollution.	Supply-chain control - Approved supplier and 3 <sup>rd</sup> party supplier audit by a qualified auditor"	X	
	Radionucleotides		X	there are no cases of radioactivity in the areas where durum wheat is grown, nor are there any confirmed cases in durum wheat products			
P None							

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
	E None		X	Tomato and spinach don't have a history of Economically Motivated Adulteration			
Receiving vegetables	B None						
	C None						
	P None						
	E None		X	Analytical checks on the incoming semolina can easily detect any deviation in the raw material profile			
Pumping water	B Environmental pathogens such as <i>Salmonella</i> or pathogenic <i>E. Coli</i>		X	Historical facility data confirm the microbiological quality of the water coming from the internal well. A preventive sanitizer equipment is present at a following step			
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	Unapproved pesticides due to the anthropic activity		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	P None						
Storing Packaging	B None						
	C None						
	P None						
Storing semolina	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Powder dosing	B None						
	C None						
	P None						
Softening	B None						
	C None						
	P None						
UV treatment	B None						

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
	C None						
	P None						
Mixing	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Extrusion and cutting	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P Metallic foreign bodies from the knives	X		Possible metallic foreign matter is detected at the metal detection step	<i>Process control</i> Metal detection		X
Drying	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Cooling	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Cutting	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
	P Metallic foreign bodies from the knives	X		Possible metallic foreign matter is detected at the metal detection step	<i>Process control</i> Metal detection		X
Packing	B None						
	C Undeclared allergen (wheat)	X		Wheat presence must be well specified in any label of the product packed on site	<i>Food allergen preventive control.</i> Formal approval of the label layout and verification at the receiving packaging		X
	P None						
Metal detection	B None						
	C None						
	P Metallic foreign bodies presence (7-25 mm)	X		Potential equipment failure against the detection of foreign material present in the packed product, generated by the equipment or introduced by the employees	<i>Process control</i> Metal detection	X	
storing	B Bacillus Cereus Salmonella spp S. Aureus		X	The product reaches temperature >70°C for more than 10 minutes and has an a <sub>w</sub> < 0.6. Historical food sector data confirm the safety profile of the semolina based dry pasta			
	C None						
	P None						
Shipping	B None						
	C None						
	P None						

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## Process Preventive Controls

### Macaroni Product

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal detection	Metallic foreign bodies presence (7-25 mm)	All pack pass through an operating metal detector  No detectable metal fragments are in the finish product passing through the metal detector	Testing the detection equipment	Challenging the detector with calibrated testers 2.0mm Fe 2.0mm no-Fe 2.5mm S/S	at the start-up, every hour during the production and at the end of the process	Packing line operator.	If the product is processed without MD is hold for metal detection  Correct the operating procedure to ensure that the product is not processed without MD.  Hold the product packed after the latest complete control.  Discard product where metal is detected  Identify the origin of the foreign body.  Adjust, repair or replace the MD.	The MD supplier provide a Validation study to determine appropriate setting for the MD  The supplier verify yearly that the MD is working properly  Challenge the MD with sensitivity tool at the start-up, every hour during the production and at the end of the process  Review records within 7 working days of production	Metal detection checks  Verification reports  Corrective action records

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Whole-wheat macaroni product

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal detection	Metallic foreign bodies presence (7-25 mm)	All pack pass through an operating metal detector  No detectable metal fragments are in the finish product passing through the metal detector	Testing the detection equipment	Challenging the detector with calibrated testers 2.0mm Fe 2.0mm no-Fe 2.5mm S/S	at the start-up, every hour during the production and at the end of the process	Packing line operator.	If the product is processed without MD is hold for metal detection  Correct the operating procedure to ensure that the product is not processed without MD.  Hold the product packed after the latest complete control.  Discard product where metal is detected  Identify the origin of the foreign body.  Adjust, repair or replace the MD.	The MD supplier provide a Validation study to determine appropriate setting for the MD  The supplier verify yearly that the MD is working properly  Challenge the MD with sensitivity tool at the start-up, every hour during the production and at the end of the process  Review records within 7 working days of production	Metal detection checks  Verification reports  Corrective action records

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Tricolor Pasta

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal detection	Metallic foreign bodies presence (7-25 mm)	All pack pass through an operating metal detector  No detectable metal fragments are in the finish product passing through the metal detector	Testing the detection equipment	Challenging the detector with calibrated testers 2.0mm Fe 2.0mm no-Fe 2.5mm S/S	at the start-up, every hour during the production and at the end of the process	Packing line operator.	If the product is processed without MD is hold for metal detection  Correct the operating procedure to ensure that the product is not processed without MD.  Hold the product packed after the latest complete control.  Discard product where metal is detected  Identify the origin of the foreign body.  Adjust, repair or replace the MD.	The MD supplier provide a Validation study to determine appropriate setting for the MD  The supplier verify yearly that the MD is working properly  Challenge the MD with sensitivity tool at the start-up, every hour during the production and at the end of the process  Review records within 7 working days of production	Metal detection checks  Verification reports  Corrective action records

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## Food Allergen Preventive Controls

### Food Allergen Ingredient Analysis

#### Macaroni Product

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation								Allergens in Supplier's Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	
Durum wheat semolina	All the approved mills	NO	NO	NO	Yes	NO	NO	NO	NO	Wheat presence in the product is well reported in the ingredient list and in other claims on the label

#### Whole-wheat Macaroni Product

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation								Allergens in Supplier's Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	
Durum whole-wheat flour	All the approved mills	NO	NO	NO	Yes	NO	NO	NO	NO	Wheat presence in the product is well reported in the ingredient list and in other claims on the label

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Tricolor pasta

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation								Allergens in Supplier's Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	
Durum wheat semolina	All the approved mills	NO	NO	NO	Yes	NO	NO	NO	NO	Wheat presence in the product is well reported in the ingredient list and in other claims on the label
Tomato Paste	Rodolfi Mansueto spa	NO	NO	NO	NO	NO	NO	NO	NO	
Spinach Powder	New foods spa	NO	NO	NO	NO	NO	NO	NO	NO	

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### Allergen Verification Listing

Product	Allergen Statement	Label Number
Macaroni Product	Wheat presence	all
Whole wheat macaroni product	Wheat presence	all
Tricolor pasta	Wheat presence	all

### Allergen Scheduling and Cleaning Implications

#### Production Line Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)
Macaroni Product	all	NO	NO	NO	Yes	NO	NO	NO	NO
Whole wheat macaroni product	all	NO	NO	NO	Yes	NO	NO	NO	NO
Tricolor pasta	all	NO	NO	NO	Yes	NO	NO	NO	NO

**Scheduling Implications:** None

**Allergen Cleaning Implications:** None

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Macaroni Product

Allergen Control Step	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving packaging (flexible plastic film)	Undeclared allergen wheat	All finished product labels must declare the allergens wheat	Wheat presence in the ingredient list	Visual check of the flexible packaging	Before releasing to the packing operation	Packaging operators	If label is incorrect reject labels and return to supplier or destroy. Identify root cause and conduct training as needed to prevent recurrence	Review of label approval process, corrective action and verification records within 7 working days.	Label verification web-center and linked logs. Corrective action records

Whole wheat Macaroni Product

Allergen Control Step	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving packaging (flexible plastic film)	Undeclared allergen wheat	All finished product labels must declare the allergens wheat	Wheat presence in the ingredient list	Visual check of the flexible packaging	Before releasing to the packing operation	Packaging operators	If label is incorrect reject labels and return to supplier or destroy. Identify root cause and conduct training as needed to prevent recurrence	Review of label approval process, corrective action and verification records within 7 working days.	Label verification web-center and linked logs. Corrective action records

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Tricolor pasta

Allergen Control Step	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving packaging (flexible plastic film)	Undeclared allergen wheat	All finished product labels must declare the allergens wheat	Wheat presence in the ingredient list	Visual check of the flexible packaging	Before releasing to the packing operation	Packaging operators	If label is incorrect reject labels and return to supplier or destroy. Identify root cause and conduct training as needed to prevent recurrence	Review of label approval process, corrective action and verification records within 7 working days.	Label verification web-center and linked logs. Corrective action records

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## Sanitation Preventive Controls

### Hygienic Zoning

*[Insert simple facility layout, indicating flow of material to aid common understanding and visualization.]*

<b>Location</b>	Internal and external areas
<b>Purpose</b>	Pest control
<b>Frequency</b>	15 days
<b>Who</b>	Contractor
<b>Procedure</b>	As described in the document "Procedura pest control"
<b>Monitoring</b>	By specific traps
<b>Corrections</b>	Extraordinary cleaning – increased monitoring – extraordinary treatment
<b>Records</b>	Contractor web portal
<b>Verification activities</b>	Quarterly audit on pest control system

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## Supply-chain-applied Preventive Controls Program

### Approved Suppliers for Ingredients Requiring a Supply-chain-applied Control

Ingredient (requiring supply-chain-applied control)	Approved Supplier	Hazard(s) requiring supply-chain-applied control	Date of Approval	Verification method	Verification records
Primary packaging	Rotomed Polifilm Polipack Icimen Maca Nuovaerreplast De Lucia Cielle Anico Masterpack Nuceria Rossetti Packaging	Residue releasing from packaging to the product	30 <sup>th</sup> December 2020	Copy of the 3 <sup>rd</sup> party audit by a qualified auditor obtained by the supplier	Audit report kept in Supplier file
				Sampling and testing of the raw material	Analytical reports
Durum wheat semolina	Casillo, Moramarco, Candeal, Ferro, Moderne semolerie Lo Iudice Molino De vita	Mycotoxins Aflatoxins DON OTA ZEA HT – H2T	30 <sup>th</sup> December 2020	Copy of the 3 <sup>rd</sup> party audit by a qualified auditor obtained by the supplier	Audit report kept in Supplier file
		Unauthorized pesticide			
		Undeclared allergen (soybeans)			
		Heavy metal Lead Cadmium			
				Sampling and testing of the raw material	Analytical reports

### Receiving Procedure for Ingredients Requiring a Supply-chain-applied Control

Primary packaging

**Istruzione:** Controllo packaging in ingresso.

Durum wheat semolina/Whole-wheat flour

**Istruzione:** Controllo sfarinati in ingresso.

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# Pastificio Lucio Garofalo S.p.A. Recall Plan

Reviewed by: *Sergio De Gennaro* - PCQI

Date: March 26, 2021

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## Recall Team

<b>Assignment</b>	<b>Person</b>	<b>Contact Information</b>
Senior Operations Manager Alternate: Gianni Schisa	Massimo Menna	Office: +39 0818011002-204 Mobile: +39 3483867369
Internal Recall Coordinator Alternate: Alessio Stellato	Sergio De Gennaro	Office: +39 0818011002-441 Mobile: +39 3201594941
Publicity and Public Relations Alternate: Gianni Schisa	Emidio Mansi	Office: +39 0818011002-214 Mobile: +39 3484959670
Sales & Marketing Alternate: Francesco Gallo	Luca De Luca	Office: +39 0818011002-211 Mobile: +39 3401804047
Scientific Advisor Alternate:	To be defined according the nature/causes of the recall	Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Logistics and Receiving Alternate: Roberta Del Vecchio	Marco di Petti	Office: +39 0818011002-217 Mobile: +39 3470622435
Quality Assurance Alternate: Sergio De Gennaro	Gianni Schisa	Office: +39 0818011002-215 Mobile: +39 3498815627
Accountant Alternate: Giuseppina Schiano	Christian Fisauli	Office: +39 0818011002-260 Mobile: +39 3343620576
Attorney Alternate:	To be defined according the nature/causes of the recall	Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Administrative Support	Giuseppina Schiano	Office: +39 0818011002-248 Mobile: +39 3246062789

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<b>Assignment</b>	<b>Person</b>	<b>Contact Information</b>
Reference contact for private label	To be defined according the product involved in the recall	Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
US Import Agent	To be defined according the product involved in the recall	Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx

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## Determining if a Recall Action Necessary

Actions taken by a firm to remove a violative product from the market may be conducted on a firm's own initiative, by FDA or state request, or by FDA or state order. The table below summarizes the methods and actions related to a possible recall

<b>Problem reported by</b>	<b>Initial Action</b>	<b>Decisions</b>	<b>Actions</b>
Regulatory Agency believe your product is causing illness	Assemble recall team and ask agency if recall is recommended	Evaluate situation; decide if, what and how much product to recall	<b>If no recall is needed:</b> Document why not and action.
News media story on problem with a type of food you produce	Assemble recall team, review internal records		<b>If recall is needed:</b>
Internal QC or customer information suggest a potential problem	Assemble recall team and review internal records		<ul style="list-style-type: none"> <li>• Assign responsibilities</li> <li>• Gather evidence</li> <li>• Analyze evidence</li> </ul>
Health Department believes your produce is causing illness	Assemble recall team, contact appropriate regulatory agency		<ul style="list-style-type: none"> <li>• Get word out</li> <li>• Monitor recall</li> <li>• Dispose of product</li> <li>• Apply for termination of recall</li> <li>• Assemble recall team and debrief</li> <li>• Prepare for legal issues</li> </ul>

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## Recall class Identification

Three classes of recalls are defined based on the potential health effects.

- Class I Recall: – Reasonable probability of serious adverse health consequences or death.;
- Class II Recall – May cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote;
- Class III Recall – not likely to cause adverse health consequences.

A rapid response is especially important for Class I and Class II recalls for which public health is at risk.

Notification of customers is required for Class 1 recalls and sometimes for Class 2 recalls when there is a threat to public health. Decisions on when notification is necessary will be determined through discussions with FDA. FDA has the authority to initiate a recall in class I situations, but typically a company voluntarily issues the recall notice.

## Recall steps

This recall procedure outlines the activities that Pastificio Lucio Garofalo S.p.A. will take to manage the recall of our product which has/have been determined to be unsafe and/or subject to regulatory action. The procedure contains the major recall elements below:

- Assignment of Roles and Responsibilities
- Evaluation of the Complaint or Condition
- Identification of Implicated Products
- Notification of Affected Parties
- Removal of Affected Products

### Assignment of Roles and Responsibilities

The roles and responsibilities of every individual on the Recall Committee are clearly defined in this recall plan. Oversight of the following recall elements should be assigned to a member of the Recall team (see the previous section).

#### Internal Recall Coordinator

The recall coordinator received authority by the management of Pastificio Lucio Garofalo S.p.A. to execute the activities of the recall. Responsibilities of the Recall Coordinator include, but are not limited to:

- Assure the documentation of all recall decisions and actions in a master recall file.
- Initiate the formation of the recall committee.
- Activate various components within the company for priority assistance.
- Make recall decisions on behalf of Pastificio Lucio Garofalo S.p.A..
- Manage and coordinate the implementation of the company's product recall.

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- Keep management informed at all stages of the recall
- Keep contact with the FDA recall coordinator
- Keep the contact with US Import agent.

#### Recall team members

Pastificio Lucio Garofalo S.p.A. Recall Team is composed of the various components of the company's organization. All members must respond to the internal recall coordinator to ensure the effectiveness of the action

#### US Import Agent

The US importer agent is in charge of:

- Keep the contact with US consignee and supply the final consignee list if necessary.
- Coordinate the withdrawal/recall operation
- Submit the mass balance data to the Internal Recall Coordinator daily.
- Support on site the FDA recall coordinator if necessary
- Collect the information about the cost related to the recall operation incurred by any customer.

#### Reference contact for private label

The reference contact for PL product is in charge of:

- Verify and approve any communication towards the authority and media related to recall that involve its own branded product.

#### Evaluation of the Complaint or Condition

Problem report receipt, processing, and evaluation are the first steps in the recall process. The steps involved in the evaluation process are:

Receive the problem report – A file should be maintained containing any product complaints the company receives. Information that should be maintained in the product complaint file is:

- i. Complainant contact information
- ii. Reported problem with the product
- iii. Product Identification
- iv. Product Storage
- v. Product purchase date and location
- vi. Illness and Injury details

Provide the complaint to knowledgeable staff for initial evaluation. If an initial assessment indicates a recall may be necessary, the Internal Recall Coordinator assembles the Recall Team for a full evaluation.

The team

- Determines the hazard and evaluate the safety concerns with the product.
- Determines the product removal strategy appropriate to the threat and location in commerce.

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- Contacts the appropriate regulatory authorities.
- Alerts legal counsel, insurance, etc. as appropriate.
- Maintains a log of the events of the recall including information such as dates, actions, communications, and decisions.

### Identification of Implicated Products

It is Pastificio Lucio Garofalo S.p.A. responsibility to ensure the identification of all products and quantities of products implicated in the recall. In addition, determination will be made if any other codes, brands or sizes of product handled by the company are affected.

A distribution list should be prepared as part of the Identification process. The distribution list will at minimum identify:

- Account name (consignees) that received the recalled product(s)
- Account addresses
- Contact names
- Contact telephone numbers
- Type of account (e.g., manufacturer, distributor, retailer)

Additional information relating to product information may include:

- Amount of product received/shipped
- Product ship date(s)
- Amount of product returned
- Amount of product consumed

### Notification of Affected Parties

Notifications during a recall will be done in a timely manner and should include the appropriate regulatory agencies, the product distribution chain, and consumers when necessary.

Recall notices are typically used to notify regulatory agencies and those businesses in the distribution chain. Press releases are generally oriented to consumers, but may be used to notify any affected party.

- ·Regulatory Agencies will be notified at the earliest opportunity after the decision has been made to conduct a recall. Regulatory guidance may be found online.
  - Subsequent to the initial notification, the regulatory authority should be updated throughout the recall process.
- Distribution Chain contacts will be notified by appropriate means (telephone, fax, email, letter, etc.). A written recall notice be provided to all consignees. The Recall Notice must include all relevant recall information (see the template in the dedicated section or the FDA website at the following link <https://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm>). The complete

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consignee list of the Pastificio Garofalo customers is present in the Template documents in the final part of this document.

- Confirm receipt of the Notice of Recall with all accounts. A record of all account communications will be maintained.
- Consumers will be notified by the most effective method available. If appropriate, a press release will be used to notify consumers. Considerations for preparing a press release include:
  - Issuance of a press release will be the highest priority and will be issued promptly.
  - The local FDA District Recall Coordinator will be consulted before issuance of a press release whenever possible.
  - All relevant information will be included in the press release (see the template in the dedicated section on the FDA website at the following link <https://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm> ).

### Removal of Affected Product

The procedure for product removal can be divided into five components including: removal, control, and disposition of affected product, recall effectiveness, and recall termination.

#### Removal

All reasonable efforts must be made to remove affected products from commerce.

Products in commerce will be detained, segregated, and handled in a manner determined by the recall team

Products that are still in the company's control (e.g. inventory located onsite, in-transit, in off-site storage, and in offsite distribution) will be detained, and segregated.

All quantities and identification codes shall be documented to assist in their conciliation of product amounts.

#### Control of Recalled Product

When Pastificio Garofalo chooses to retain recalled product, control must be regained to prevent reentry of the product into commerce.

All affected product returned will be clearly marked, not for sale or distribution, and stored in an area that is separated from any other food products.

All quantities and identification codes will be documented to assist in the reconciliation of product amounts.

#### Product Disposition

The final disposition of the recovered product must be determined. The final disposition must be reviewed and approved by the regulatory agency. Options include:

- Redirection – Products may be re-directed for uses other than human consumption.
- Destruction - Products determined to be unsafe for human consumption may be destroyed or denatured, and disposed by appropriate means.

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- Recondition – Products may be reworked to remove the safety risk. For example, would be relabeling a product to declare an allergen originally omitted from the label.

All quantities, identification codes, and disposition will be documented.

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## Identification and Verification of Lot Information

Lots involved in a recall must be accurately identified. How this is done is dictated by the Pastificio Garofalo traceability system.

Recall efforts involve identifying specific lots that might be implicated and then tracing those products through the distribution system to ensure that all product that has not already been consumed is recovered.

Specific information on how lots are identified will be communicated in order to be easily understood by all the stakeholders that receive this information during a recall investigation. If rework from an implicated batch is used in subsequent batches, the amount of product involved in a recall will be expanded beyond the implicated batch.

All information will be cross checked against multiple sources and through multiple people within the Recall team so that the accuracy will be verified prior to initiation of the recall.

## Effectiveness Checks

The Recall Team will determine whether its recall is progressing satisfactorily. The team has an obligation to conduct effectiveness checks as part of its recall process. These checks are used to verify that all affected consignees were notified about a recall and have taken appropriate action.

The checks will include:

- Daily reconciliation of quantity recovered versus total;
- Consignee response and follow up;
- Recall effectiveness
  - $100 \times (\text{\#cases recovered} / \text{total cases shipped})$
- Regulatory effectiveness audits.

Recall coordinator will be responsible to keep records about the effectiveness checks.

## Corrective Action Related to Recalls

When a food safety recall occurs, reanalysis of the Food Safety Plan is required to determine how to prevent a recurring situation. In some cases, modification of the Food Safety Plan may be required. For example, if a new hazard is identified, then the hazard analysis will be updated to include that hazard and preventive controls will be modified or added to ensure ongoing control.

In other cases, the Food Safety Plan may be adequate, but implementation of the plan may need to be improved through enhanced training, equipment upgrades or other relevant corrections.

In any case, the food safety team will strive to determine the root cause of the problem and act quickly to take corrective actions, as appropriate.

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Recall coordinator will keep a log of all decisions made throughout the recall and maintain this as part of your recall records. This includes a summary of actions taken at the final recall review meeting.

## Periodical System Tests – Mock Recall

It is important to periodically test the system to ensure that it will work if a recall is necessary. This is sometimes referred to a “mock recall.” These mock recalls will include verifying that the information in the recall plan is current, and testing the recall team to determine if they can do what needs to be done if there was a recall.

Tracing products and ingredients one-step forward and one-step back in the supply chain will be the elements of the mock recall, however, actual customers and suppliers will be not contacted to avoid confusion.

Traceability will be an important part of a mock recall. These checks determine how long it takes identify where a specific lot of product was sent (one step forward) and to identify the source and lot code(s) of all ingredients used in the production lot (one step back).

In addition, the recall team will be tested to see if they can determine if a recall is actually necessary, if they know who and how to contact for technical help if needed, if they can create the required documentation to perform a recall.

A test of the system will be performed yearly and the recall coordinator will keep records about the trials.

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## Information Templates for FDA Communication

### FDA Contact detail

Alternate to be confirmed at the link <https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators>

FDA Recall Coordinator:	ORA Headquarters Cecilia M. Wolyniak Office of Enforcement and Import Operations - Recall Branch	WO 32 RM 4352 10903 New Hampshire Ave. Silver Spring, MD 20993 Phone: 301-796-8209 Fax: 301-847-8635 <a href="mailto:orahqroe@fda.hhs.gov">orahqroe@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations East I  CT; MA; ME; NH; NY; RI; VT	Melissa A. Henaghan	Albany Resident Post One Winners Circle, Suite 110 Albany NY 12205 Phone: 518-453-2314 x 1017 Fax: 518-453-2443 <a href="mailto:orahafeast1recalls@fda.hhs.gov">orahafeast1recalls@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations East II  DC; DE; MD; NJ; PA; VA; WV	Ruark Lanham	900 US Customhouse, Suite 904 200 Chestnut Street Philadelphia, PA 19106 Phone: 215-717-3738 Fax: 215-517-6649 <a href="mailto:orahafeast2recalls@fda.hhs.gov">orahafeast2recalls@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations East III  GA; NC; SC	Emma Nesbit	60 Eighth Street, NE Atlanta, GA 30309 Phone: 404-253-1224 Fax: 404-253-1201 <a href="mailto:orahafeast3recalls@fda.hhs.gov">orahafeast3recalls@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations East IV  FL; PR; US Virgin Islands	Wanda J. Torres	466 Fernandez Juncos Avenue San Juan, PR 00901-3223 Phone: 787-729-8709 Fax: 787-729-8826 <a href="mailto:orahafeast4recalls@fda.hhs.gov">orahafeast4recalls@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations East V  AL; KY; LA; MS; OH; TN	Caitlin Almonrode	404 BNA Drive, Suite 500 Nashville, TN 37217 Phone: 615-366-7859 <a href="mailto:orahafeast5recalls@fda.hhs.gov">orahafeast5recalls@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations East VI  IL; IN; MI	Michael Larson	300 River Place, Suite 5900 Detroit, MI 48207 Phone: 313-393-8118 Fax: 313-393-8139 <a href="mailto:orahafeast6recalls@fda.hhs.gov">orahafeast6recalls@fda.hhs.gov</a>

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FDA Local Recall Coordinator Division of Human and Animal Food Operations West I  MN; ND; SD; WI	Kristine Zuroski	250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 Phone: 612-758-7120 Fax: 612-334-4134 <a href="mailto:orahafwest1recalls@fda.hhs.gov">orahafwest1recalls@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations West II  IA; KS; MO; NE	Matthew Sleeter	8050 Marshall Drive Suite 205 Lenexa, KS 66214 Phone: 913-495-5151 Fax: 913-495-5105 <a href="mailto:orahafwest2recalls@fda.hhs.gov">orahafwest2recalls@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations West III  AR; OK; TX	Casey Hamblin	4040 N. Central Expressway Suite 300 Dallas, TX 75204 Phone: 214-253-5222 Fax: 214-253-5314 <a href="mailto:orahafwest3recalls@fda.hhs.gov">orahafwest3recalls@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations West IV  AZ; CO; NM; UT; WY	Patricia D. Stahnke	Building 20, Denver Federal Center 6th Avenue & Kipling Street PO Box 25087 Denver, CO 80225-0087 Phone: 303-236-3045 Fax: 303-236-3551 <a href="mailto:orahafwest4recalls@fda.hhs.gov">orahafwest4recalls@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations West V  CA; HI; NV	Marjorie Schultz	1201 Harbor Bay Parkway Alameda, CA 94502 Phone: 510-337-6898 Fax: 510-337-6705 <a href="mailto:orahafwest5recalls@fda.hhs.gov">orahafwest5recalls@fda.hhs.gov</a>
FDA Local Recall Coordinator Division of Human and Animal Food Operations West VI  AK; ID; MT; OR; WA	Anh Trinh Nguyen	22215 26th Ave. SE, Suite 210 Bothell, WA 98021 Phone: 425-302-0467 Fax: 425-302-0403 <a href="mailto:orahafwest6recalls@fda.hhs.gov">orahafwest6recalls@fda.hhs.gov</a>

**PRODUCT INFORMATION:**

Modify the "Product Description, Distribution, Consumers and Intended Use" form as needed to reflect only the product involved, including:

- Product name (including brand name and generic name)

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- Product number/UPC or product identification
- Remove any names of products that are not involved in the recall

Assemble TWO COMPLETE SETS OF ALL labeling to the Local FDA District Recall Coordinator. Include:

- Product labeling (including ALL private labels)
- Individual package label
- Case label (photocopy acceptable)
- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

**CODES (Lot Identification Numbers):**

- UPC code(s) involved: \_\_\_\_\_
- Lot number(s) involved: \_\_\_\_\_
- Lot numbers coding system: *Describe how to read your product code:* -  
\_\_\_\_\_  
\_\_\_\_\_
- Expected shelf life of product: \_\_\_\_\_

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### RECALLING FIRM Contacts

Provide this information to FDA for clear communication:

**Manufacturer name:** Pastificio Lucio Garofalo S.p.a. – via dei Pastai, 42 – 80054 Gragnano (NA) Italy

<b>Position</b>	<b>Name, Title</b>	<b>Contact Information</b>
Internal Recall coordinator	Sergio De Gennaro (Quality System Manager)	Office: +39 0818011002-215 Mobile: +39 3201594941 Fax: +39 0818012937 email: degennaro@pastagarofalo.it
Most responsible individual	Gianni Schisa Operation Manager	Office: +39 0818011002-215 Mobile: +39 3498815627 Fax: +39 0818012937 email: schisa@pastagarofalo.it
Public contact:	Emidio Mansi Sales Manager	Office: +39 0818011002-214 Mobile: +39 3484959670 Fax: +39 0818012937 email: mansi@pastagarofalo.it

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**REASON FOR THE RECALL:**

Explain in detail how product is defective or violative	
Explain how the defect affects the performance and safety of the product, including an assessment of a health risk associated with the deficiency, if any.	
If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.	
If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant.	
If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) it occurred.	
Explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.	
Explain why this problem affects only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: <ul style="list-style-type: none"> <li>• Date of complaint</li> <li>• Description of complaint -include details of any injury or illness</li> <li>• Lot Number involved</li> </ul>	
If a State agency is involved in this recall, identify Agency and contact.	

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**VOLUME OF RECALLED PRODUCT:**

Total quantity produced	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on HOLD	
Indicate how the product is being quarantined	
Estimate amount remaining in marketplace <ul style="list-style-type: none"> <li>• distributor level</li> <li>• customer level</li> </ul>	
Provide the status/disposition of marketed product, if known, (e.g. used, used in further manufacturing, or destroyed).	

**DISTRIBUTION PATTERN:**

Number of DIRECT accounts (customers you sell directly to) by type

Type	Number
▪ wholesalers/distributors	
▪ repackers	
▪ manufacturers	
▪ retail	
▪ consumers (internet or catalog sales)	
▪ federal government consignees	
▪ foreign consignees (specify whether they are wholesale distributors, retailers or users)	
▪ Geographic areas of distribution, including foreign countries	

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### Consignee List

Provide this list to the local District Recall Coordinator. Include US customers, foreign customers and federal government consignees (e.g., USDA, Veterans Affairs, Department of Defense)

#### Commercial customers

Name	Street Address	City	State	Recall contact name	Contact phone number	Recalled product was shipped?	Recalled product was sold?	Recalled product may have been shipped or sold
P&L Imports	10051 East Dynamite Blvd, Suite G-160	Scottsdale	AZ - 85262	Chris Mohrweis	+1 480.493.5304			
				Charlotte Davis	+1 425.898.4724			
Garofalo USA	10 East 39th street Fl.12 Office 6	New York City 10016	NY	Flavia Garzia	+1 9176024431 or 6465819340			
Riviana	2362 Prospect Street	Memphis	TN	Michael Hoar	+1 502.396.1746			
////								

### Private label contact list

Provide this list to the local District Recall Coordinator. Include US customers, foreign customers and federal government consignees (e.g., USDA, Veterans Affairs, Department of Defense)

#### Commercial customers

Name	Street Address	City	State	Recall contact name	Contact phone number	Recalled product was	Recalled product was sold?	Recalled product may have

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						shipped?		been shipped or sold
Trader Joe's company	800 SOUTH SHAMROCK AVE.	MONRO VIA, CA 91016-6346	CA	Sigi Keenan skeenan@traderjoes.com	(626) 599-3700			
Pastene	330 Turnpike Street PO Box 256	Canton, MA 02021	MA	Jennifer LeClair jleclair@pastene.com	(781) 830-8200			

**Was product sold under Government Contract?**

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, include contact name and information above AND complete information below.

Contracting Agency	Contract Number	Contract date	Implementation date

**School Lunch Program:**

If product was sold to federal, state or local agency for the school lunch program, complete table and notify "ship to" (so they can retrieve product) and "bill to" customers (so they can initiate the sub-recall).

Consignee	Quantity	Sale date	Shipment date

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**RECALL STRATEGY:**

Level in the distribution chain

Level	Included		Rationale if “No”
	Yes	No	
Wholesale/distributor			
Retail			

Instructions for Consignee Notification

Write instructions on how consignees will be notified (i.e. by mail, phone, facsimile, e-mail). NOTE: It is advisable to include a written notification so customers will have a record of the recall and your instructions. Include instructions such as:

- How letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)
- Draft phone script, if you decide to use phone. NOTE: If initial notification is by phone, be prepared to provide a copy of the phone script to FDA.
- Draft recall notification (see example on last page) for website and instructions for posting it, if applicable. NOTE: The web is not recommended as a sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. If there is a recall, FDA will want a copy of final instructions.
- Consider what to do for out-of-business distributors.

Effectiveness Checks

**Effectiveness checks by account** – Consider filling in the Consignee’s recall contact name and information to make it easier to contact them in the event of a recall.

Consignee	Recall contact		Date contacted	Method of contact				Date if response	Number of products returned or corrected
	Name	Contact info		Phone	Email	Fax	Letter		

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<b>PLANT NAME: Pastificio Lucio Garofalo S.p.A.</b>		<b>ISSUE DATE</b>	03/26/2021
<b>ADDRESS: via dei Pastai, 42 – 80054 Gragnano (NA)</b>		<b>SUPERSEDES</b>	-05/10/2019

**Effectiveness check summary – to be provided to FDA periodically**

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date

**Product destruction/ reconditioning**

- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. It is recommended that you provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable GMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
- It is recommended that you contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- You and your customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, like product relabeling, be performed by recalling firm representatives, or under their supervision and control. Contact your local FDA District Recall Coordinator prior to release of reconditioned goods.

<b>Recall Plan</b>	<b>PAGE 24 of 24</b>	
<b>PLANT NAME: Pastificio Lucio Garofalo S.p.A.</b>	<b>ISSUE DATE</b>	03/26/2021
<b>ADDRESS: via dei Pastai, 42 – 80054 Gragnano (NA)</b>	<b>SUPERSEDES</b>	-05/10/2019

DRAFT Recall Notice

***[Company Name] Voluntarily Recalls [insert summary info] Representing [X quantity]  
[--No Other Products Affected--]***

**Contact**

Consumer:

1-xxx-xxx-xxx

Media Contact:

xxx-xxx-xxxx

**FOR IMMEDIATE RELEASE** – [date] – [Company name] is voluntarily recalling [X] Lot Codes of [COMPANY/BRAND name] [insert specific product name and description], representing [insert quantity]. [Insert reason for recall].

**This action relates only to Patificio Lucio Garofalo S.p.A. products with any of these Lot Codes printed on the package:**

- [insert lot codes]

**No other Lot Codes, or any other [COMPANY NAME] products, are involved in this action.**

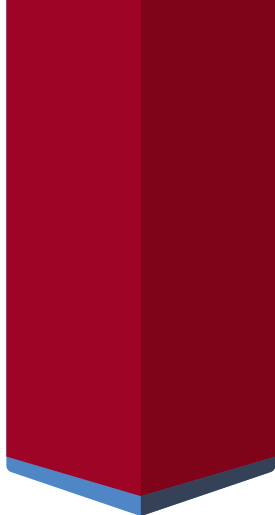
Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

PRODUCT	LOT CODE	ITEM NO.
---------	----------	----------

[Company Name] [insert product name(s)] [insert product codes(s)] [insert item number(s)]

[Company Name] is conducting this voluntary recall because [insert product name(s)] [modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.]

For more information or assistance, please contact us at 1-xxx-xxx-xxxx (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at [www.xxx.com](http://www.xxx.com)



# SUPPLIER QUESTIONNAIRE

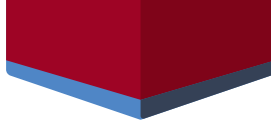
*for*

U.S. IMPORT ENTRY

UNDER FSVP



- Confidential -



## O V E R V I E W *o f* R E G U L A T I O N S

The Foreign Supplier Verification Program (FSVP) was published by the FDA on November 27, 2015. FSVP is fundamentally concerned with food safety. As a validly designated and qualified United States (*U.S.*) representative, United Safety Agents LLC's (*USA*) FDA-mandated goal is to verify that a product's innate physical, chemical and biological hazards are being controlled prior to public consumption, and in a manner that provides at least the same level of public health protection as the FDA's domestic standards (*Preventive Controls Rule, Produce Safety Rule, etc.*). To accomplish this goal, insight into each product's production process and control methods will be required.

## I N S T R U C T I O N S

We respectfully request that every entity/facility that controls any food safety hazard complete this Questionnaire. All sections are required, unless explicitly noted otherwise. **Complete via computer, do not print.**

Upon completion: Please return this questionnaire and accompanying documents via:

**Method One:** e-mail completed questionnaire to [info@unitedsafetyagents.com](mailto:info@unitedsafetyagents.com)

**Method Two:** upload completed questionnaire to USA's [ShareFile](#)

## C O N F I D E N T I A L I T Y

All information shared will remain strictly privileged & confidential and will ONLY be used during FSVP certification activities. An accurate and truthful response is required to successfully complete your company's FSVP certification. This document contains information which is privileged, confidential, and protected. Any disclosure, copying, distribution, or use of the contents of this message is prohibited. Document may contain Non-binding recommendations. United Safety Agents provides FSVP compliance services to businesses and has no direct affiliation with the FDA.

## C O N T A C T

If you have any questions or require additional information, please contact United Safety Agents LLC directly via Email: [info@unitedsafetyagents.com](mailto:info@unitedsafetyagents.com); Phone: +1 (888) 551-7403; Fax: +1 (888) 557-2649; [UnitedSafetyAgents.com](http://UnitedSafetyAgents.com), or by Mail: 715 West Park Avenue, No. 222, Oakhurst, New Jersey 07755, United States of America.



## GENERAL INFORMATION

Company Name: Pastificio Lucio Garofalo S.p.A. Today's Date: October 11 2021  
Factory Address: via dei pastai, 42  
City: 80054 Gragnano Province: NA Country: Italy  
Office Address: via dei pastai, 42  
City: 80054 Gragnano Province: NA Country: Italy  
FDA Registration No.: 19493040738 DUNS No.: 630998235  
FDA Establishment Id.: 630998235 Phone No.: +39 0818011002  
QC/QA's Name: Sergio De Gennaro E-mail: degennaro@pastagarofalo.it

## SUPPLIER CLASS

*Please select all actions/roles that apply to your facility/operation.*

- |  |   |                                  |                                      |
|--|---|----------------------------------|--------------------------------------|
| <input type="checkbox"/> Manufacturer ( <i>Raw Material</i> )                | <input type="checkbox"/> Processor                        | <input type="checkbox"/> Packer  | <input type="checkbox"/> Re-Packer   |
| <input checked="" type="checkbox"/> Manufacturer ( <i>Finished Product</i> ) | <input type="checkbox"/> Distributor                      | <input type="checkbox"/> Shipper | <input type="checkbox"/> Warehouse   |
| <input type="checkbox"/> Importer ( <i>US-based</i> )                        | <input type="checkbox"/> Exporter ( <i>Non US-based</i> ) | <input type="checkbox"/> Broker  | <input type="checkbox"/> Other _____ |

## RESPONSIBILITIES for HAZARD CONTROLS

*Please select the appropriate response for each hazard type that your facility/operation controls.*

- Is your factory/facility responsible for controlling Biological Hazards?  Yes  No
- Is your factory/facility responsible for controlling Chemical Hazards?  Yes  No
- Is your factory/facility responsible for controlling Physical Hazards?  Yes  No
- Is/Are product(s) in Ready-to-Eat form when exiting your factory/facility?  Yes  No

## PRODUCTS SUPPLIED

*Please list the name (and variation) of each product that your facility/operation supplies.*

No. 01, Product Name: Garofalo Spaghetti Product Code: 04 A G H 02  
No. 02, Product Name: Garofalo Penne Product Code: 04 A G H 02  
No. 03, Product Name: Garofalo Casarecce Product Code: 04 A G H 02  
No. 04, Product Name: Garofalo Gemelli Product Code: 04 A G H 02  
No. 05, Product Name: \_\_\_\_\_ Product Code: \_\_\_\_\_  
No. 06, Product Name: \_\_\_\_\_ Product Code: \_\_\_\_\_

Resources

FDA Product Codes and Product Code Builder

## FDA - IDENTIFIED BIOLOGICAL HAZARDS

FDA-identified Biological Hazards associated with the product(s) that your company supplies.

- |  |   |   |   |
|--|---|---|---|
| <input checked="" type="checkbox"/> Bacillus cereus  | <input checked="" type="checkbox"/> Clostridium botulinum | <input checked="" type="checkbox"/> C. perfringens  | <input type="checkbox"/> Brucella spp.        |
| <input type="checkbox"/> Campylobacter spp.          | <input checked="" type="checkbox"/> Pathogenic E. coli    | <input checked="" type="checkbox"/> Salmonella spp. | <input checked="" type="checkbox"/> S. aureus |
| <input checked="" type="checkbox"/> L. monocytogenes | <input type="checkbox"/> Trichinella spiralis             | <input type="checkbox"/> Giardia lamblia            | <input type="checkbox"/> Shigella spp.        |

Resources



Appendix 1



Description of Hazard



Bad Bug Book

## CRITICAL CONTROLS for BIOLOGICAL HAZARDS

Please select and describe the method by which Biological Hazard(s) are controlled. Please be as detailed as possible. Include time/temperature, chemical names, or any other information.

- Heat
- Chemical
- CGMPs
- Testing
- Other

### DESCRIPTION of CRITICAL CONTROLS

The product reaches temperature  $>70^{\circ}\text{C}$  for more than 10 minutes and has an  $a_w < 0.6$ . Historical food sector data confirm the safety profile of the semolina based dry pasta

### FREQUENCY of VALIDATION

quarterly

### U. S. FDA HAZARD PROFILE

Category Name:  
Category Number: #8  
Subcategory Name: Side dishes  
Storage Type: Shelf-Stable

Resource

U.S. FDA Product Category Hazard Profiles – Appendix 1

## FDA - IDENTIFIED CHEMICAL HAZARDS

FDA-identified Chemical Hazards associated with the product(s) that your company supplies.

- Drug residues       Heavy metals       Industrial chemicals       Pesticides  
 Mycotoxins/Toxins       Radiological       Unapproved colors & additives       Other

Resources



Appendix 1



Description of Hazard



Bad Bug Book

## CRITICAL CONTROLS for CHEMICAL HAZARDS

Select and describe the method(s) by which Chemical Hazard(s) are controlled. Please be as detailed as possible.

- CGMPs  
 Testing  
 Other

### DESCRIPTION of CRITICAL CONTROLS

product manufactured according the Italian regulation on dry pasta. the site is free from additives and colors

### FREQUENCY of VALIDATION

n.a.

### U. S. FDA HAZARD PROFILE

Category Name:  
Category Number: #8  
Subcategory Name: Side dishes  
Storage Type: Shelf-Stable

Resource

U.S. FDA Product Category Hazard Profiles – Appendix 1

## FDA - IDENTIFIED ENVIRONMENTAL / PROCESS HAZARDS

*FDA-identified Environmental Hazards associated with the product(s) that your company supplies.*

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Recontamination with environmental pathogens.                           | <input checked="" type="checkbox"/> Bacterial pathogen survival of a lethal treatment.            |
| <input type="checkbox"/> Bacterial growth and/or toxin formation due to lack of time / temperature control. | <input type="checkbox"/> Recontamination due to lack of container integrity.                      |
| <input type="checkbox"/> Bacterial growth and/or toxin formation due to reduced oxygen packaging.           | <input type="checkbox"/> Bacterial growth and/or toxin formation due to poor formulation control. |

 Appendix 1
 Description of Hazard
 Bad Bug Book

## CRITICAL CONTROLS for ENVIRONMENTAL HAZARDS

*Select and describe the method(s) by which Environmental Hazard(s) are controlled. Be as detailed as possible.*

- Heat
- Chemical
- CGMPs
- Testing
- Other

DESCRIPTION of CRITICAL CONTROLS
the residual moisture content is tested for any batch produced.
the environmental condition are confirmed through a documented cleaning plan .

FREQUENCY of VALIDATION
environmental hygiene is validated yearly

U. S. FDA HAZARD PROFILE
Category Name: Category Number: #8 Subcategory Name: Side dishes Storage Type: Shelf-Stable

Resource
U.S. FDA Product Category Hazard Profiles – Appendix 1

## FDA - IDENTIFIED PHYSICAL HAZARDS

FDA-identified Physical Hazards associated with the product(s) that your company supplies.

- |   |                                |  |                                   |
|---|--------------------------------|--|-----------------------------------|
| <input checked="" type="checkbox"/> Metal | <input type="checkbox"/> Glass | <input type="checkbox"/> Extraneous Matter         | <input type="checkbox"/> Plastics |
| <input type="checkbox"/> Stones           | <input type="checkbox"/> Wood  | <input type="checkbox"/> Natural Component of Food | <input type="checkbox"/> Other    |

Resources



Appendix 1



Description of Hazard



Bad Bug Book

## CRITICAL CONTROLS for PHYSICAL HAZARDS

Select and describe the method(s) by which Physical Hazard(s) are controlled. Please be as detailed as possible.

- CGMPs
- Testing
- Raw Material Inspection
- Filter
- Screen
- Metal Detector  
*see below*
- Magnet
- X-Ray
- Radar
- Other

### DESCRIPTION of CRITICAL CONTROLS

semolina is screen in plansichter at 0.8 mm of mash  
 the dough is filtered at 2.0 mm of mash  
 the dry pasta (short cut) is sieved at 5 mm of mash

### FREQUENCY of VALIDATION

metal detectors are tested hourly

### U. S. FDA HAZARD PROFILE

Category Name:  
 Category Number: #8  
 Subcategory Name: Side dishes  
 Storage Type: Shelf-Stable

**Metal detection standards**

Ferrous:	<u>1.5</u> mm
Non-Ferrous:	<u>2.0</u> mm
Stainless Steel:	<u>2.0</u> mm

Resource

U.S. FDA

Hazard Profile – Appendix 1

**ALLERGEN & CROSS-CONTAMINATION CONTROLS**

Component or Ingredient	Present in product?	Present on same equipment?	Present in same facility?
<b>Peanuts</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Tree Nuts</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Milk or Milk Derivatives</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Egg or Egg Products</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Fish</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Shellfish</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Soy</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Gluten</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>Wheat</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>Sesame</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Celery	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Mustard	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Sulfates	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Monosodium Glutamate	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Colorings	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Aflatoxins	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>ALL ALLERGENS</b>	<input type="checkbox"/> Absent	<input type="checkbox"/> Absent	<input type="checkbox"/> Absent

**DESCRIPTION of ALLERGENIC CONTROLS**

Cereal products have a history of presence of soybeans trace due to post harvesting operation and storing. Mills release the semolina after a check with ELISA kit with a LoD 2.5 ppm. We check monthly the Soybeans trace in semolina by an external accredited lab (Elisa method) with a LoD 2.5 ppm.

Cereal products have a history of presence of mustard trace due to an infestation on field. Mills release the semolina after a check with ELISA kit with a LoD 1.0 ppm. We check monthly the mustard trace in semolina by an external accredited lab (Elisa method) with a LoD 1.0 ppm.

## ONSITE AUDITING INFORMATION

Does the manufacturing/processing site have a recognized GFSI certification (BRC, SQF, Etc.)?  Yes  No

**If Yes;** Please provide a copy of the **full audit report** (written in English).

What standard is the GFSI certification? BRC - IFS - FSMA-VQIP

**If No;** 1. Does the site have a documented quality manual?  Yes  No

2. Does the site undergo internal hygiene audits?  Yes  No

3. Does the site undergo quality system audits?  Yes  No

4. Does the site undergo process audits?  Yes  No

## CLEANING INFORMATION

Does the site have documented hygiene procedures in place?  Yes  No

Does the site have a designated hygiene team?  Yes  No

Are all cleaning staff formally trained?  Yes  No

Do the cleaning schedules include: Chemicals used?  Yes  No

Concentration levels?  Yes  No

Dilution method?  Yes  No

Please list the chemical type(s) used on all food contact lines and surfaces:

Oxygen peroxydes

## STAFF HYGIENE INFORMATION

Have all staff undergone formal food hygiene training?  Yes  No

In-house hygiene training?  Yes  No

Accredited hygiene training?  Yes  No

Training level certification obtained: \_\_\_\_\_

Are staff issued protective clothing?  Yes  No

Are operatives required to cover head/facial hair within the processing/manufacturing area?  Yes  No

Are adequate toilet and hand washing facilities provided?  Yes  No

Are hand washing/swabbing validation checks carried out?  Yes  No

What is the total number of staff employed on site? 150

## PEST CONTROL

Is a pest control contractor employed?  Yes  No

If yes, please provide: Name of contractor used: Anticimex

Number of yearly visits: 24

If no, by what means is pest prevention carried out? \_\_\_\_\_

## HACCP & TACCP & VACCP

Does a fully documented and audited HACCP system exist for the site?  Yes  No

Has a hazard analysis study been completed for each site operation?  Yes  No

Does the business have a trained & certified in-house HACCP team?  Yes  No

*If yes, please provide copies of current & relevant HACCP training certificates.*

Does the business outsource the HACCP management to a certificated consultant?  Yes  No

*If yes, please provide copies of current & relevant HACCP training certificates.*

Are records maintained for all CCPs?  Yes  No

Does the HACCP system include the following: Sieving of ingredients?  Yes  No

Sieving of finished products?  Yes  No

Glass & hard plastic breakage procedure?  Yes  No

Metal detection of final product?  Yes  No

Magnets within the mixing & filling stages?  Yes  No

Do you use blue metal detectable plasters in the manufacturing/processing areas?  Yes  No

*Please detail any other prevention systems used on-site: metal detectable pens*

Has a full threat assessment of your supply chain been conducted & tested?  Yes  No

*Please provide details: \_\_\_\_\_*

Has a full product vulnerability assessment within the supply chain been conducted & tested?  Yes  No

*Please provide details: \_\_\_\_\_*

## TRACEABILITY

Does full traceability exist for all products supplied to your customer base?  Yes  No

If yes, please give details of traceability codes on the final packaging: LYxxx L=lot; Y=last digit of the year; x

## RAW MATERIAL

Are materials used by your company sourced from approved suppliers?  Yes  No

Are certificates of conformance/analysis received for all raw ingredients?  Yes  No

Are raw materials positively released before use?  Yes  No

Please describe your supplier approval system:

GFSI certification; incoming testing by internal lab; yearly validation by analytical screening with an accredited laboratory

## FINISHED / PACKED PRODUCT

Are finished / packed products positively released?  Yes  No

Are reference samples from finished / packed products retained?  Yes  No

Are finished products submitted to an 17025:2005 accredited laboratory for validation purposes?  Yes  No

If yes, please give details of the testing routines conducted:

## CUSTOMER COMPLAINTS

Does a formal customer complaint procedure exist?  Yes  No

Please describe your customer complaint procedure.

reference person identification, root cause analysis, eventual corrective action implementation, report to the customer

## RECALL / IMPORT ALERT / FOOD SAFETY ISSUE

Has your company ever experienced a recall or other food safety related issue of any kind?  Yes  No

If yes, please describe fully.

not in the last three years

**C E R T I F I C A T I O N**

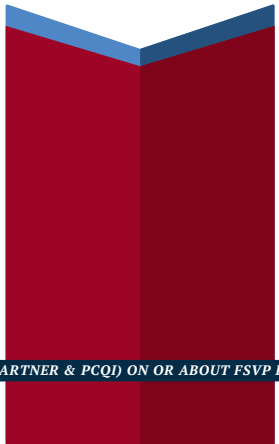
I certify that the information I provided on and in connection with this form is true, accurate and complete. I also understand that any false statements or deliberate omissions on this document or any other document I file with United Safety Agents, LLC may be grounds for disqualification from successful Foreign Supplier Verification Program (FSVP) approval or, if discovered after FSVP approval takes place, could result in my company's FSVP approval status being revoked or terminated, and may result in my shipments being rejected from entry into the United States. I confirm that all products that my company trades are in compliance with the Food Safety Modernization Act and all other U.S. & FDA Food Safety legislation.

**C O N F I R M A T I O N - R E Q U I R E D**

**Representative's Name:** Sergio De Gennaro \_\_\_\_\_

**Title:** Quality Assurance \_\_\_\_\_

**Today's Date:** 10/12/21 \_\_\_\_\_



## Audit Report

Global Standard for Food Safety Issue 8: August 2018

1. Audit Summary			
Company name	Pastificio Lucio Garofalo S.p.A.	Site Code	1383818
Site name	Pastificio Lucio Garofalo S.p.A.		
Scope of audit	Production and packing of dried durum wheat pasta in cardboard, plastic material, big-bag.		
Exclusions from scope	none		
Justification for exclusion	none		
Audit Finish Date	2020-11-12	Re-audit due date	2022-01-16
Head Office	Choose an item		

Additional modules included			
Modules	Result	Scope	Exclusions from scope
Choose a module	Choose an item		
Choose a module	Choose an item		

2. Audit Results					
Audit result	Certificated	Audit grade	AA+	Audit type	Unannounced
Previous audit grade	AA+		Previous audit date	2019-12-09	
Certificate issue date	2020-12-21		Certificate expiry date	2022-02-27	
Number of non-conformities			Fundamental	0	
			Critical	0	
			Major	0	
			Minor	2	

SGS ITALIA SPA Via Caldera, 21 20153 Milano - Tel +39 02 7393 1 email [it.cts.tech@sgs.com](mailto:it.cts.tech@sgs.com)

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If you would like to feedback comments on the BRCGS Standard or the audit process directly to BRCGS, please contact [tell.brcgs.com](mailto:tell.brcgs.com)

3. Company Details			
Address	Via dei Pastai 42 80054 Gragnano (NA)		
Country	ITALY	Site Telephone Number	+39 081 8011002
Commercial representative Name	Emidio Mansi	Email	mansi@pastagarofalo.it
Technical representative Name	Sergio De Gennaro	Email	degennaro@pastagarofalo.it

4. Company Profile					
Plant size (metres square)	10-25K sq.m	No. of employees	51-500	No. of HACCP plans	1-3
Shift Pattern	3				
Subcontracted processes	No				
Other certificates held	IFS, ISO 14001, OHSAS 18001; ISO 50001, SA8000, Organic, Spiga Barrata, Kosher, Halal, Vegan				
Regions exported to	North America Europe Africa Asia Oceania South America				
Company registration number	Aut. 27.05.16				
Major changes since last BRCGS audit	New short pasta production line, new silos for semolina storage in completion, substitution of old metal detector, decontamination station for access in packaging area.				

SGS ITALIA SPA Via Caldera, 21 20153 Milano - Tel +39 02 7393 1 email <a href="mailto:it.cts.tech@sgs.com">it.cts.tech@sgs.com</a>			
F834 English Food Template v8 09/09/2020	Page 2 of 36	Report No. IT/TU.20130506.0	Auditor: MAURIZIO GALLO



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**4. Company Profile**

Company Description

The company belongs to the Spanish Group HEBRO FOODS. The factory is placed near Naples. Year of construction on 1987. 3 lines for long pasta, 1 special pasta (nests), 5 for short pasta. 16 packaging lines and 8 pallet preparation and wrapping stations are present. All lay out is arranged on a single floor, other floors are present for offices. An internal lab is present. Turnover for 2019 has been 170,5 million €, of which 44% for domestic market and 56 % for foreign markets. Private labels are around 17% production. Emergency contact data: Name: Sergio De Gennaro, +39 320 1594941, Fax (+39) 0818012937, mail degennaro@pastagarofalo.it. Only dry pasta is produced, in some cases with ingredients (spinaches, tomatoes). No. of employees: 215 of which 3 manager, 58 employees, 126 workers fixed full time, 7 workers fixed part time; 21 apprentices (7 full, 14 part-time); no. of shifts: 3 shift/day for 7 days/week are performed. The company trades numerous products: pasta and other different products are produced by other approved suppliers. All of them are BRCGS and/or IFS certified. Some branded (C.) and some company formats of GPI (IGP) products (Pasta di Gragnano) are produced by other companies (e.g. Pastai Gragnanesi soc. coop.) where the company name of production site is clearly written on the packages. Some company branded products are also outsourced. Site area in square meters: 30.000 sqm. total, of which 20.000 sqm. are covered surface. Traded goods: EVO oil, gluten free, fresh pasta (filled and not), couscous, bulgur, quinoa, condiments (sauce, pesto), flour, special flour, dumplings, tomato products. BRCGS logo is not used.

**5. Product Characteristics**

Product categories		15 - Dried food and ingredients Category Category Category			
Finished product safety rationale		dried at moisture < 12,5%, Aw < 0.6			
High care	No	High risk	No	Ambient high care	No
Justification for area		The BRC decision tree approach of the company led to the identification of low risk and enclosed product areas.			

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5.Product Characteristics	
Allergens handled on site	Cereals containing gluten Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	Pasta di Gragnano GPI, 100% semola da grano italiano, Organic
Product recalls in last 12 Months	No
Products in production at the time of the audit	Wheat durum pasta in different size capellini L0314, vermicelli L0314, tagliatelle nest L0314, route L0314, elicoidali L0315, fusilli IGP L0315, mezze maniche rigate L0315, macaroni L0315, casarecce bio L0315, vermicelli IGP L0315.

6.Audit Duration Details			
On-site duration	26 man hours	Duration of production facility inspection	13 man hours
Reasons for deviation from typical or expected audit duration	extra time 0,5 MD added due to IFS 'combined' audit		
Next audit type selected	Unannounced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2020-11-09	08:30	18:00
2	2020-11-10	08:30	18:00

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Audit Duration per day			
3	2020-11-11	08:30	18:00
4 (end date)	2020-11-12	08:30	11:30

	Auditor (s) number	Name	Role
Auditor Number	051031	M. Gallo	Lead Auditor
Second Auditor Number	N/A		Please select

Present at audit					
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)					
	Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Giovanni Schisa Operational Director	x				x
Sergio De Gennaro QA Manager	x				x
Alessio Stellato QA	x	x	x	x	x
Rosanna Mainardi CQ Production		x	x		
Germana Amadoro CQ Packaging		x	x		
Domenico Esposito Receipment semolina Manager		x			
Francesco Esposito Packing operator		x			
Roberta Venanzoni Quality Control		x	x		
Annalisa Minichiello Product Development			x		
Ernesto Serrapica Packing operator		x			
Gerardo Serrapica Packing operator		x			
Antonio Carpentieri Packing operator		x			

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Present at audit				
Bonaventura Paletta Packing operator		x		
Luigi Delle Donne Storage & Shipping		x	x	
Raffaele Ottone Production operator		x		
Lucia Napodano Quality Control		x	x	
Carlo Caracciolo IT system				

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced
2020-11-09	BRCGS	Unannounced

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Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements				
No.	Requirement ref.	Details of non-conformity	Critical or Major?	Anticipated re-audit date

Critical			
No.	Requirement ref.	Details of non-conformity	Anticipated re-audit date

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Major							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	4.12.2	Bags for the collection of processing waste (powders, fresh pasta, dry pasta) are not correctly identified/coded according to destination.	Communication on correct waste management has been written and shared with C&P cleaning departments and companies.	Prepare an instruction for the management of waste and processing waste, with particular focus on those intended for livestock use (powders, extruded, fresh and ground pasta). Share instruction with external industrial Cleaning staff.	The management of processing waste for "livestock use" has not been clearly codified and shared with staff.	2020-12-10	MG

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2	4.15.2	Some packaging is delivered by suppliers non-fully protected.	Pallets were checked and where necessary coils has been covered and protected from accidental contamination.	The Flexible Packaging Delivery Specifications have been updated in which the requirements for the supply of the primary packaging are defined, including the full protection of the individual reels. These specifications were shared with all suppliers, who were asked to countersign for acceptance. During the year, monthly hygiene inspections will continue to verify the effectiveness of the actions implemented.	The specifications for the supply of the existing flexible packaging did not specify the requirement that the individual coils be fully covered.	2020-12-10	MG
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Comments on non-conformities

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**1. Senior management commitment**

**1.1 Senior management commitment and continual improvement**

Quality Policy dated 15.10.2020 it refers to safety and security matters, compliance to specifications and no defects policy, good in taste and for sensory characteristics, communicated in social area and IT portal. All personnel are informed with e-mail regarding to publication of document in IT system and invited to consult.

Declaration of intent for the improvement of food quality and safety culture 02.09.19, shared with the staff. Food Safety Culture Road Map dated 20.09.19. Three-year development plan provides for improvement actions to achieve specific objectives: training for whistle blowing 19.07.19, for concetto di consapevolezza 30.10.2020, questionnaire has been distributed by food safety culture to determine the gaps, the company is checking the questionnaires and will be defined a plan to cover the necessary training activities.

Confidential communication system in place

QMS Review annually, seen records dated 05.03.2020 in which they were analysed objectives for 2019 gave been defined into "Obiettivi 2020". In 2019 objectives for process: complaints reduction (CPMU complaints/million units produced <60), (CQI complaints x critical factor / tons products sold <24), complaints for different format, pasta macchiato, foreign bodies, bottatura (-10%). "Transparency" project has been completed, full compliance with MRLs on finished products.

Objectives 2020 and KPI have been confirmed, ex.: NC from GMP during internal audits and second part (<15), reduction of complaints critical (<4), semolina tanks rejected, complaints reduction (CPMU complaints/million units produced <60), (CQI complaints x critical factor / tons products sold <24), complaints for different format, pasta macchiato, foreign bodies, bottatura (-10%). Training plan 2020 output of QMS review.

Monthly meetings are performed after the monthly site inspections performed by the external auditor. Seen monthly meetings dated 08.09.2020 (food safety, legal conformity, integrity and vulnerability, quality, ...)

Quarterly meeting march, June, September, December to analyse a trend of KPI and monthly meeting report. Quarterly meeting for Objective performed on 15.10.2020 with trend analyses and objective achievement.

The company is associated with AIDEIPI and Union Food for legislation update. BRC logo is not in use.

The auditor verified satisfactory during the audit the closing of NCs from last audit.

**1.2 Organisational structure, responsibilities and management authority**

Organization chart updated at 21.10.2020. The President is Spanish (the company is owned by Hebro Foods sa), the CEO is Massimo Menna, QA is also Security and SA 8000 manager, Operation Manager is responsible for all production / packaging and QC areas. Job descriptions have been revised for all functions. The document "Mansionario - Sezione

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01 processo aziendale - Allegato 01 Manuale dei Processi (dated 24.01.17) describes all functions included in the Organization chart with their deputy.

Details of non-applicable clauses with justification

Clause/Section reference	Justification

**2 The Food Safety Plan – HACCP**

HACCP team listed in the Manual. The CEO, Operation Manager, QA Manager, QC at packaging QC at doughing, Production manager and Head of Maintenance are present. Signature of all participants is present at bottom of the document. Team Leader is Sergio De Gennaro, evidence of HACCP competence for previous work experience as BRC auditor for certification bodies.

HACCP Manual (Procedura analisi dei rischi) date 30.10.19. Pre-requisite programmes are described at par. 4 and include Work environment hygiene, Personnel housekeeping and hygiene rules, Pest control, Cleaning, Training, Maintenance, extraneous matters.

Description of product is in par.3 of HACCP Manual, the specifications are present for each product into technical specifications. Wheat durum semolina dry pasta. Aw <0,6, Humidity 12%, drawn at high pressure and dried, chemical (e.g. ashes, moisture, gluten content,) merceological parameters (e.g. black and red spots, color), and microbiological (TVC, E. coli, Yeasts and moulds, Cl. perfringens, B. cereus) parameters are defined, together with pesticides and heavy metals are described. Frequency of checks is defined for each category of parameters; semolina specifications are also present in the document. Only gluten allergen presence is defined for restriction to users, soy contamination recently taken into consideration for the unavoidable presence into flour declared by suppliers.

Two flow diagrams are present.

1. Internal production
2. Full Outsourced products

The second process described flow and activities for control of outsourced products and inspection / testing. In the flow diagram for internal productions (dated 31.10.20) the following data are described:

- the process steps
- the process controls for each step
- the key process parameters
- raw materials and packaging materials
- secondary processes and by products (e.g. water)
- secondary processes controls

Each step id coded with number for easy identification.

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CCPs are highlighted in red, while ingredients are highlighted in yellow, by products and discards are highlighted in pink, while packaging materials are coloured in green.

A documented hazard analysis and risk assessment is defined in "Analisi HACCP" in HACCP Manual, in which a list of potential hazards linked to process, equipment, personnel work environment, product is listed.  
 The residual risk evaluation after preventive measures taken has been added for each hazard. For each step the potential hazards are identified for probability and gravity, a risk index is defined, and a criterion is of evaluation in the process when risk is > 2. Main hazards take in account: physical (metal, wood, plastic, glass, ...), chemical (mycotoxins, pesticide, radiological, ...), microbiological (Salmonella, E. Coli, Bacillus cereus).  
 Preventive measures have been taken into consideration for each step to give support for evaluation of Gravity and Severity of each hazard.

1 CCP has been identified:

CCP1: metal detection on packed product (metallic extraneous matters)  
 Critical limits are metal detection on packed product (metallic extraneous matters with testes as follows: (Fe= 1,5 mm; Non-Fe = 2,0 mm; SS = 2,0 mm).  
 Validation based upon consideration about dimensions of extraneous matters which may pass through and do not represent a risk food safety of consumers.

Corrective actions are described in the document "Piano della Qualità" dated 31.10.19, which include segregation and actions to investigate (rot cause analysis).

Verification procedures are described into chapter 11 of HACCP manual. Inspections and audits are used for verifications. Results are defined in the Management review dated 31.01.19 which takes into consideration:  
 - sampling from Authorities - internal lab results  
 - sampling from customers - RASFF results  
 - Customer complaints - Internal audit

Last review of the HACCP study performed in a specific review dated 31.10.19, annually foreseen which include the status of CCP monitoring and results, customer complaints evaluation, personnel training and equipment calibration status.

Details of non-applicable clauses with justification

Clause/section reference	Justification

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**3. Food safety and quality management system**

**3.1 Food safety and quality manual**

Manuale dei Processi updated 31.01.17, all process descriptions have been modified in documented procedure. The structure was based on Manual, documented procedures, relative operative instructions and record forms apart from other supporting documents. Direction approves the documents.  
The documents are clearly legible in sufficient detail and in appropriate languages, managed with IT system and properly software archive, management and distribution.  
Automatic backup with notification of effective saving performed daily.

**3.2 Document Control**

Documented procedure for Document Control dated 18.09.2020. An electronic system of data recording is available in intranet portal Gestione Qualità in which all documents are being introducing for sharing (only reading format for different users than administrator = QAM).

**3.3 Record completion and maintenance**

Documented procedure for Document Control dated 18.09.2020. A retaining time is described being 4 years for record sheets, while certificates of analysis are retained for 5 years.

**3.4 Internal audits**

Audits are conducted by an external consultant, qualification through CV. In documented procedure Verifiche Ispettive Interne dated 02.07.2020 the company has defined the modality to manage and report internal audit. According to risk assessment dated 19.06.2019 the company has planned the internal audit through the year, at least 4 dates per year, but planned monthly. Audit are scheduled on the internal company portal "Gestione Qualità – Registro Verifiche Ispettive". Audits in 2020 performed monthly, seen records dated 22.10.2020 factory, maintenance, equipments, chemical and foreign bodies management, process control, calibration, weight control, labelling, hygiene, clothing, dated 28.09.2020 HACCP, dated 06.08.2020 staff facilities, inspection and products analysis, storage and distribution, traded products, For each date the planning of all chapters of BRC /IFS are reported.

A report has been prepared by the consultant; some observations have been raised. The company included them in the Portal for "Quality Management - nonconformity management". For each "observation" a NC has been opened. The portal includes a tag for each task. "Trattamento non conformità" (nonconformity treatments), "Analisi delle cause" (root cause analysis), "azione correttiva" (corrective action) and "verifica" (verification) are included in the NC management.

Self-inspections are foreseen monthly by an external consultant. A report is present on electronic format in which pictures are attached for each deviation found, seen inspection date 24.10.2020.

**3.5 Supplier and raw material approval and performance monitoring**

**3.5.1 Management of suppliers of raw material and packaging**

The company has implemented a documented procedure "Supplier Approval Process" dated 11.09.19. Raw material risk assessment takes in account all requirements (allergens, microbiological, chemical and radiological, foreign bodies, pest, fraud adulteration, variety, legal conditions) for each raw material (included traded) updated 21.01.20, reviewed at least annually.  
Low risk suppliers are qualified according to GFSI certification or external audit or questionnaire (tomato and spinach powder, storage services).  
Medium risk suppliers are qualified according to GFSI certification or external audit (semolina suppliers).

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High risk suppliers are qualified according to GFSI certification and external audit (traded suppliers).  
 A list of approved suppliers is present in SW Gestione Qualità and shared with office purchase.  
 In the same document (risk analysis) the evidence of monitoring for annual evaluation of qualification status is present.  
 A legend for criteria for each scoring is present. Criteria include certification GFSI confirmed, n° NC with block of products, n° analytical NC, customer service.  
 No agents and brokers in use.  
 The exceptions are used in case of the supplier is mandatory required by a customer, these suppliers are however subjects to the routine qualification and monitoring processes; exceptions in case of tomato products in glass/can that provide also an audit on site relating to HACCP.

**3.5.2 Raw material and packaging acceptance, monitoring and management procedures**

A dedicated area for receipt, sampling and acceptance is present in which an employee in charge for routine truck inspection and sampling/acceptance analysis is present. A weekly receipt plan is received from planning department to inform the employees on semolina receipts and types of semolina. At this area the instruction for truck inspection, sampling, checks at receipt and acceptance criteria is clearly posted at walls (operative instruction "Controllo analitico Sfarinati in ingresso con metodo NIR",  
 The pictures of most common pests into semolina are also present attached to the instruction. During the site inspection a truck with semolina (STO internal code) from "Candeal" supplier with DDT 7572 dated 09.11.2020 n° weighs 244820, has been sampled, analysed and accepted according to operative instruction, seen records in IT system regarding to U, proteins, ashes, gluten, gluten index, colour, seal integrity, conformity declaration, cleaning of truck.  
 NIR analysis is performed for release to unloading of semolina at each delivery, also the certificate of washing of trucks is mandatory for acceptance, together with the declaration of conformity (at any delivery) for compliance with agreed specifications. These documents are checked at receipt and the consigned to the internal lab for storage.  
 NIR Analysis includes protein, moisture, ash, colour. The results are to be compared with acceptance values reported in the instruction. The NIR software upload automatically the analysis results in the company portal "Gestione Qualità" and are available to be seen by the internal lab. Also, visual checks for hygiene and absence of pests is recorded by on NIR and automatically uploaded on Quality portal.  
 A sample is taken with an aluminium probe at each delivery, sampling from the top of the truck. Some supplier requires 4 samples, 2 of which are retained by the company and 2 are given to the truck driver, while for other suppliers 3 samples (2 for the company, 1 to the driver) are prepared.  
 The samples are identified with a label in which the following data are recorded: barcode (for electronic reading), date of receipt, progressive nr (given by the gate receptionist), ship doc nr, weight (as declared by the ship doc), type of semolina, truck plate. On this label the employee at receipt manually records the number of bin for semolina storage and the hour of start loading. The semolina sample is identified with this label, vacuum packed (a manual machine is present at receipt area) and then transferred to the internal lab for retaining (3 months storage).

**3.5.3 Management of suppliers of services**

Service suppliers are included in the evaluation. External labs, pest control service criteria are defined in the procedure. Pest control, service is based on documentation available by the suppliers and references (pest control companies which worked with mill companies are required). External labs have to be ISO 17025 certified.

**3.5.4 Management of Outsourced processing**

NA

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*Claudio Innocenti*

**3.6 Specifications**

The company electronically stores specifications by the suppliers, while for semolina an internal specification is present and agreed with all suppliers. Around 40 finished product specifications, 22 specification for semolina, 3 for other ingredients. Randomly checked

INGREDIENTS all semolina specifications are shared and agreed with relative supplier, seen records regarding to semolina standard SAE rev.3 dated 10.01.2020, semolina IGP 100% Italia SIC rev.1 dated 06.02.2018, semolina organic whole wheat SBP rev.2 dated 02.09.2020.

FINAL PRODUCT PTRM018408ae Linguine IGP, PREV0X8707AE Penne Rigate IGP Regione che vai 11.11.2020, Spaghetti Bio PPAU10426BI rev. 11.11.2020.

PLASTIC PACKAGING MATERIALS are handled by the company, in some cases also paper + plastics is present. Different plastic packaging materials are present:

- BoPP + PP cast for retail products. <sup>[1]</sup><sub>[SEP]</sub> - paper / PPL coex+PPL cast <sup>[1]</sup><sub>[SEP]</sub>
- LDPE for catering packages <sup>[1]</sup><sub>[SEP]</sub>
- Bags in paper plastics,

certificates of conformities are available for each supplier, seen PPcoex+PPcast, supplier Esseplast, conformity declaration according to Reg. 10/2011 dated 13.06.2020; supplier Bioplast, PP+PP conformity declaration dated 09.02.2020, Anico, paper+PPcoex, conformity declaration dated 02.10.2020, supplier De Lucia, PP+PP conformity declaration 14.09.2020.

Review every 3 years of all specifications required and performed by the company. All specifications have been included in the company software "Gestione Qualità".

**3.7 Corrective and preventive actions**

The company described into documented procedure NC, AC, AP dated 24.09.2020 the corrective and preventive actions management.

Seen AC management relative to complaint regarding to foreign bodies (metal tape) in spaghetti, complete of cause analyses (seen report dated 02.11.2020) and corrective action in implementation.

**3.8 Control of non-conforming product**

The company described into documented procedure NC, AC, AP dated 24.09.2020 the nonconformities management and consequent actions. The company included the nonconformity treatment and corrective action management in the Portal for "Quality Management, a dedicated area is present "Nonconformity management". For each NC raised during company activities (e.g. during internal audits, during in-process controls, at raw materials inspection for acceptance) a specific nonconformity is opened. The portal includes a column for each activity needed: "Trattamento non conformità" (non conformity treatments), "Analisi delle cause" (root cause analysis), "azione correttiva"(corrective action) and "verifica" (verification) are included in the NC management. Final release of potential blocked products is only made by Head of Quality, the task may be operatively conducted by the Head of in process QC for packaging areas when electronic blockage is foreseen (e.g. for finished product in storage areas).

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**3.9 Traceability**

The company described traceability system in a specific procedure "Tracciabilità". Traceability is electronically managed by the use of a dedicated software ("SAP") in charge of recording each product and process movement from raw materials receipt up to delivery to customers or to the external warehouse. The system is allowed for recoding also process control at production step, while at packaging the packaging orders ("Ordine di confezionamento" are directly printed by this software.

Reworked products are present and traced: dry pasta which is recovered (e.g. curves of spaghetti long pasta), grinded directly on the production line and stored into dedicated bins. A lot is given by the date of collection into a dedicated bin, allowing the identification of semolina suppliers. Traceability on semolina bins is managed according to the loading of the quantities into each bin. At extraction the quantity of semolina is automatically loaded in a way to calculate the exact amount of semolina lot still remaining into each silo.

Traceability test carried out once every 12 months to cover both directions (raw material to finished product and vice versa) per year. Seen records dated 18.09.2020: from FP Fusilloni bronzo IGP L0197, production date 15.07.2020, pack date 15.07.2020, seen records complete of mass balance and document list. Reconciliation time < 4 hours; dated 17.10.2020 from RM organic semolina Casillo lot 1000858778, 30560 kg, used to produce following lot of semi- finished products L4268158, to finished products spaghetti bio lots L0242, L0243, L0244, L0245, complete of mass balance and document list; dated 16.10.2020 from Spaghetti bio packaging, pack code IPALU01425B, lot 0445720276, received 220 units, used from 06.08.2020 to 31.08.2020, complete of mass balance.

Auditor chose to follow through PENNE RIGATE IGP REGIONE CHE VA 500g packed into double squared bottom and shelf ready 8x500 g, L0246, BB 02.09.2023, produced in date 02.09.2020, packed in date 02.09.2020, produced 2130 cartons, 1232 cartons delivered to A. from 30.10.2020 to 06.11.2020,898 cartons in stock. All documents issued during the manufacturing process are immediately available during the test.

**3.10 Complaint-handling**

A specific procedure is present "Gestione reclami" dated 02.11.2020. The company reports on the printed packages of products a specific e-mail address for consumers complaints. Therefore, the company records either consumers and customers complaints.

From consumers a total number of 573 confirmed complaints have been received from the last audit, of which 415 for pest infestation, 2 for foreign bodies (extraneous matters).

From customers a total number of 125 complaints have been received from the last audit, 20 for pest infestation, 6 for foreign bodies (extraneous matters).

Seen complaint regarding to foreign bodies (metal tape) in spaghetti, complete of cause analyses (seen report dated 02.11.2020) and corrective action in implementation.

**3.11 Management of incidents, product withdrawal and product recall**

A procedure for emergencies and crisis situations management is defined "Gestione crisi" rev.5 dated 01.07.19. Information about emergencies are posted at different areas inside and outside. A document "Gestione delle Emergenze" is posted at external areas where electrical power plant (co-generation unit) is present for electrical accidents, flood is also considered. A recall procedure is also present into "Gestione crisi" procedure. The contact names and crisis team (the same of HACCP team) are listed. The evidence of contact of certification body within 3 working days in the event of a recall is present.

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During the last year, the Company have carried out n. 1 withdrawal/recall test in date 04.05.2020 involved customer MC, supposing the presence of foreign bodies in Fettucce Pasta di Gragnano IGP lot L9353G ex. date 19.12.2020. The company decide to recall and conclude test in date 05.05.2020, seen records complete of mass balance and document list.

No real recall since last audit

Details of non-applicable clauses with justification

Clause/section reference	Justification
3.5.1.5	No agents and brokers is present
3.5.2.3	No live animals are received at this company
3.5.4	No processes are outsourced

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<b>4. Site standards</b>
<b>4.1 External standards</b>
<p>The company is located in a semi-industrial area close to urban area (Gagnano town). The site is completely fenced, 2 barriers are, the main one (equipped with also a gate) at entrance with 24/7 surveillance presence, while the second one, for trucks access, is monitored by camera and handled with remote control by the receptionist at gate. A new parking area has been obtained externally at a site of the company for employees, which have access by the main gate by the receptionist. No significant risks are present for natural events like flooding, or chemical pollution. All external areas are asphalted and allow movements of vehicles and trucks. Additional buildings present outside are the maintenance workshop (completely separated from the main building), close to the area for water extraction from the well (locked), a main roof where dismantled equipment are stored, the storage area for chemicals (locked), and a new plastic curtain used for plastic packaging materials. Externally at a side of the main building there are also the offices building, while in the same area for the receptionist at the main gate the changing area at first floor is present for packaging area employees.</p>
<b>4.2 Site security and food defence</b>
<p>A Crisis team is defined being the same for Food Defence evaluation. A risk assessment has been performed dated 18.06.2020 for each area and production step the potential risks have been listed and an evaluation in terms of Probability and Severity has been done. The company has defined a Food Defence Plan updated 29.11.19, that provide also the security of sensitive and computer-managed data, checked during monthly site inspection. The evaluation led to the identification of no critical area.</p> <p>The company is equipped with continuous surveillance by internal employees, surveillance for 7 days/24 h of accesses is guaranteed by numerous cameras placed externally. Records are maintained on a disk for at least 3 days. Some cameras are present also internally (no records) for inspection of some equipment (e.g. production areas where wet pasta is laid on frames). All accesses are controlled and locked where restricted access is present (e.g. external lockers for cleaning agents). The employees and workers have been trained for food defence in feb-mar 2019. Visitors at reception gate are registered for entrance and exit times, identification badge is given to visitor for clear identification, the company contact is also registered on the document "Registro visitatori". In the company rules for visitors instruction for hygiene and security are described, which foresee that a representative of the company for internal visits is present. The company has tested alert system in date 06.11.2020, the corrective actions has been defined following the test results.</p> <p>Evaluation of food defence updating is on the annual management review. The company is approved (registration nr. 19493040738 dated 10.10.2018) by the FDA for export in the US.</p>
<b>4.3 Layout, product flow and segregation</b>
<p>Maps with flows are present and dated July 2020. In the HACCP Manual the identification of areas for zoning is present. In the map the well water and distribution plant is also present and used for evaluation of sampling points for water (quarterly). No refurbishments were found during the site inspection. Due to the product rationale and the process (almost an enclosed system) no high care or high-risk areas were found. An analysis lab is present, placed outside production areas (just before entrance to production areas).</p>
<b>4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas</b>
<p>The structure was not recently built nevertheless it has been maintained to get acceptable levels for hygiene and to avoid contamination from the building. Floors are in all areas smooth, in some areas (e.g. ingredient preparation area) they are washed with water. Vacuum equipment is used at bin storage areas for floor cleaning. Doors are self-closing</p>

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or vertical sliding doors not openable from the exterior. Lighting units were recently replaced into LED lighting units to reduce risks from breakage. Walls do not allow dirt accumulation and are included in the periodic cleaning and maintenance plan. No false ceilings are present at production or packaging areas.

**4.5 Utilities – water, ice, air and other gases**

Water comes from a well in the company, 4 tests per year are foreseen in the Analysis Plan. 2 are for “general” evaluation (chemical parameters), other 2 are for “routine” monitoring (microbial and chemical parameters) according to validation report to water sampling. Furthermore, a control plan is present from the internal lab, which performs every 15 days microbiological tests for TVC and Total Coliforms. Seen internal microbiological analyses (CBT, Coli total). Seen external analysis report according to D.lgs 31/2001: 20/000216956 dated 11.06.2020 process water, 20/000386557 dated 06.10.2020 well water (routine), 20/000273774 dated 20.07.2020 well water (complete according to legal requirements), 20/000164900 dated 05.05.2020 well water (routine).

Compressed air used to transport semolina and to form nest, low risk because oil free used in compressors. At least annually the company verify MOSH e MOAH in air food contact, seen report n°19/000116865 dated 27.03.19, report n°19/000116868 dated 27.03.19 on flour feed compressors.

In special pasta area the air is filtered <0,1 micron.

Compressed-air GHH RAND declaration of conformity from SILU compressors dated 25.05.2015 with oil free compressed air.

**4.6 Equipment**

Equipment are specific for the process produced. Some new equipment has been bought at doughing area, some new mixers have been placed at production area, checked specification of conveyor line Chiornino and conformity declaration dated 12.12.2018, specification of new production line Fava and conformity declaration dated 24.06.2020. Unused equipment has been transferred outside close to workshop area, stored under a roof and covered with plastic protection.

**4.7 Maintenance**

Maintenance program is present and divided for production and packaging area. An electronic maintenance program is present into an Excel file. Preventive maintenance is performed mostly during the 2 main production stops planned during the year (on August and December, during holydays). All planned activities are performed internally by maintenance personnel available.

Small maintenance activities may be also performed by production employees (e.g. lubrication). When extra-ordinary repairs are needed, they are also recorded in the same excel file. After this repair the cleaning of equipment is made by maintenance personnel while verification for release for further production is given by the employee at production area.

A small area for storage of blades of dies and for small maintenance is available at doughing area. A larger maintenance workshop is present (mostly for packaging area maintenance) outside the main building in a separate area. A contract for intervention on demand is present with external service suppliers. Lubrication in some parts at production areas (e.g. lubrication of transmission chains for short pasta production lines) is done with food grade lubricants, checked “OPTILEB F&D Spray” lubricant appropriately stored, specification available dated Sept 2015 with NSF H1 and “Stac 5” (Saca) specification dated 07.01.16 and into which allergen information is available (no cross contamination described).

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4.8 Staff facilities

The changing areas is located outside production area (men and women), the workers must attraversare un'area scoperta, per cui è stata predisposta una stazione di sanificazione per mani e suole all'ingresso dell'area di confezionamento. Production area changing room are close at a side of the internal lab and just before entering into production areas. In production area changing facilities lockers by the external cleaning service company are available (AlSCO), separated into production and maintenance personnel. Before entering into production area, a hand washing station together with dispensers of blue disposable tools are present (overall, headgear and beard covering). Hand washing station is equipped with soap detergent and disposable paper, the correct sequence is posted at walls in a pictogram. Before entering into production areas all visitors must read and sign company hygiene rules at gate reception area. At entrance a microbiological carpet for soles is present. Close to the changing area a small break area is present for employees where lunch may be consumed. The company hygiene rules (posted in the company showcase) describe that working clothes must be removed before food consumption in break areas. Smoking (included electronic cigarettes) is allowed only in dedicated, equipped and identified areas. No catering areas are present in this company.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

Cleaning agents are stored in a locked dedicated room placed externally (keys are owned by the external service provider). Cleaning activities which include the use of chemicals are performed only at the end of the week when no production activities are performed. All cleaning agents are provided with specifications and technical sheets, which are electronically stored by the Head of Quality and are also present in the cleaning agent storage area.

4.9.2 Metal control

Blade policy is present and posted at production area in the employee showcase. Blades to employees are present at packaging, only single blade detectable blades are used. Safe storage (out of production area) of blades used to cut pasta at dies is present. An electronic record of the state of blades of dyes is present on company software at production area where at any change of pasta format either the integrity of sieve present and the integrity of blade is verified and recorded on the system by the employees. Only detectable pens are allowed at production and packaging area, no staples or pins are allowed by the internal hygiene rules.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Glass and hard plastics risk assessment evaluated in the HACCP study, preventive and control measures have been consequently defined. A list of hard plastics and glass (only at external windows) is present on an excel document "Mappa del vetro e della plastica dura", different colours describe the state of glass and hard plastics (green = OK, yellow = under Maintenance, Red = broken), the monitoring frequency (daily, weekly, monthly) has been defined according to risk assessment location (exposed products, no exposed products).

Daily inspection of glass and hard plastics is performed by personnel and recorded on appropriate documents, checked into "Ordine di Confezionamento" the request of evaluation of all sources before starting packaging activities. An instruction is present: "Gestione rottura vetro e plastica dura" dated 28.10.19, it includes also breakage management, cleanliness and inspection of shoes and clothes after cleaning of area, seen training report 10/2020. No glass or hard plastics breakage claimed since last audit regarding to dried pasta, nor the auditor found signs of breakage during the site inspection.

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4.9.4 Products packed into glass or other brittle containers
N/A
4.9.5 Wood
Wood is not present in open product areas. Only wooden pallets are allowed at storage areas for packaging materials and finished product, no risks of contamination of the process is possible.
4.9.6 Other physical contaminants
At the moment the company does not use ingredients for de cartooning. All process is enclosed starting from tanks and pipeline. The pens in the production facility are detectable.
4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of foreign-body detection and removal equipment
<p>The company has defined a documented procedure to manage the hazard of Physical Contamination, dated 02.07.2020.</p> <p>The HACCP plan includes in the assessment the evaluation of steps in which controls are made possible to identify potential extraneous matters contamination. Steps have been investigated to evaluate process controls. CCPs have been found at both inspection of screens placed at dies in production areas and the verification of effectiveness of metal detector at packaging area.</p> <p>Furthermore, some process controls are present for foreign body detection: the inspections of magnets and Plansichters placed after semolina silos storage. Records of these monitoring activities are available. Training has been done to employees for foreign body detection end equipment control, a supervision is routinely made by in-process QC personnel to verify the effective functioning of detectors. Also these records are available and have been inspected during the audit.</p> <p>All detectors are online and recording of rejected packs is present for each packaging line. The head of in process QC performs daily checks of correspondence between discarded pieces and those effectively available in the rejection box. Those packages are only handled by in process QC, who performs the investigation on the source of contamination of rejected packages. Records of these investigations are on "Rilevamento corpi metallici", where information is sent to Maintenance for detailed investigation on the source and actions.</p>
4.10.2 Filters and sieves
Filters are present at semolina unloading from silos (Plansichters), each of them is equipped by numerous sieves one on each other 0,6-0,8-0,1 mm each. Inspection and status of cleaning (presence of insect) is verified at each change by production workers and recorded on Registro Produzione in IT system.
4.10.3 Metal detectors and X-ray equipment
<p>The company has defined a documented procedure Gestione metal Detector dated 11.09.2020, define operative modality to correct functioning and monitoring, the responsibility to monitoring and control, the modality to manage potential contaminated products, the responsibility to verify.</p> <p>Metal detectors are present at each packaging line and inspect all packed products. New metal detectors have been recently bought and replaced older ones. All metal detectors are equipped with failsafe systems for pressure of ejection and effective discard into the rejection box.</p> <p>Record of the effective functioning of failsafe system is made at start of any packaging batch and recorded on packaging record sheet "Ordine di Confezionamento". All detectors are also equipped with locked box and air blow system for rejection, key are owned by in process QC personnel, in charge for routine extraction of testers (placed inside) and</p>

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consignment to employees for routine testing. A daily test is also performed by in process QC for verification of effective discard for each packaging line and recorded on "Ordine di confezionamento".  
 Testers are present and are the same dimensions for all packaging lines. CCP1: metal detection on packed product (metallic extraneous matters with testes as follows: (Fe= 1,5 mm; Non-Fe = 2,0 mm; SS = 2,0 mm; real ferrous contaminant 20 mm). Effectiveness of detectors is performed at start, with hourly frequency and at end of each packaging batch, recorded on the "Ordine di Confezionamento".

Test for effective stop of belt have been tested by the auditor during the site inspection (e.g. Wheat durum pasta in different size capellini L0314, vermicelli L0314). Positive functioning observed

**4.10.4 Magnets**

The company has defined an operative instruction Verifica e Pulizia Magneti dated 02.07.2020. Magnets are present at semolina silos unloading, magnets may be either made by neodymium bars (6.000 Gauss) or Ferrite plates (2,500 Gauss). Inspection and cleaning performed each 15 days by the silos workers and recorded on appropriate sheets. In case of presence of piece >1mm, is needed to alert a QC to subsequent investigation. The company check the magnets strength with Gaussometro to verification of effectiveness of strength, at least semi-annually.

**4.10.5 Optical sorting equipment**

NA, no optical sorting in use

**4.10.6 Container cleanliness – glass jars, cans and other rigid containers**

NA, no rigid containers in use

**4.11 Housekeeping and hygiene**

The external service company (C&P) is present for overall cleaning of production and storage areas, even though the employees in charge for cleaning purposes are the same of last year. Capitolato 01.10.19 which defines the areas, the equipment and frequencies to be respected. Istruzione Operative 01.03.18, defines the methods of execution, the equipment and the products to be used

- instructions for cleaning
- cleaning agent list with characteristics and instructions for use
- instructions for floor cleaning with automatic machine

It has been transferred to the C&P portal, with restricted access, in which the operations to be performed have been defined for each area / equipment, complete with PPE and tutorials.

Cleaning records are available in Mod.FF/02 organized by month and by working day, are posted at walls or on equipment (e.g. packaging machines).

An industrial vacuum cleaner is present at semolina storage areas for dry cleaning at this area.

A list of chemical products including cleaning agents is present in C&P Portal shared with company , MSDS, DPI, job description according to competence, quality policy. P3-gamo80 detergente utilizzato nella lava-asciuga (pavimento) dated 26.04.2017, XPLURI detergente senza risciacquo 30.08.2017.

Evaluation of effectiveness of cleaning is performed by pre-operative inspections (start-up), performed by employees and recorded on aper documents ("Ordine di Confezionamento" at packaging). Analytical evaluation is also performed by QC personnel through bioluminescence method (Lumitester PD-30), in compliance with an instrucion "Test controllo luminescenza".

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3 different levels of results in terms of RLU have been defined by the company (<500, 501-1000, > 1000 RLU), a warning is given for intermediate level while for unacceptable results (> 1000 RLU) a re-cleaning of the surface is required, but the trend is <500 RLU.

Training performed by C&D responsible for all operators, seen records dated 26.10.2020, 04.11.2020 complete of effectiveness verification.

Adequate cleaning level highlighted during the site tour (processing area and equipment)

4.11.7 Cleaning in place (CIP)

NA, no CIP in place.

4.11.8 Environmental monitoring

NA, according to BRC decision and Environmental Monitoring Risk Assessment dated 21.02.2020. Product is wheat durum dry pasta with low Aw that dose not support the microbial growth

4.12 Waste

Wastes small containers are identified all along the production and packaging areas. Wet pasta discards are collected into grey large plastic boxes (tanks). Blue bags are for wet pasta discards which need recovery treatment (performed by an external supplier). Plastics are collected into transparent bags and daily transferred to a compactor. Paper discards are collected into grey boxes and then daily transferred to the external compactor area. Service providers are present for disposal. "SEA" company is for plastics and cartons (recycling company), "Tortora Guido" for plastics, while "Pasquale Saporito" is an authorized feed animal production company in charge for disposing all products and by-products downgraded at animal feed. Registers for traceability and records of quantities disposed of these discards are present.

Minor 4.12.2 – Bags for the collection of processing waste (powders, fresh pasta, dry pasta) are not correctly identified/coded according to destination.

4.13 Management of surplus food and products for animal feed

Seen contracts with external contractor, waste management for use for animal feed, cat.3, according to legal requirements Reg. 183/2005 registration n°IT/063035/07.

4.14 Pest management

A contract with external provider "ANTICIMEX" is present and updated to implement extraordinary monitoring plan for shipping area. Rodents are monitored monthly. A technical project is present by the provider. The company has been completed the monitoring system into a "safe" system in which no chemicals substances are used externally, and no glue is used internally for rodents. Electronic catch stations are present with "Smart" systems. Electric shock is given to rodents coming into the devices and are automatically transferred into a closed box into the station. Contemporary a signal is generated which sends an email to the company informing about the catch in a specific position. Internally snap traps are placed internally to the stations. A map is present inside the service provider portal updated at any reporting. For each pest the limits of acceptable values are defined as maximum allowable sum in each area.

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Environmental thermal treatment with hot air (>55°C for > 30 h) has been used for pest control interventions during summertime, checked last intervention performed by "Soges S.r.l." dated 21-23.08.2020.

Trends are continuously available on Anticimex portal. Last monitoring report dated 10.11.2020, during the audit has been possible interview the operator and verify the monitoring activities.

Quarterly expert survey by field biologist available 10/2020

**4.15 Storage facilities**

Semolina bins storage are present in an inner part of the company. Bin connections are present outside this area into a controlled external area, inside a room. Cameras for inspections are being including the vision of this area also. Metal bins are present for different dimensions and different types of semolina storage (e.g. organic, high protein content, standard, whole grain semolina). At bottom of each bin, before semolina is transferred (by air compressors) into production area, a sieving is present with a battery of plansichters, equipped with sieve 0,8 mm wide. Magnets are also present before plansichters. Instructions are present at this area for daily cleaning with vacuum cleaner (checked "Controlli e pulizia sala silos"), for cleaning of air filter compressor for semolina transferring to production area ("Pulizia filtri compressor", rev. 1). Inspection and cleaning of magnets and plansichters is performed by the employee at bin receipt and storage area at any change of pasta format. A weekly verification is made by the in-process QC at production area for the state of cleaning and integrity of sieve and magnets, recorded on "Pulizia filtri e magneti" rev. 1. On this document the extraneous matters rejected by the plansichter and presence of insects is recoded, a limit has been defined by the company (max 10 insects), after which control measures are taken together with the pest control company (e.g. insect treatment of bin when empty). No controlled temperature areas are present for storing raw materials. Outside storage is linked to cleaning agents, where a dedicated external area is present (locked), the keys are owned by the external service provider and the head of maintenance. Finished product storage area completely automated, at the end of palletization (automatic) a barcode is printed for recording of location of the pallets in the finished product warehouse. From them the Head of Logistics unloads a defined product, FIFO rules are automatically applied and have been verified randomly during the site inspection on the company PC. An external storage is foreseen at an external service provider: "Number One Logistica spa", placed at Marcianise-Caserta,

Minor 4.15.2 – Some packaging is delivered by suppliers non-fully protected.

ha formattato: Inglese (Stati Uniti)

**4.16 Dispatch and transport**

All vehicles are inspected before loading by employee at delivery area. The hygiene and cleaning of trucks and integrity of protection are checked, a printing on the shipping document "Veicolo idoneo al carico". During the audit seen inspection records regarding to DDT n° 100015690 del 11.11.19, destination Number 1, container sealed with n° 0427478.

**Details of non-applicable clauses with justification**

Clause/section reference	Justification
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4.3.5	No temporary structures are present
4.5.3	No use of non-potable water
4.7.3	No temporary repairs were found during the site inspection
4.9.1.2	No strongly scented materials are present
4.9.4	No products are packed into glass containers
4.10.5	No optical sorting equipment is present
4.10.6	No glass jars or other rigid containers are present in this process
4.11.7	No CIP system is present in this process
4.14.3	No internal pest activity is performed by the company
4.15.4	No controlled atmosphere storage is present
4.16.4	No internal trucks are present

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**5. Product control**

**5.1 Product design/development**

A dedicated person at QA office is present for supervision and recording of activities related to new product development. NPD activities are supervised by QA with reports which summarize meeting performed with different units participating to NPD (Production, MKTG, Commercial). NPD activity mostly refers to new packaging for dry pasta, even though also fresh pasta produced to outsourcing companies is included.  
 Checked study for new packaging limited edition "13 minuti", data collection and start project in date 16.10.2020, in risposta al reclamo di un cliente relativo alla poca lettura del tempo di cottura, packaging date 24.10.2020. The project is temporary and will be conserved for 6 months.

**5.2 Product labelling**

Product labelling performed according to national and international rules, where organic production is present preliminary approval by the certification body for compliance is required. Other new labelling is handled by Quality personnel, the Head of Quality in charge for final label approval for company products whereas private labels are approved by the customers. Checked SW Inciflex portal to manage label approval with packaging supplier. seen records regarding to PENNE RIGATE IGP approval date 07.05.2020.

**5.3 Management of allergens**

The company evaluated in the HACCP study the risk of allergen presence and contamination. Seen "relazione sulla gestione del rischio di contaminazione da soia" date 21.02.2020. At section 3 of HACCP it is specified that for AIDEPI line-guide on possible warning for possible traces of soya for accidental contamination during logistic operations, before semolina arrival at premise, for legal protection decided of sharing the policy of inserting an eventual warning on the label 'may contain soy traces' with each client as well as adding warning on own brand label. Only semolina from gluten is present as allergen ingredient (declared in all recipes). Regarding soy presence, even though a monthly program is present for routine monitoring of semolina with external accredited lab (ELISA testing method, LoQ at 2,5 ppm), the company is being changing all packaging materials after a study performed by suppliers and the unavoidable declaration recently made by wheat millers from soy into wheat or into the process. No other allergens are present, at staff facilities the risk of potential cross contamination from food with relevant training annually performed on preventive measures (overall required before entering into break areas, hand washing required before re-entering in production areas). A monthly program is present for routine monitoring of semolina with external accredited lab (ELISA testing method, LoQ at 2,5 ppm).

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5.4 Product authenticity, claims and chain of custody

The company evaluated product authenticity risks in the HACCP manual, during the raw materials risk assessment and vulnerability assessment dated 24.12.2019. Different factors are considered as raw material characteristics, supply chain, economical factors, historical event, detectability.

The company received semolina, conventional semolina is analysed at any receipt, protein content declared in the specification is analysed at any time. Organic production is monitored every week with mass balance. A document is present "Registro Generale del biologico" where weekly mass balances are performed by the Head of QA with incoming raw materials, organic pasta produced, conversion into equivalent semolina used and comparison with raw materials used, the percentage of downgraded products (from organic to conventional or discarded for animal feed). Kosher certification is present even though all raw materials are declared Kosher therefore no segregation is required for these products/raw materials.

Seen traceability test and mass balance for organic semolina in date 03.11.2020 during the CCPB audit.

Seen inspection report CSQA for IGP production, date 08.06.2020, con prova di tracciabilità Spaghettoni Gragnanese L059G, production date 07.06.2020, data 14.10.2020, con prova di tracciabilità Mezze Maniche L0266, production date 22.09.2020.

5.5 Product packaging

Plastic packaging materials are handled by the company, in some cases also paper + plastics is present. Different plastic packaging materials are present:

- BoPP + PP cast for retail products. <sup>[1]</sup><sub>[2]</sub><sup>[3]</sup><sub>[4]</sub>
- paper / PPL coex+PPL cast <sup>[1]</sup><sub>[2]</sub><sup>[3]</sup><sub>[4]</sub>
- LDPE for catering packages <sup>[1]</sup><sub>[2]</sub><sup>[3]</sup><sub>[4]</sub>
- Bags in paper+plastics,

certificates of conformities are available for each supplier, seen PPcoex+PPcast, supplier Esseplast, conformity declaration according to Reg. 10/2011 dated 13.06.2020; supplier Bioplast, PP+PP conformity declaration dated 09.02.2020, Anico, paper+PPcoex, conformity declaration dated 02.10.2020, supplier De Lucia, PP+PP conformity declaration 14.09.2020.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

An analysis plan is present "Piano della Qualità" (on electronic excel file) into which different items are listed:

- Step of the process
- Process control
- Critical factors
- Responsibility
- Frequency
- Specifications and reference documents
- Record sheets
- Nonconformity management In this plan raw materials, finished products, water and surfaces tests are summarized.

Raw materials: semolina is tested by the internal lab with a single check/day with official methods of incoming analysis foreseen with NIR at receipt area, seen records in "Controllo analitici sfarinati in ingresso NIR". Protein, ash and moisture content are tested with the official methods by the internal lab, together with granulometry with vibrating screen. All results are transferred on the company portal "Gestione Qualità".

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Semolina is analysed also externally by accredited lab, according to plan:  
 - monthly for semolina type, CBT, E. Coli, mufle lieviti, clostridium. perfringens, bacillus cereus, soya,  
 - annually, fitofarmaci for supplier, filth test, mycotoxin, metalli pesante, OGM, soft whey, seen report n° 20/000430255 dated 30.10.2020

Finished products: tests are conducted for verification of shelf life according to the internal plan. Tests include cooking test performed internally. Process controls of pasta are also performed: pasta dimensions and thickness, texture (a specific instrument is present internally). These process controls are performed to verify the status of consumption of dies. A document is present "Monitor trafilerie" in which their results of thickness and dimensions are listed to assess the need of change dies. Cooking tests are also performed at start and end of placement of any die. Thickness is tested with calibres linked to a personal computer for recording data.

Water is tested internally by the lab every 15 days for microbiology, while external accredited lab performs quarterly tests for microbiology and chemistry according to national rules. "Legionella pneumophila" is also tested on UTA system for air conditioning at production area for evaluation of presence.

The company started an internal project called "Progetto Trasparenza" in which a contract has been agreed with an external accredited lab (Merieux) for sampling of pasta products on retail shelves in Italy. A total amount of 100 samples/year is foreseen. The results of these checks will be published on company website for customers. Tests include Furosins, heavy metals (lead and cadmium), soy presence, glyphosate, pesticides content, all mycotoxins, chlormequat. etc.

From electronic document "Tracciabilità materie prime" for production order nr 000020054686 the quantity of semolina used and silo for storage (nr. 12), together with supplier name ("Candeal Commercio srl"). On document "Controllo di processo di produzione pasta lunga" checked for 31.07.2019 "Linguine bronzo IG (corresponding to "Linguine IGP Tre Mulini 12x500 g").

From electronic document "Visualizzazione Analisi Materie prime" – 223515, 223515-001, 223604, 223604-001 the receipt of semolina supplier is recorded. Internal analysis performed with NIR which include ash, protein and moisture content, values include target values (in brackets):

- Ash: 0.83% (max 0,86%)
- Protein: 14.32% (min 13.0%)
- Moisture %: 14.69% (max 15,0%)
- Ash: 0.81% (max 0,86%)
- Protein: 13,70% (min 13.0%)
- Moisture %: 15,10% (max 15,0%). Analysis repeated in the laboratory, measured 14,90%.

On the same document the analyses performed by the laboratory on pasta is present.

- Ash 0.86% (max 0,86%)
- Moisture 12.00% (12,5%)
- Protein: 13,69% (min 13%)
- Stability test: 0% (max 3%)

**5.6.2 Laboratory testing**

An internal lab is present even though official analyses for compliance to customer requirements are performed at external accredited laboratories. An internal ring test is performed for moisture, protein and ash content. An instruction has been prepared for this task, "Ring test interno" rev.2. Quarterly tests are conducted between NIR (semolina receipt area, internal lab and thermoscale at production area. A semolina sample is tested internally, and acceptance

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criteria have been defined into the instruction. 3 replicates are performed by each tester and a max acceptable deviation from average results are defined. External laboratory work according to ISO 17025

5.7 Product release

Finished products are automatically transferred into an automatic warehouse where all pallets are electronically identified with labels for identification of storage. All products are automatically blocked by managing warehouse software "SAP". The result of analyses performed along the process and on loose pasta for protein, ash and moisture are tests for positive release, performed daily by the head of in process QC for packaging area.

5.8 Pet Food

NA, no Pet Food.

Details of non-applicable clauses with justification

Clause/section reference	Justification
5.8	No pet food is produced at this site.

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**6. Process control**

**6.1 Control of operations**

Process controls are present either at production and at packaging departments. At doughing area process controls are mainly related to the process performance, where the PLCs are in charge for automatic setting and control of speed and pressure of screws, temperature of water, temperature of cylinders and engines, moisture at different steps of the production process and at end of production before loading loose pasta into bins. All these are recorded on document "Controllo di processo di produzione pasta corta". Moisture control is performed with 3 thermobalances available at work station into production area, they are calibrated and an internal ring test has been performed for verification of data. At packaging area the process controls are included in the "Ordine di confezionamento" (Packaging order) and include correct usage of packaging material, correctness and readability of lot / expiry date, routine checks for correct weight (with a calibrated offline scale), defects at sealing, lot coding on cardboard cartons, average weight of packages (periodically recorded by the display of the checkweigher). Process controls of pasta are also performed off line by the QC lab : pasta dimensions and thickness, texture are performed to verify the status of consumption of dies. A document is present "Monitor trafille" in which there results of thickness and dimensions are listed to assess the need of change dies. Cooking tests are also performed at start and end of placement of any die.

**6.2 Labelling and pack control**

On each packaging order "Ordine di confezionamento" the article code of each packaging material to be used is present. On the label of each packaging material the article code is required to be present. The absence of other packaging on the packing line is recorded on start-up check record. The number of article code and type must also be reported by the employee on the "Ordine di Confezionamento" for confirmation of correct use. Further verification is performed during packaging by in process QC. The labels used for each packaging lot are attached to the Packaging Order for evidence of usage. When change of product is needed, the packaging roll is placed on a pallet and warehouse employee for packaging materials is asked to return in the storage warehouse, where it is replaced in their original plastic bag and appropriately stored. At the audit time randomly checked packaging operation for wheat durum pasta capellini L0314, vermicelli L0314, tagliatelle nest L0314, route L0314, helicoidal L0315, fusilli IGP L0315, half sleeves rigate L0315, macaroni L0315, organic casarecce L0315, vermicelli IGP L0315.

**6.3 Quantity, weight, volume and number control**

All packaging lines are equipped with automatic checkweighers for online weight check according to national rules (L. 690/78). Underweight packages are available according to the law requirements and are passed before starting packaging for effective functioning of rejection system. Identification with a red belt of packages is present to avoid accidental use of these packages. Routine monitoring of effective weight by checkweighers is performed by in process QC personnel using calibrated and legally verified offline scales. "Radweg" scale is present on a mobile tray which is transferred at packaging lines and a package is weighed either at checkweigher and then at offline scale. A maximum tolerance range has been defined for acceptance (+-2 g), in the event of deviation line is stopped and maintenance / verification procedure to the checkweigher is required. From traceability test Auditor chose to follow through Penne Rigate 500g packed into flowpack and cardboard cartons 8 x 500 g, L0246.

**6.4 Calibration and control of measuring and monitoring devices**

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A list of equipment under calibration is present and updated 04.02.2020. Scales (checkweigher and offline scales), 2 primary probes (used for internal calibration of probes) and thermobalance are present. Primary instruments and working instruments are defined for each area. 2 primary probes are present (calibrated every 3 years), other primary instruments are parallel shapes for micrometres (calibrated every 10 years). A list of scales is present on document "Elenco machine confezionamento". 20 checkweighers are reported being present, while 3 offline scales are present at packaging area for verification of dynamic weight check. Annual legal verification required, seen report 03.11.2020 Certificate of calibration for primary probes are present by LAT 141 ("Migliore Russo") certificate of calibration nr LAT 141 17-065 and 17-066. Dated 31.03.17 (30-60-90°C the first one and 500-600°C the second one for the mitten at lab).  
Metal detector are calibrated at least quarterly, seen records dated sept 2020.

Details of non-applicable clauses with justification

Clause/section reference	Justification
6.1.3	No in-line monitoring devices in place.
6.2.4	No on-line vision equipment used to check product labels and printing.

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**7. Personnel**

**7.1 Training: raw material handling, preparation, processing, packing and storage areas**

Training program electronically managed by the software system "Gestione Qualità" on 'piano formazione del personale 2020'. Training is mostly performed for CCPs monitoring and company hygiene rules). Internal training has been also provided for competence of employees in the identification of insects for routine daily internal monitoring of stations available. A record of training is manually performed on "Intervento formativo / informativo", checked training for culture dated 30.10.2020, USA labelling dated 24.01.2020, PCQI dated 04.09.2020,OCA 05.10.2019, metal detector management dated 03.02.2020 and 22.09.2020, process control dated 28.-01.2020,cleaning 09-12-13-14.10.2020. During the annual management review the results of annual training sessions are discussed and evaluated for compliance.

**7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas**

A suitable hygiene policy has been defined by the company into "Prescrizioni igieniche per gli ambienti lavorativi". recently updated for the forbidden use of electronic cigarettes, the possibility of usage of glasses, the communication of hand washing pictograms posted at walls. Instruction include no smoking rules (all over the company), the prohibition of any usage of food and drink consumption in production, packaging and storage areas, jewellery policy (no jewels are allowed apart from a plain wedding ring), the exclusive usage of blue plasters (distributed by QA personnel and tested at each new lot under the metal detectors), blade policy (controlled distribution of detectable cutters, single blade). Medicinals are not allowed in the company apart from the changing areas. Clothing rules are also defined and the need of daily change of clothes.

Visitors rules include the need of registration at receipt on a register, the receipt of a leaflet for security aims, the need to be accompanied by an authorized person in production areas, the signing for acceptance of hygiene and safety rules at receipt. Hand cleaning station is available at entrance of production areas where electronic command for water, blue disposable paper and liquid soap is present. At this station the distribution of disposable clothes (blue overall, headgear) is present. A microbiological carpet at floor is present at entrance for cleaning of foot soles.

**7.3 Medical screening**

A medical nurse is present in the company twice/week for visits and medical assistance to employees, while once/year a medical doctor is required to come in the company for legal visits according to the national law. Confidential document is given to the company, together with the release for production in food companies. At entrance the auditor has been required to fill a questionnaire for health status declaration.

**7.4 Protective clothing: employees or visitors to production areas**

Due to the process performed (mostly an enclosed process) and the zoning (no high care or high-risk areas have been identified) the clothing rules foresee only white shirts and trousers, security white shoes and a disposable headgear are worn. Maintenance personnel wear blue clothes while the external cleanin company is identified with a green headgear. A new external service provider is present (AlSCO, certification for biocontamination removal after washing available) for external laundry. Dedicated lockers are present for each employees for clean clothes (which are returned to employees sealed into transparent packaging). No high care or high-risk areas are present therefore no use of gloves is required by the company. No items which cannot be laundered are present.

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Details of non-applicable clauses with justification	
Clause/section reference	Justification

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<b>8. High-Risk, High-Care and Ambient High-Care Production Risk Zones</b>	
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones	
NA	
8.2 Building fabric in high-risk and high-care zones	
NA	
8.3 Maintenance in high-risk and high-care zones	
NA	
8.4 Staff facilities for high-risk and high-care zones	
NA	
8.5 Housekeeping and hygiene in the high-risk high-care zones	
NA	
8.6 Waste/Waste disposal in high risk, high care zones	
NA	
8.7 Protective clothing in the high-risk high-care zones	
NA	
Details of non-applicable clauses with justification	
Clause/section reference	Justification
8	No high risk, high care, ambient high care

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9 - Traded Products

9.1 Approval and performance monitoring of manufacturers/packers of traded food products

Pasta Garofalo brands are also produced by other pasta producer: Gluten free is produced either at "Pasta Lensi" (Verolanuova – BS), an BRC code 1190705; Labor srl certified BRC code 7401572, Newlat SPA certified BRC code 5135442, De Matteis Agroalimentare spa certified BRC code 7051424, La Bolognese Srl certified BRC code 8640686; Wheat flour: "Selezione Casillo srl - Corato via sant'Elia" BRC code 1605047; Special mix flour: Geovita srl - Bruno site FSSC certified expiry date 28/12/2020; extra virgin olive oil: "Manfredi Barbera&Figli" BRC code 6825701; Fresh pasta: filled pasta: "Bertagni 1882 srl" (VI) BRC code 1716913; 'Pastificio Gaetarelli srl' BRC code 1705057; not filled pasta: P.A.C. srl BRC code 5257017; Dumpling/gnocchi: Il pastaio Srl - Torbole site BRC code 7815886;pasta souse: Montanini Conserve alimentari sas BRC code 1139444; La Doria SpA Parma site - BRC code 6398602;dried tomatoes in oil: Fiordelisi srl BRC code 5614174;bulgur, quinoa and cous cous: Geovita srl Villanova Monferrato BRC code 2005023;Tomatoes: suppliers are "Calispa spa", BRC code 1282243; SICA srl BRC code 1361183; ICAB/La Fiammante SpA BRC code 1154829. The company has defined an agreement with suppliers, seen Bertagni 1882 dated 01.04.19, Selezione Casillo, dated 19.04.19.

9.2 Specifications

The specifications are defined according to suppliers, seen Mezzeluna ricotta di bufala con porcini e tartufo dated 27.06.19, Garofalo specification dated 23.07.19 with label approval; Gnocchi farina integrale dated 12.07.19, Garofalo specification dated 12.07.19 with label approval.

9.3 Product inspection and laboratory testing

"Piano della Qualità prodotti commercializzati" includes requirement for supplier qualification:

- Pre-requisites (GFSI certification)
- Incoming controls and tests

A sampling and testing procedure is also present for products when received at service provider's finished product warehouse ("Number One Logistica"). Records of inspections and testing are on document "Quantità idonea alla vendita", a flag for each reference sample by the employee is present for compliance with checks performed. After these checks the document is passed to the Head of in process QC at packaging area for electronic release (products loaded on warehouse software are automatically blocked).

9.4 Product legality

All products different from dry pasta are tested for legal compliance according to a sampling plan on shelves at retailers by an external accredited lab (Merieux). For dry pasta all pasta lots are received from outsourcers and are tested at receipt for legal compliance for chemical parameters (ash, protein, moisture content). Piano della qualità prodotti commercializzati date 14/12/2017 "Controllo analitico prodotti copaker" include analysed for semolina ash protein and Moisture content.

9.5 Traceability

All outsourced products are traced with electronic system "SAP". All products are received at the company, traced on electronic software. Some products may be transferred directly to external warehouse "Number One Logistica" a dedicated unit in charge for checks directly at the storage provider where inspection and sampling are performed. "Modulo ispezione e campionamento prodotti provenienti da copacker" is a document in which the sampling and inspections at receipt or at storage area are performed.

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Facility Name	<b>Pastificio Lucio Garofalo SpA</b>		
Facility identifier (if designated by FDA)	630998235	FDA registration number (if applicable)	19493040738 expir. 12.31.22 last upd. 12.09.20
Address	Via dei Pastai 42		
City & State/Province	Gragnano (NA)	Postcode	80054
Country	Italy		
Key Contact Name	Sergio De Gennaro	Key Contact Phone	039 0818011002
Key Contact E-mail	degennaro@pastagarofalo.it	Job Number	IT/CT.20200020.0/1
Auditor Name	Ferruccio Marello	Report Date	05.12.2021
Auditor acknowledgement: I acknowledge that I have been trained on the SGS code of integrity and the FDA notification requirements.			
Signed			

<b>Overarching (primary) regulatory scope(s) :</b>			
Scheme Reference	Preventive Controls for Human Food - 21 CFR part 117		<input checked="" type="checkbox"/>
	Preventive Controls for Animal Food - 21 CFR part 507		<input type="checkbox"/>
	Dietary Supplements - 21 CFR part 111		<input type="checkbox"/>
	Low Acid Canned Food - 21 CFR part 113		<input type="checkbox"/>
	Seafood HACCP - 21 CFR part 123		<input type="checkbox"/>
	Juice HACCP - 21 CFR part 120		<input type="checkbox"/>
	Produce Safety Rule - 21 CFR part 112		<input type="checkbox"/>
Client Representative:	Sergio De Gennaro	Site Preventive Controls Qualify Individual (PCQI):	Sergio De Gennaro
Audit Type:	VQIP Regulatory Audit	Visit Type:	Initial audit
Date(s) of audit:	05.10.2021	Total Days on-site	3
No. of Employees (FTE):	216	No. of Shifts:	3
Lead auditor:	Ferruccio Marello	Additional audit team member(s):	none
Scope of audit:	Manufacture of macaroni (04 A G T 02), whole wheat macaroni (04 A G T 10) and tricolor pasta (04 A G T 02).		



<b>Audit Findings</b>	
The food safety system documentation and records demonstrated conformity with the requirements of the regulation(s) and provided sufficient structure to support implementation and maintenance of the food safety system.	Yes
The organization has demonstrated effective implementation and maintenance / improvement of its food safety system.	Yes
Preventive Controls have been established and managed adequately.	Yes
Qualifications and training requirements have been implemented effectively.	Yes
Recall processes have been established and are adequate.	Yes
Throughout the audit process, the food safety system demonstrated overall compliance with the requirements of the regulation(s).	Yes

<b>Significant Audit Trails Followed</b>	
The specific processes, activities and functions reviewed are detailed in the Audit Planning Matrix and the Audit Plan. In performing the audit, various audit trails and linkages were developed, including the following primary audit trails that were followed throughout the audit:	
Recent changes including organization, documentation, products, facilities, processes, key personnel, client activities, management system, level of integration etc. during the past 2 years.	<p>The Top Management has started an important augment of the process area, constructing a new area, more big then after, but only for improve producted tons and not for modifying products or process, neither about USA reference, nor about other Countries.</p> <p>So, this changes don't impact over Food Safety Plan or Food Safety Program, Preventive Controls or cGMP, because the same already in place will be applicated as is in the new area.</p> <p>Work is in progress and it will be reasonably finished within the end of 2021.</p> <p>Food Safety Team (5 PCQI) has scheduled a specific meeting for evaluating existent Food Safety Plan and for determining if changes are requested or not.</p>
<b>Process overview:</b> <i>Process flow of specific process followed. Audit trail demonstrates process approach audit</i>	<p>The process flow of "Macaroni Product" is: 1) Receiving packaging; 2) receiving semolina; 3) pumping water; 4) storing packaging; 5) storing semolina; 6) softening water; 7) water UV treatment; 8) mixing of ingredients; 9) extrusion and cutting; 10) drying; 11) cooling; 12) milling pasta; 13) cutting; 14) shredding pasta edges; 15) packing; 16) metal detection; 17) storing; 18) shipping.</p> <p>Process Flow Diagram rev. 12.30.2020 (supersedes 05.10.2019).</p> <p>Process Narrative rev. 12.30.2020 (supersedes 05.10.2019).</p> <p>NB: there are 3 flow diagrams, one for each product sent in USA, but there il only 1 production line and so the 3 process are quite the same.</p>





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

# CERTIFICATE OF TRAINING

is awarded to

## SERGIO DE GENNARO

in recognition for having successfully completed  
the Food Safety Preventive Controls Alliance course:

### FSPCA Preventive Controls for Human Food

delivered by Lead Instructor,

Mario Sangiorgi

completed on,

02/08/2017

Robert Brackett, VP and Director  
Institute for Food Safety and Health

Gerald Wojtala, Executive Director  
International Food Protection Training Institute

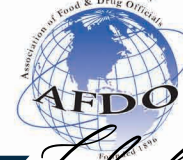
Joseph Corby, Executive Director  
Association of Food and Drug Officials



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TRAINING INSTITUTE



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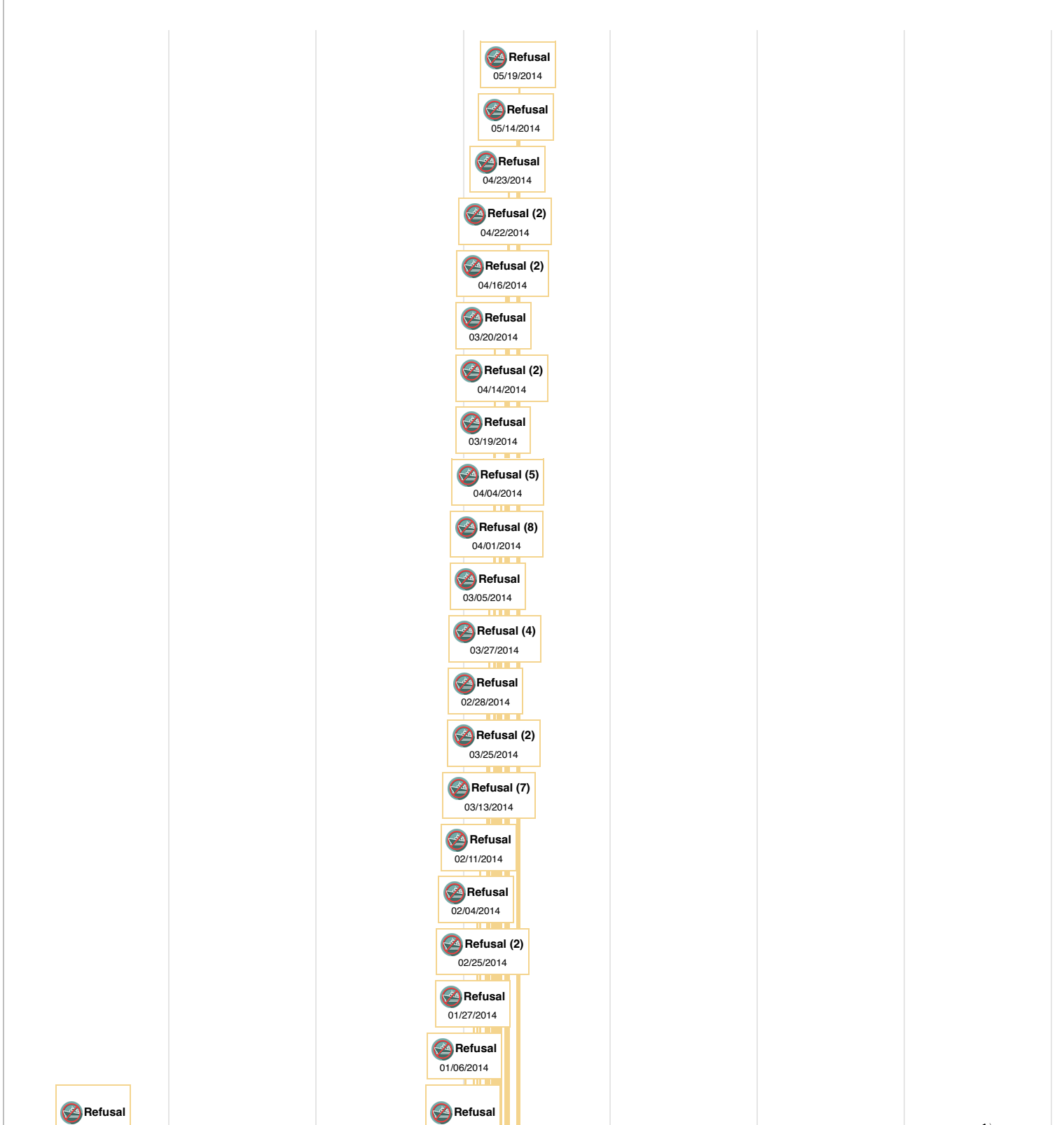
CONFIDENTIAL TREATMENT REQUESTED

## Search Results

<b>FEI Number</b>	<b>Firm Name</b>	<b>Physical Address</b>	<b>Mailing Address</b>
3003845382	Pastificio Lucio Garofalo S.p.a.	Via Dei Pastai 42, Gragnano, Naples, 80054, IT	Via Dei Pastai 42, Pastai, IT

## FDA Actions Timeline

Display Filter: Inspections  Compliance Actions  Recalls  Refusals





**3003845382 – Pastificio Lucio Garofalo S.p.a.**

**Inspections**

Inspections	Classifications
1	1

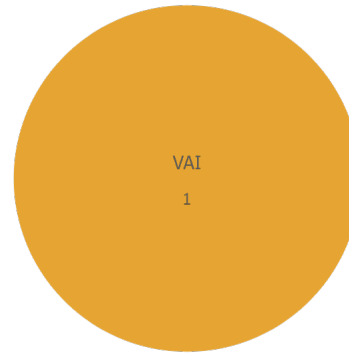
**Inspection Classifications by Fiscal Year**

Fiscal Years: 2019 - 2019



**Inspection Classifications by**

Fiscal Years: 2019 - 2019



**Inspections Details**

Inspection ID	Inspection End Date	Project Area	Product Type	Classification
1084534	03/20/2019	Foodborne Biological Hazards	Food/Cosmetics	VAI

3003845382 – Pastificio Lucio Garofalo S.p.a.

### Inspections Citations Details

Inspection ID	Inspection End Date	Program Area	Act/CFR Number	Short Description	Long Description
1084534	03/20/2019	Foods	21 CFR 117.145(b)	Process Controls Monitoring Frequency	Your process controls monitoring frequency was not adequate.
1084534	03/20/2019	Foods	21 CFR 117.150(a)(1)	Process Controls Corrective Action Proced: Estab Implement	You did not establish and implement adequate written corrective procedures for process controls.
1084534	03/20/2019	Foods	21 CFR 117.165(b)	Process Controls Verification Procedures: Establish Implement	You did not establish and implement adequate written process verification procedures.

## Compliance Actions

Warning Letters	Injunctions	Seizures
0	0	0

### Actions by Percentage

Fiscal Years: 2009 - 2022

No data found for the selected firm

### Compliance Actions Details

No data found for the selected firm

## Recalls

### Recalled Products by Classification

Fiscal Years: 2012 - 2022

F

No data found for the selected firm

No d

### Recalls Details

No data found for the selected firm

3003845382 – Pastificio Lucio Garofalo S.p.a.

## Import Refusals

### Refusals by Product Category

Fiscal Years: 2011 - 2014



### Import Refusals Details

Product Code and Description	Refused Date	Refusal Charges	Shipment ID
04AGT01 \ MACARONI ENRICHED	04/23/2014	3721	DF4-0364124-7/2/3/
04AGT01 \ MACARONI ENRICHED	04/22/2014	3721	DF4-0364124-7/1/2/

04AGT01 \ MACARONI ENRICHED	04/22/2014	3721	DF4-0364203-9/1/6/
04AGT01 \ MACARONI ENRICHED	04/14/2014	3721	EE9-0232570-7/1/1/
04AGT01 \ MACARONI ENRICHED	04/14/2014	3721	EE9-0232570-7/2/2/
04AGT01 \ MACARONI ENRICHED	04/01/2014	3721	DF4-0363854-0/1/2/
04AGT01 \ MACARONI ENRICHED	04/01/2014	3721	DF4-0363854-0/1/4/
04AGT01 \ MACARONI ENRICHED	04/01/2014	3721	DF4-0363854-0/1/5/
04AGT01 \ MACARONI ENRICHED	04/01/2014	3721	DF4-0363854-0/1/32/
04AGT01 \ MACARONI ENRICHED	04/01/2014	3721	DF4-0363885-4/1/1/
04AGT01 \ MACARONI ENRICHED	04/01/2014	3721	DF4-0363896-1/1/4/
04AGT12 \ ALIMENTARY PASTE	03/27/2014	3721	224-0537345-1/1/4/
04AGT01 \ MACARONI ENRICHED	03/25/2014	3721	DF4-0363805-2/2/6/
04AGT01 \ MACARONI ENRICHED	03/25/2014	3721	DF4-0363805-2/2/10/
04AGT01 \ MACARONI ENRICHED	01/06/2014	3721	906-2234910-9/4/1/
04AGT05 \ SPAGHETTI	01/03/2014	3721	906-2236955-2/9/1/
04AGH05 \ SPAGHETTI	01/27/2014	325	906-2233072-9/1/1/
04AGT01 \ MACARONI ENRICHED	05/19/2014	253	DF4-0363711-2/1/1/
04AGT05 \ SPAGHETTI	05/14/2014	253	906-2253287-8/6/1/
04AGT05 \ SPAGHETTI	04/16/2014	253	AJY-0228466-8/1/2/
04AGT05 \ SPAGHETTI	04/16/2014	253	AJY-0228466-8/1/11/
04AFT05 \ SPAGHETTI	04/04/2014	253	417-0294075-4/1/2/
04AGH05 \ SPAGHETTI	04/04/2014	253	906-2233076-0/1/1/
04AGT05 \ SPAGHETTI	04/04/2014	253	DF4-0362519-0/1/5/
04AGT05 \ SPAGHETTI	04/04/2014	253	DF4-0362519-0/1/6/
04AGT05 \ SPAGHETTI	04/04/2014	253	DF4-0362519-0/1/12/
04AGT05 \ SPAGHETTI	04/01/2014	253	DF4-0361766-8/1/1/
04AGT05 \ SPAGHETTI	04/01/2014	253	DF4-0361766-8/1/2/
04AGT01 \ MACARONI ENRICHED	03/27/2014	253	DF4-0363805-2/2/16/
04AGT05 \ SPAGHETTI	03/27/2014	253	DF4-0363805-2/2/12/
04AGT05 \ SPAGHETTI	03/27/2014	253	DF4-0363805-2/2/17/
04AGT05 \ SPAGHETTI	03/20/2014	253	DF4-0362510-9/1/1/
04AGT05 \ SPAGHETTI	03/19/2014	253	906-2249870-8/7/1/
04AGT05 \ SPAGHETTI	03/13/2014	253	DF4-0361965-6/1/2/

04AGT05 \ SPAGHETTI	03/13/2014	253	DF4-0361965-6/1/3/	
04AGH05 \ SPAGHETTI	03/05/2014	253	906-2233078-6/1/1/	
04AGT05 \ SPAGHETTI	02/28/2014	253	DF4-0361964-9/1/2/	
04AGT05 \ SPAGHETTI	02/25/2014	253	DF4-0361647-0/1/1/	
04AGT05 \ SPAGHETTI	02/25/2014	253	DF4-0361647-0/1/2/	
04AGT05 \ SPAGHETTI	02/11/2014	253	DF4-0361961-5/1/11/	
04AGT05 \ SPAGHETTI	02/04/2014	253	906-2236955-2/1/1/	
04AGT05 \ SPAGHETTI	03/13/2014	249	DF4-0361965-6/1/21/	
04AGT12 \ ALIMENTARY PASTE	03/13/2014	249	DF4-0361965-6/1/19/	
04AGT12 \ ALIMENTARY PASTE	03/13/2014	249	DF4-0361965-6/1/20/	
04AGT12 \ ALIMENTARY PASTE	03/13/2014	249	DF4-0361965-6/1/22/	
04AGT12 \ ALIMENTARY PASTE	03/13/2014	249	DF4-0361965-6/1/23/	
04AGT05 \ SPAGHETTI	06/29/2011	249	551-9384403-7/4/1/	

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## Import Alerts



- Search results are not returned based on an exact match of the firm name. Users should review the search results to determine whether the firm appears in the Import Alerts database.
- Only current/active Import Alerts are displayed. For more information see [Import Alerts](#).

No Import Alerts data found for the selected firm.

**3003845382 – Pastificio Lucio Garofalo S.p.a.**

## Warning Letters



- The search results below should be reviewed to determine whether the firm is directly or indirectly referenced in the Warning Letter.
- Only Warning Letters issued in the last 5 years are displayed. For more information see [Warning Letters](#).

No Warning Letters data found for the selected firm.

### Caveats:

- Certain information in these datasets may not be presented or may have changed since the posting. The datasets are updated weekly and only include final actions. If you need to use this information for official purposes or have questions about obtaining other data, please contact the [Division of Freedom of Information](#) about what materials may be available in electronic reading or print format to satisfy your needs.
- Compliance data provide information on a subset of the actions used by the FDA to bring firms into compliance, specifically data pertaining to Warning Letters, Seizures, and Injunctions. Only finalized and completed actions and are primarily used in the domestic arena.
- More than one establishment may be associated with one compliance action. The counts provided in this section reflect the number of establishments linked to the compliance action.
- For more information regarding the Center for Tobacco Products (CTP) issued warning letters click [here](#).

ASC_ID	CHRG_CODE	CHRG_STM	SCTN_NAME
71	NO LICENSE-		The article is 801(a)(3), 505, 502(f)(1); UNAPPROVED, MISBRAND
72	NEW VET DR		The article is 501(a)(5), 801(a)(3); ADULTERATION
73	DRUG COLOI		The article a  502(m), 801(a)(3); MISBRANDING
74	GINSENG-74		The article a  402(a)(2)(C), 801(a)(3); ADULTERATION
75	UNAPPROVE		The article a  505(a), 801(a)(3); UNAPPROVED NEW DRUG
78	STERILITY-78		The article a  501(a)(2)(A), 801(a)(3); ADULTERATION
82	RX LEGEND-8		The article a  502(a) & (f)(1), 801(a)(3); MISBRANDING
83	NO PROCESS		The article 402(a)(4), 801(a)(3); ADULTERATION
84	RX DEVICE-8		The article a  502(a),(f)(1), 801(a)(3); MISBRANDING
115	DR QUALITY-		The article a  501(b), 801(a)(3); ADULTERATION
117	DANGEROUS		The article a  502(j), 801(a)(3); MISBRANDING
118	NOT LISTED-		It appears th 502(o), 801(a)(3); MISBRANDING
122	ANTIBIOTIC-		The drug app 502(l), 801(a)(3); MISBRANDING
123	BANNED-123		The article a  501(g), 801(a)(3); ADULTERATION
126	FAILS STD-12		The article a  501(e), 801(a)(3); ADULTERATION
152	SOAKED/WE		The article a  402(a)(4), 801(a)(3); ADULTERATION
154	FLUOROCAR		The article a  402(a)(2)(A), 801(a)(3); ADULTERATION
156	NO PERMIT-		The article o 1, 2; PROHIBITION WITHOUT PERMIT
157	FOREIGN OB		The article a  402(a)(3), 801(a)(3); ADULTERATION
160	LEAK/SWELL		The article a  402(a)(3), 801(a)(3); ADULTERATION
170	CONTAM CAI		The article a  402(a)(1), 801(a)(3); ADULTERATION
171	CONTAINER-		The containe 402(a)(6), 801(a)(3); ADULTERATION
173	IMITATION-1		The article a  403(c), 801(a)(3); MISBRANDING
175	ALCOHOL-17		The article a  402(d)(2), 801(a)(3); ADULTERATION
178	COL ADDED-		The article a  501(a)(4)(A), 801(a)(3); ADULTERATION
179	AGR RX-179		The article a  801(d)(1),(2); IMPORTATION RESTRICTED
181	UNDER PRC-		The article a  402(a)(4), 801(a)(3); ADULTERATION
185	REDUCED-18		It appears to 501(d)(1), 801(a)(3); ADULTERATION
186	INSANITARY		The article a  501(a)(2)(A), 801(a)(3); ADULTERATION
188	FLUOROCAR		The article a  501(a)(5), 801(a)(3); ADULTERATION
189	FLUOROCAR		The article a  601(a), 801(a)(3); ADULTERATION
197	COSM COLOI		The article is 601(e), 801(a)(3); ADULTERATION
198	COLOR LBLG		The color ad 602(e), 801(a)(3); MISBRANDING
199	FEED & NAD		The article a  501(a)(6), 801(a)(3); ADULTERATION
218	LIST INGRE-2		The article is 403(i)(2), 801(a)(3); MISBRANDING
223	FALSE-223		The labeling 502(a), 801(a)(3); MISBRANDING
226	DEVICE GMP		The methods 501(h), 801(a)(3); ADULTERATION
231	LENS CERT-2		The lenses a  502(a), 801(a)(3); MISBRANDING
235	NOT IMPACT		The article a  501(c), 801(a)(3); ADULTERATION
237	NO PMA-237		The article is 501(f)(1)(B), 801(a)(3); ADULTERATION
238	UNSAFE ADI		The article is 402(a)(2)(C)(i), 801(a)(3); ADULTERATION
241	PESTICIDE-24		The article is 402(a)(2)(B), 801(a)(3); ADULTERATION

245 EXCESS SUL- The article a| 402(a)(1), 801(a)(3); ADULTERATION  
 249 FILTHY-249 The article a| 402(a)(3), 801(a)(3); ADULTERATION  
 251 POISONOUS- The article is 402(a)(1), 801(a)(3); ADULTERATION  
 253 STD IDENT-2 The article 403(g)(1), 801(a)(3); MISBRANDING  
 254 STD QUALIT- The article 403(h)(1), 801(a)(3); MISBRANDING  
 255 STD FILL-255 The article is 403(h)(2), 801(a)(3); MISBRANDING  
 256 INCONSPICU The article is 403(f), 801(a)(3); MISBRANDING  
 258 FLAVR LBLG- The article a| 403(k), 801(a)(3); MISBRANDING  
 260 FALSE-260 The article is 403(a)(1), 801(a)(3); MISBRANDING  
 3580 TP VIOL911- The article is 902(8); 801(a)(3), Adulteration  
 3661 INADQ PAST- The article is 402(a)(4), 801(a)(3); ADULTERATION  
 3600 REFUSE EI-3 The article is 801(a)(1); INSANITARY MANUFACTURING, PROCESS  
 3741 FRNMFGRCC The article is 510(i); 801(o)  
 3641 CHOKE HZRD The article is 402(a)(3), 801(a)(3); ADULTERATION  
 3761 FILTH-3761 The article is 501(a)(1)Adulteration  
 2060 AGRINSULIN The article a| 801(d)(1),(2);IMPORTATION RESTRICTED  
 2080 COUMARIN- The article a| 402(a)(1), 801(a)(3), Adulteration  
 2100 POISONOUS- listeria (test' 402(A)(3)  
 2120 UNSFDIETSP The article a| 402(f)(1)(B), 801(a)(3) Adulteration  
 2140 -2140 %402(a)(1)%  
 2160 LACK NOTIF- Adulterated, 301(s)  
 2161 -2161 301(s)  
 2162 -2162 333333  
 2180 -2180 402(a)  
 2200 DIET INGRE- The article is 402(a)(3), 801(a)(3); Adulteration  
 2201 BSE FILTH-2 The article is 402(a)(3), 801(a)(3); Adulteration  
 2202 INSAN BSE-2 The article is 402(a)(4), 801(a)(3); Adulteration  
 2220 INGRED FIL- The article a| 402(a)(4), 801(a)(3); Adulteration  
 2240 COSMETIC-2 The article is 601(c), 801(a)(3); Adulteration  
 2260 -2260 %402%  
 2261 -2261 %501%  
 2262 -2262 %321%  
 2263 -2263 %402(a)%  
 2264 -2264 %402%  
 2280 DIRSEXMPT- The article is 502(f)(1), 801(a)(3); MISBRANDING  
 2300 DIETARYLBL- The article is 403(s)(2)(B), 801(a)(3), misbranded  
 2340 -2340 The article a| 402(a)(1), 402(a)(2)(A), 402(a)(2)(A);801(a)(3)-ADUL  
 2341 DIOXIN-2341 The article a| 402(a)(1),402(a)(2)(A),402(a)(2)(C)(i),801(a)(3)-Adul  
 2360 HISTAMINE- The article a| 402(a)(1), 801(a)(3); Adulteration  
 2380 NO PMA/PDI The article a| 501(f)(1)(A); 801(a)(3); ADULTERATION  
 2400 COLOR-2400 601%  
 2420 RADIONUC-2 Article appea 402(a)(1); 801(a)(3); Adulteration  
 2440 -2440 \*501\*

2460 UNSFDIETLB The article a| 402(f)(1)(A), 801(a)(3) Adulteration  
 2461 UNSFDIETUS The article is 402(f)(1)(D), 801(a)(3) Adulteration  
 2480 RXPERSONA The article a| 502(a), 502(f)(1), 801(a)(3), MISBRANDING  
 2540 -2540 402%  
 2580 MFRHACCP-2 The product ; 402(a)(4), 801(a)(3)  
 2640 CYCLAMATE- The article a| 402(a)(2)(C); 801(a)(3)  
 2660 -2660 403%  
 2680 SACCHARLBL The article c| 403(i); 803(a)(3) Misbranding  
 2720 DULCIN-2720 The article a| 402(a)(2)(C); 801(a)(3)  
 2740 DR QUALITY-2740 501b  
 2760 -2760 402(a)(3)%  
 2780 DEVICEGMP5 The methods 501(h), 801(a)(1); ADULTERATION  
 2800 POSS N/STR The article a| 501(a)(1); 801(a)(3) ADULTERATION  
 2820 CALIBRATED The article is 502(f)(1); 801(a)(3), misbranding  
 2840 BSE DRUGS- The article is 501(a)(2)(A), 801(a)(1); Adulteration  
 2860 VETDRUGRE The article is 402(a)(2)(C)(ii); 801(a)(3); ADULTERATION  
 2880 RXCOMPOU the labeling ; 503(b)(4)(A) & 502(c), 801(a)(3); MISBRANDING  
 2900 CHLORAMP-; The article a| 402(a)(2)(C)(i), 801(a)(3); ADULTERATION  
 2920 PESTICIDES-2 The article is 402(a)(2)(B), 802(a)(B); ADULTERATION  
 2940 COSM MISB- The cosmetic 602(a) & 801(a)(3); MISBRANDING  
 2960 FALSECAT-25 The article is 403(t), 801(a)(3)  
 2980 BIO TOXIN-2980 801  
 2981 BIO TOXIN-2 The article is 402(a)(1), 801(a)(3), Adulteration  
 3000 N-RX INACT- The article a| 502(e)(1); 801(a)(3); Misbranding  
 3020 STARANISE-; The article a| 402(a)(2)(C)(i), 801(a)(3), Adulteration  
 3040 HEPATITISA- The article is Section 801(a)(3), 402(a)(1); ADULTERATION  
 3060 POIS CHLOR- The article a| 402(a)(1), 801(a)(3); ADULTERATION  
 3080 DEVNOEXPT-3080 501(i), 801(a)(3)  
 3081 INVDEVICE-3 The article is 501(i), 801(a)(3); ADULTERATION  
 3100 ANDRO-3100 The article is 402(f)(1)(B), 801(a)(3); ADULTERATION  
 3120 EPHEDALK-3: The product ; 801(a)(3), 402(f)(1); ADULTERATION  
 3140 SBGINSENG- The article is 801(a)(3); 403(u) Misbranding  
 3160 NONRSP-VEI The article 402(a)(4), 801(a)(3); ADULTERATION  
 3161 NONRSP-PR The article a| 402(a)(4), 801(a)(3); ADULTERATION  
 3340 DE/RX KIT-35 The article a| 801(d)(1),(2); IMPORTATION RESTRICTED  
 3361 NUTR DEF-3: the infant fo 412(a)(1), 801(a)(3); Adulterated  
 3362 NUTR UNIT-; The article is: 403(f), 801(a)(3); MISBRANDED  
 3400 PB-FOOD-34 The article is 402(a)(1); 801(a)(3); Adulteration  
 3220 NITROFURAI The article is 402(a)(2)(C)(i), 801(a)(3); Adulteration  
 3500 RXLABEL-350 The labeling 503(b)(4)(A), 801(a)(3); MISBRANDING  
 3480 E COLI 157-3 The article a| 402(a)(1), 801(a)(3); ADULTERATION  
 3200 COSM MISB2 The article is 602(a) & 801(a)(3); MISBRANDING  
 3240 NOCONTCOI The low acid 402(a)(4), 801(a)(3); ADULTERATION

3380 EXPIRED-338 the product s 501(c); 801(a)(3) Adulteration  
 3300 ALLERGEN-3 the label fail 403(w) 801(a)(3); Misbranding  
 3420 MELAMINE- The article a| 402(a)(1), 801(a)(3), Adulteration  
 3421 MELAMINE- The article a| 402(a)(2)(C)(i), 801(a)(3); ADULTERATION  
 3422 UNFIT4FOOD The article is 402(a)(3), 801(a)(3); ADULTERATION  
 3440 MELAMINE- The article is 402(a)(2)(C)(i), 801(a)(3); ADULTERATION  
 3520 TP FLAVOR- The article is 902(a)(5), 927(a)(1)(A), 801(a)(3); ADULTERATION  
 3540 NO EXP DAT- The article a| 402(g), 801(a)(3); ADULTERATION  
 3460 VIBRIO-3460 The article a| 402(a)(1), 801(a)(3); ADULTERATION  
 3560 SUPPL GMP- The article a| 402(g)(1), Adulteration, 801(a)(3), Adulteration  
 3260 NO ENGLISH Required lab 502(c); 801(a)(3);Misbranding  
 3320 TRANSFAT-3 The product i 403(q), 801(a)(3) ;MISBRANDING  
 3180 PATULIN-31 The article a| 402(a)(1), 801(a)(3); ADULTERATION  
 3280 FRNMFGR The article is 502(o), 801(a)(3); MISBRANDING  
     9 SALMONELL The article is 402(a)(1), 801(a)(3); ADULTERATION  
 11 UNSAFE COL The article a| 402(c), 801(a)(3); ADULTERATION  
 16 DIRECTIONS- The article a| 502(f)(1), 801(a)(3); MISBRANDING  
 27 DRUG GMPS It appears th 501(a)(2)(B), 801(a)(3); ADULTERATION  
 47 NON STD-47 It appears th 536(a),(b); NON STANDARD  
 48 NEEDS ACID- The food app 402(a)(4), 801(a)(3); ADULTERATION  
 55 OMITTED-55 It appears th 402(b)(1), 801(a)(3); ADULTERATION  
 62 NEEDS FCE- It appears th 402(a)(4), 801(a)(3); ADULTERATION  
 64 YELLOW #5- (The food app 402(c), 403(m), 801(a)(3); ADULTERATION, MISBRAI  
 262 DIETARY-262 The article p| 403(j), 801(a)(3); MISBRANDING  
 265 SUBSTITUTE The article is 402(b)(2), 801(a)(3); ADULTERATION  
 268 CONCEALED- The article is 402(b)(3), 801(a)(3); ADULTERATION  
 274 COLOR LBLG The article a| 403(k), 801(a)(3); MISBRANDING  
 276 PRESRV LBL- The article a| 403(k), 801(a)(3); MISBRANDING  
 278 NO TAG-278 It appears th 536(a),(b); NOT CERTIFIED  
 280 UNSAFE SUE The article a| 402(a)(2)(A), 801(a)(3); ADULTERATION  
 281 BACTERIA-2 The article a| 402(a)(1), 801(a)(3); ADULTERATION  
 283 INSULIN-283 The drug app 502(k), 801(a)(3); MISBRANDING  
 286 POISON PKG The article a| 502(p), 801(a)(3); MISBRANDING  
 288 STD LABEL-2 The article a| 502(s), 801(a)(3); MISBRANDING  
 289 RECORDS-28 The article a| 502(t), 801(a)(3); MISBRANDING  
 290 DE IMP GMP The methods 801(a)(1); NON CONFORMING MANUFACTURING PF  
 292 SUBSTITUTE It appears to 501(d)(2), 801(a)(3); ADULTERATION  
 293 SHIGELLA-29 The article a| 402(a)(1), 801(a)(3); ADULTERATION  
 295 LISTERIA-29 The article is 402(a)(1), 801(a)(3); ADULTERATION  
 297 AFLATOXIN- The article a| 402(a)(1), 801(a)(3); ADULTERATION  
 299 IMBED OBJT The article a| 402(d)(1), 801(a)(3); ADULTERATION  
 300 NONNUT SU The article a| 402(d)(3), 801(a)(3); ADULTERATION  
 302 BUTTER-302 The article a| 402(e), 801(a)(3); ADULTERATION

304 STERILITY-3C The article a| 501(a)(1), 801(a)(3); ADULTERATION  
306 INSANITARY The article a| 402(a)(4), 801(a)(3); ADULTERATION  
308 MFR INSAN- The article is 801(a)(1); INSANITARY MANUFACTURING, PROCESS  
309 FORBIDDEN- The article is 801(a)(2); FORBIDDEN OR RESTRICTED IN SALE  
310 POISONOUS The article 601(a), 801(a)(3); ADULTERATION  
312 FILTH-312 The cosmetic 601(b), 801(a)(3); ADULTERATION  
313 HELD INSAN- The cosmetic 601(c), 801(a)(3); ADULTERATION  
314 CONTAINER- The containe 601(d), 801(a)(3); ADULTERATION  
315 ADDED BULK The article is 402(b)(4), 801(a)(3); ADULTERATION  
316 \*\*\*-316 The food app 402(a)(5), 801(a)(3); ADULTERATION  
318 VITAMN LBL The food app 403(a)(2), 801(a)(3); MISBRANDING  
319 WRONG IDE The article is 403(b), 801(a)(3); MISBRANDING  
320 LACKS FIRM- The article 403(e)(1), 801(a)(3); MISBRANDING  
321 LACKS N/C-3 The article is 403(e)(2), 801(a)(3); MISBRANDING  
324 NO ENGLISH The article is 403(f), 801(a)(3); MISBRANDING  
325 STD NAME-3 The article is 403(g)(2), 801(a)(3); MISBRANDING  
327 OPTION ING It appears to 403(g)(2), 801(a)(3); MISBRANDING  
328 USUAL NAM The article is 403(i)(1), 801(a)(3); MISBRANDING  
329 JUICE %-329 It appears th 403(i)(2), 801(a)(3); MISBRANDING  
330 UNSAFE COL The article a| 501(a)(4)(B), 801(a)(3); ADULTERATION  
331 DR QUALITC- The drug app 501(c), 801(a)(3); ADULTERATION  
332 CONTAINER- The containe 501(a)(3), 801(a)(3); ADULTERATION  
333 LACKS FIRM- The article is 502(b)(1), 801(a)(3); MISBRANDING  
335 LACKS N/C-3 The article is 502(b)(2), 801(a)(3); MISBRANDING  
336 INCONSPICU Information | 502(c), 801(a)(3); MISBRANDING  
337 OFF ODOR-3 The article a| 402(a)(3), 801(a)(3); ADULTERATION  
339 TAMPERING It appears th 501(a)(2)(B), 801(a)(3); ADULTERATION  
341 REGISTERED It appears th 502(o), 801(a)(3); MISBRANDING  
342 PERSONALR The article a| 502(a) & (f)(1), 801(a)(3); MISBRANDING  
343 VET LEGEND The article a| 502(a) & (f)(1), 801(a)(3); MISBRANDING  
344 WARNINGS- It appears to 502(f)(2), 801(a)(3); MISBRANDING  
346 REJECT TEA- The article is 1 (21USC41); PROHIBITED TEA  
469 DISEASED-46 The food app 402(a)(5), 801(a)(3); ADULTERATION  
471 CSTIC LBLG-4 The labeling 602(a) and/or (b), and/or (c), 801(a)(3); MISBRANDII  
472 NO ENGLISH Required lab 502(c); 801(a)(3) ;MISBRANDING  
473 LABELING-4 The article a| Section 4(a); 801(a)(3) Misbranding  
474 COSMETLBL (It appears th 5(c)(3)(A); 801(a)(3) Misbranding  
475 COSMETLBL (It appears th 5(c)(3)(B); 801(a)(3) Misbranding  
476 NO REGISTR The article a| 536(a); Failure to file initial report  
477 HOLES-477 The quality o 501(c); 801(a)(3) Adulteration  
478 TISSUE-478 This human c 361  
479 DV QUALITY- The article is 501(c); 801(a)(3) Adulteration  
480 STAINSTEEL- The article a| 501(c); 801(a)(3) Adulteration

481 LBL STEEL-4 The labeling 502(a); 801(a)(3); Misbranding  
 482 NUTRIT LBL- The article a| 403(q); 801(a)(3); Misbranding  
 483 DRUG NAME The article a| 502(e)(1); 801(a)(3); Misbranding  
 484 DV NAME-4 The article a| 502(e)(2); 801(a)(3); Misbranding  
 487 SACCHARIN- The article c| 403(o); 801(a)(3) Misbranded  
 488 HEALTH C-48 The article a| 801(a)(3); 403(r)(1)(A)/(B) misbranding  
 508 NO 510(K)-5 The article is 801(a)(3); 502(o) Misbranding  
 509 NONSTEEL-5 Labeling app 502(a) and/or 502(f)(1); Misbranding  
 2000 IMPTRHACCF The food app 801(a)(3) , 402(a)(4) Adulteration  
 2020 LBLG ADVER The art appr 502(a), 201(n) and 801(a)(3) Misbranding  
 2040 SULFITE LBL- The article is 403(a)(1), 801(a)(3) ;MISBRANDING  
 3601 IMITN DR-36 The article 502(i) (2), 801(a)(3); MISBRANDING  
 3602 DR PACKNG The article is 502(i) (1), 801(a)(3); MISBRANDING  
 3603 OTHER DRUG The article is 502(i) (3), 801(a)(3); MISBRANDING  
 3701 ALRGN 402A it appears to 801(a)(3); 402(a)4; Adulterated  
 3621 JUICE HACCP- The article is 801(a)(3);402(a)(4)  
 3721 PESTICIDE 2- The article is 402(a)(2)(B); 801(a)(3); ADULTERATION  
 3801 FALSERXLBL- The article is 503(b)(4)(B), 801(a)(3)  
 3681 NCONTACTS The product i 403(y), 801(2)(3); Misbranding  
 3781 TPNOWRNLE This article is 903(a)(8)(B)(i);801(a)(3);MISBRANDING  
 3782 TPLBLFALSE- This article 903(a)(1);801(a)(3);MISBRANDING  
 3841 AF-NONRSP- The article 402(a)(4), 801(a)(3);ADULTERATION  
 3842 TP NO PMTA This article 801(a)(3);902(6)(A);ADULTERATION  
 3843 TP NO SE-38 This article is 801(a)(3);903(a)(6);MISBRANDING  
 3844 SACCHARLBL The article a| 403(i), 801(a)(3); Misbranding  
 3846 807REFUSAL The food is s 807(b)  
 3847 FDF4APIGMF The article is 501(a)(2)(B), 801(a)(3); ADULTERATION  
 3864 NCONTACT- The article is 403(y), 801(a)(3); MISBRANDING  
 3848 TP NO ING-3 This article is 903(a)(10)(A); 801(a)(3) MISBRANDING  
 3849 TP NO HPHC- This article is 903(a)(10)(A); 801(a)(3) MISBRANDING  
 3850 TPNOHLDOC This article is 903(a)(10)(A); 801(a)(3) MISBRANDING  
 3865 COLORLABEL The article is 403(f);801(a)(3);MISBRANDING  
 3866 708NEWANI The article h| 501(a)(5), 801(a)(3); ADULTERATION  
 3867 708NORX-38 The article f 502(a) & (f)(1), 801(a)(3); MISBRANDING  
 3868 708VETLGNC The article f 502(a) & (f)(1), 801(a)(3); MISBRANDING  
 3869 708LBLFIRM The article f 502(b)(1), 801(a)(3); MISBRANDING  
 3870 708NOENGL Required lab 502(c); 801(a)(3) ;MISBRANDING  
 3871 708NODIREC The article f 502(f)(1), 801(a)(3); MISBRANDING  
 3872 708LISTING- It has been d 502(o), 801(a)(3); MISBRANDING  
 3873 708NOREG- It has been d 502(o), 801(a)(3); MISBRANDING  
 3874 708NEWDRU The article h| 505(a), 801(a)(3); UNAPPROVED NEW DRUG  
 3875 708REIMPRT The article f 801(d)(1),(2); IMPORTATION RESTRICTED  
 3876 GDUFA FEE- The article is 502(aa), 801(a)(3);MISBRANDING

3877 GDUFA SELF The article is 502(aa),801(a)(3); MISBRANDING  
3878 POISONORD The article is 402(a)(1), 801(a)(3); ADULTERATION  
3879 708UDECAPI The article is 502(a), 801(a)(3); MISBRANDING  
3880 708FALSE-38 The labeling 502(a), 801(a)(3); MISBRANDING  
3862 DIETARYING The article is 403(s)(2)(A),801(a)(3); MISBRANDING  
3863 PLANT PART The article is 403(s)(2)(C), 801(a)(3); MISBRANDING  
3821 MFR INJ-382 The article is 402(a)(4),801(a)(3); ADULTERATION  
3851 TPLACKFIRM This article is 903(a)(2)(A); 801(a)(3); MISBRANDING  
3852 TPLACKSNC- This article is 903(a)(2)(B); 801(a)(3); MISBRANDING  
3853 TPLKDOMFO This article is 903(a)(2)(C); 801(a)(3); MISBRANDING  
3854 TPLKUSSLLB- This article is 903(a)(2)(D); 801(a)(3); MISBRANDING  
3855 TPFDA1LBLG This article is 903(a)(1); 801(a)(3); 301(tt)(1); MISBRANDING  
3856 TPFDA2LBLG This article is 903(a)(1); 801(a)(3); 301(tt)(2); MISBRANDING  
3857 TPFDA3LBLG This article is 903(a)(1); 801(a)(3); 301(tt)(3); MISBRANDING  
3858 TPFDA4ALBL This article is 903(a)(1); 801(a)(3); 301(tt)(4)(A); MISBRANDING  
3859 TPFDA4BLBL This article is 903(a)(1); 801(a)(3); 301(tt)(4)(B); MISBRANDING  
3845 DRG REF EI- The article is 801(a)(3), 501(j); ADULTERATION  
3860 TP USERFEE- This article is 902(4);801(a)(3); ADULTERATION  
3861 CYCLAMATE- The article is 801(a)(3)  
3722 RXVETLACK- The article is 503(f)(4), 801(a)(3)  
3723 RXVETLACK2 The article is 503(f)(4), 801(a)(3)  
3724 DEVGMP5-3 The article is 520(f); 801(a)(1)  
3725 NONCOMEL It appears th 534, 536(a)  
3726 ELTNOCERT- It appears th 534, 536(a)

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# Audit Report

Global Standard for Food Safety Issue 8: August 2018

1. Audit Summary			
Company name	Pastificio Lucio Garofalo S.p.A.	Site Code	1383818
Site name	Pastificio Lucio Garofalo S.p.A.		
Scope of audit	Production and packing of dried durum wheat pasta in cardboard, plastic material, big-bag.		
Exclusions from scope	none		
Justification for exclusion	none		
Audit Finish Date	2019-12-12		
Re-audit due date	2021-01-16		

Additional modules included			
Modules	Result	Scope	Exclusions from scope
Choose a module	Choose an item		
Choose a module	Choose an item		

Head Office	No
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2. Audit Results					
Audit result	Certificated	Audit grade	AA+	Audit type	Unannounced
Previous audit grade	AA+		Previous audit date	2018-11-28	
Certificate issue date	2020-01-22		Certificate expiry date	2021-02-27	

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	3

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3. Company Details			
Address	Via dei Pastai 42 80054 Gragnano (NA)		
Country	Italy	Site Telephone Number	+39 081 8011002
Commercial representative Name	Emidio Mansi	Email	mansi@pastagarofalo.it
Technical representative Name	Sergio De Gennaro	Email	degennaro@pastagarofalo.it

4. Company Profile					
Plant size (metres square)	10-25K sq.m	No. of employees	51-500	No. of HACCP plans	1-3
Shift Pattern	3				
Subcontracted processes	No				
Other certificates held	IFS, ISO 14001, OHSAS 18001; ISO 50001, SA8000, Organic, Spiga Barrata, Kosher, Halal, Vegan				
Regions exported to	North America Europe Africa Asia Oceania South America				
Company registration number	Aut. 27.05.16				
Major changes since last BRC audit	New short pasta production line being tested, new MDs purchased to replace the old ones, replacement of the special formats packaging line, implementation of a production planning software.				
<p><b>Company Description</b></p> <p>The company belongs to the Spanish Group HEBRO FOODS. The factory is placed near Naples. Year of construction on 1987. 3 lines for long pasta, 1 special pasta (nests), 4 for short pasta. 14 packaging lines and 8 pallet preparation and wrapping stations are present. All lay out is arranged on a single floor, other floors are present for offices. An internal lab is present. Turnover for 2018 has been 160 million €, of which 44% for domestic market and 56 % for foreign markets. Private labels are approx. 17% production. Emergency contact data: Name: Sergio De Gennaro, +39 320 1594941, Fax (+39) 0818012937, mail degennaro@pastagarofalo.it. Only dry pasta is produced, in some cases with ingredients (spinaches, tomatoes). No. of employees: 200 of which 125 workers fixed full time and 17 workers fixed part time; 54 employees, 3 manager, 1 apprentice; no. of shifts: 3 shift/day for 7 days/week are performed.</p>					

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**4. Company Profile**

The company trades numerous products: pasta and other different products are produced by other approved suppliers. All of them are BRC and/or IFS certified. Some branded (C.) and some company formats of GPI (IGP) products (Pasta di Gragnano) are produced by other companies (e.g. Pastai Gragnanesi soc. coop.) where the company name of production site is clearly written on the packages. Some company branded products are also outsourced. Site area in square meters: 30.000 sqm. total, of which 20.000 sqm. are covered surface. Traded goods: EVO oil, gluten free, fresh pasta (filled and not), cous-cous, bulgur, quinoa, condiments (souce, pesto), flour, special flour, dumplings, tomato products. BRC logo is not used.

**5. Product Characteristics**

Product categories		15 - Dried food and ingredients Category Category Category			
Finished product safety rationale		dried at moisture < 12,5%, Aw < 0.6			
High care	No	High risk	No	Ambient high care	No
Justification for area		The BRC decision tree approach of the company led to the identification of low risk and enclosed product areas			
Allergens handled on site		Cereals containing gluten Soya Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen			
Product claims made e.g. IP, organic		Pasta di Gragnano GPI, 100% semola da grano italiano, Organic			
Product recalls in last 12 Months		No			
Products in production at the time of the audit		Linguine "Tre Mulini IGP" L93431A BB 09.12.22, Mafalda corta "Garofalo" L9343H1 BB 09.12.22, Pappardelle "Garofalo" L9344G 10.12.22.			

6. Audit Duration Details			
On-site duration	22 man hours	Duration of production facility inspection	11 man hours
Reasons for deviation from typical or expected audit duration	extra time 0,5 MD added for the IFS 'combined' audit		
Next audit type selected	Unannounced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-12-09	09-30	19:00
2	2019-12-10	09-30	19-00
3	2019-12-11	09-30	19-00
4 (end date)	2019-12-12	09-30	15-00

	Auditor (s) number	Name	Role
Auditor Number	051031	MAURIZIO GALLO	Lead Auditor
Second Auditor Number	N/A		Please select

Present at audit					
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)					
	Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Giovanni Schisa Operational Director	x				x
Sergio De Gennaro QA Manager	x			x	x
Alessio Stellato QA	x	x	x	x	x
Rosanna Mainardi CQ Production			x	x	
Germana Amadoro CQ Packaging			x	x	

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Present at audit				
Domenico Esposito Receipment semolina Manager		x		
Francesco Esposito Packaging long pasta		x		
Roberta Venanzoni Quality Control		x	x	

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## Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No.	Requirement ref.	Details of non-conformity	Critical or Major?	Anticipated re-audit date

Critical			
No.	Requirement ref.	Details of non-conformity	Anticipated re-audit date

Major							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

Minor							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	4.7.3	Some temporary repairs are present and the company has not defined timescale for permanently reparation.	Has been check all temporary repairs in order to fix them within next plant shut down (end of dec 2019 and beginning of jan 2020). Has been train the maintenance staff as well.	We will issue a formal risk assessment in order to clearly define a timescale for temporary maintenance. Different time for permanent reparation will be used in case of the product is exposed to potential contamination and in case no contamination to food is possible.	Temporary repairs instruction and risk assessment. Training report to maintenance staff.	2020-01-09	MG

2	4.8.3	The cleaned clothes are supplied in plastic bag to protect from contamination until use, but during the audit some cleaned clothing were outside the bag and outside the locker.	Has been train workers about the correct handling and storing of cleaned clothes.	Assure that the service supplier supplies clothes protected as per agreement and we'll check the adequate handling/storing of protective clothes during monthly site inspections.	Training report to workers. Site inspection report.	2020-01-09	MG
3	4.11.6	Cleaning tools are identified and coloured, a specific storage area on panel in which dedicated areas for collection of tools is present, but some cleaning equipment are not correctly stored and identified when not in use.	Has been performed an additional training session to workers in order to explain them how to manage cleaning tools when not in use.	We'll identify dedicated areas in order to store in an adequate manner the required cleaning tools, when not in use. Moreover we'll add some signs explaining the location to store tools used for cleaning activity.	Training report to workers. Signs attached at the plant.	2020-01-09	MG

**Comments on non-conformities**

## Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No.	Requirement ref.	Details of non-conformity	Anticipated re-audit date

**Critical**

**Major**

No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph,	Date reviewed	Reviewed by
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					visit/other		

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Minor							
No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by



## Detailed Audit Report

### 1. Senior management commitment

#### 1.1 Senior management commitment and continual improvement

Quality Policy dated 06.05.19 it refers to safety and security matters, compliance to specifications and no defects policy, good in taste and for sensory characteristics, communicated in social area and IT portal. All personnel are informed with e-mail regarding to publication of document in IT system and invited to consult.

Declaration of intent for the improvement of food quality and safety culture 20.09.19, shared with the staff.  
Food Safety Culture Road Map dated 20.09.19.

Three-year development plan provides for improvement actions to achieve specific objectives:  
training for whistle blowing 19.07.19

questionnaire to be distributed by food safety culture to determine the gaps and plan the necessary training activities, distributed and collected already for the responsible functions, to be extended to all factory operators.

QMS Review annually, seen records dated 31.01.19 in which they were analyzed objectives for 2018 gave been defined into "Obiettivi 2019". In 2018 objectives for process: cleaning standard (NC/inspections <15), complaints reduction (complaints/milion units produced <10%), food safety (% legal conformity 100). "Transparency" project has been completed, full compliance with MRLs on finished products. Objectives 2019 and KPI: NC from GMP during internal audits and second part (<15), reduction of complaints (complaints / million of packs produced <10%) also proposed following improvement actions (re-production of bottura, a year of pasta with formats different).

Training plan 2019 output of QMS review.

Meeting for Objective performed on 31/3/2018, 30/6/2018 (formalized on 10/7/2018) and on 30/9/2018 with trend analyses and objective achievement.

Monthly meetings are performed after the monthly site inspections performed by the external auditor.

Seen Monthly meetings dated 08.10.19 as monthly meeting (food safety, legal conformity, integrity and vulneranibility, quality, ...)

Quarterly meeting march, june, september, december to analyse a trend of KPI and monthly meeting report.

The company is associated with AIDEIPI and Union Food for legislation update.

BRC logo is not in use.

The auditor verified satisfactory during the audit the closing of NCs from last audit.

#### 1.2 Organisational structure, responsibilities and management authority

Organization chart updated at 09.01.19. The President is Spanish (the company is owned by Hebro Foods sa), the CEO is Massimo Menna, QA is also Security and SA 8000 manager, Operation Manager is responsible for all production / packaging and QC areas. Job descriptions have been revised for all functions. The document "Mansionario - Sezione 01 processo aziendale - Allegato 01 Manuale dei Processi (dated 24.01.17) describes all functions included in the Organization chart with their deputy.

### 2 The Food Safety Plan – HACCP

HACCP team listed in the Manual. The CEO, Operation Manager, QA Manager, QC at packaging QC at doughing, Production manager and Head of Maintenance are present. Signature of all participants is present at bottom of the document. Team Leader is Sergio De Gennaro, evidence of HACCP competence for previous work experience as BRC auditor for certification bodies.

HACCP Manual dated 30.10.19. Pre-requisite programmes are described at par. 4 and include Work environment hygiene, Personnel housekeeping and hygiene rules, Pest control, Cleaning, Training, Maintenance, extraneous matters.

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Description of product is in par.3 of HACCP Manual, the specifications are present for each product into technical specifications.

Aw <0,6, Umidity 12%, drawnd at high pressure and dried chemical (e.g. ashes, moisture, gluten content,) merceological parameters (e.g. black and red spots, color), and microbiological (TVC, E. coli, Yeasts and moulds, Cl. perfringens, B. cereus) parameters are defined, together with pesticides and heavy metals are described. Frequency of checks is defined for each category of parameters, semolina specifications are also present in the document. Only gluten allergen presence is defined for restriction to users, soy contamination recently taken into consideration for the unavoidable presence into flour declared by suppliers.

Codex Alimentarius has been followed for HACCP annual planning.

Two flow diagrams are present.

1. Inner production
2. Full Outsourced products

The second process described flow and activities for control of outsourced products and inspection / testings. In the flow diagram for internal productions (dated 31.10.19) the following data are described:

- the process steps
- the process controls for each step
- the key process parameters
- raw materials and packaging materials
- secondary processes and by products (e.g. water)
- secondary processes controls

Each step id coded with number for easy identification.

CCPs are highlighted in red, while ingredients are highlighted in yellow, by products and discards are highlighted in pink, while packaging materials are coloured in green. The flow diagram has been confirmed on site in date 31.10.19 discussed in HACCP management review specifically performed on 11.03.19 and 31.10.19.

A documented hazard analysis and risk assessment is defined in "Analisi HACCP" in HACCP Manual, in which a list of potential hazards linked to process, equipment, personnel work environment, product are listed.

The residual risk evaluation after preventive measures taken has been added for each hazard. For each step the potential hazards are identified for probability and gravity, a risk index is defined and a criterion is of evaluation in the process when risk is > 2. Main hazards take in account: fisici (metallo, legno, plastica, vetro, ...), chimici (micotossine, pesticide, radiologico, ...), microbiologico (Salmonella, E.Coli, Bacillus cereus).

Preventive measures have been taken into consideration for each step to give support for evaluation of Gravity and Severity of each hazard.

1 CCP has been identified:

CCP1: metal detection on packed product (metallic extraneous matters)

Critical limits are:

CCP1: metal detection on packed product (metallic extraneous matters with testes as follows: (Fe= 1,5 mm; Non Fe = 2,0 mm; SS = 2,0 mm). For catering products (5-10 kg packages) testers are Fe= 2,0 mm; Non Fe = 2,5 mm; SS = 2,5 mm. For industrial finished products (in big-bag) testers are Fe= 2,0 mm; Non Fe = 2,5 mm; SS = 2,5 mm

Validation based upon consideration about dimensions of extraneous matters which may pass through and do not represent a risk food safety of consumers.

Corrective actions are described in the document "Piano della Qualità" dated 31.10.19, which include segregation and actions to investigate (rot cause analysis).

Verification procedures are described into chapter 11 of HACCP manual. Inspections and audits are used for verifications. Results are defined in the Management review dated 31.01.19 which takes into consideration:

- sampling from Authorities
- internal lab results
- sampling from customers
- RASFF results
- Customer complaints
- Internal audit

Last review of the HACCP study performed in a specific review dated 31.10.19, annually foreseen which include the status of CCP monitoring and results, customer complaints evaluation, personnel training and equipment calibration status.

**3. Food safety and quality management system**

**3.1 Food safety and quality manual**

Manuale dei Processi updated 31.01.17 in review, some process descriptions have been modified in documented procedure. The structure was based on Manual, documented procedures, relative operative instructions and record forms apart from other supporting documents. Direction approves the documents.  
The documents are clearly legible in sufficient detail and in appropriate languages, managed with IT system and properly software archive, management and distribution.  
Automatic backup with notification of effective saving performed daily.

**3.2 Document Control**

Section 4 of document “Manuale dei Processi” deals with procedure management. An electronic system of data recording has been added since last audit with an intranet portal in which all documents are being introducing for sharing (only reading format for different users than administrator = QAM).

**3.3 Record completion and maintenance**

Section 5 “Gestione delle registrazioni” at QMS Manual “Manuale dei Processi” describes record sheet management. A retaining time is described being 4 years for record sheets, while certificate of analyses are retained for 5 years.

**3.4 Internal audits**

Audits are conducted by an external consultant, qualification through CV.  
In Sect.8 Verifiche Ispettive Interne the company has defined the documented procedure to manage internal audit.  
For 2019 audits have been distributed through the year as audit planning at least 4 dates according to risk assessment  
Audit are scheduled on the internal company portal “Gestione Qualità – Registro Verifiche Ispettive”.  
Audits in 2019 performed monthly, seen records dated 17.25.10.19 NC-AC-AP, incidents, factory, maintenance, equipments, chemical and foreign bodies management, process control, zoning, 13.09.19 HACCP, 19.11.19 cleaning, allergens, waste, surplus food. For each date the planning of all chapters of BRC /IFS are reported.

A report has been prepared by the consultant, some observations have been raised. The company included them in the Portal for “Quality Management - non conformity management”. For each “observation” a NC has been opened. The portal includes a tag for each task. “Trattamento non conformità” (non conformity treatments), “Analisi delle cause” (root cause analysis), “azione correttiva” (corrective action) and “verifica” (verification) are included in the NC management.

Self-inspections are foreseen monthly by an external consultant. A report is present on electronic format in which pictures are attached for each deviation found, seen inspection date 22.11.19.

**3.5 Supplier and raw material approval and performance monitoring**

**3.5.1 Management of suppliers of raw material and packaging**

The company has implemented a documented procedure “Supplier Approval Process” dated 11.09.19.  
Raw material risk assessment takes in account all requirements (allergens, microbiological, chemical and radiological, foreign bodies, pest, fraud adulteration, variety, legal conditions) for each raw material (included traded and outsourced) updated 10.07.19, reviewed at least semi-annually.

Low risk suppliers are qualified according to GFSI certification or external audit or questionnaire (tomato and spinach powder, storage services).  
Medium risk suppliers are qualified according to GFSI certification or external audit (semolina suppliers).  
High risk suppliers are qualified according to GFSI certification and external audit (traded, outsourced products).  
A list of approved suppliers is present in SW Gestione Qualità and shared with office purchase.

In the same document (risk analysis) the evidence of monitoring for annual evaluation of qualification status is present. A legend for criteria for each scoring is present. Criteria include certification GFSI confirmed, n° NC with block of products, n° analytical NC, customer service.

No agents and brokers in use.  
The exceptions are used in case of the supplier is mandatory required by a customer, these suppliers are however

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subjects to the routine qualification and monitoring processes; exceptions in case of tomato products in glass/can that provide an external audit relating to HACCP.

**3.5.2 Raw material and packaging acceptance, monitoring and management procedures**

A dedicated area for receipt, sampling and acceptance is present in which an employee in charge for routine truck inspection and sampling/acceptance analysis is present. A weekly receipt plan is received from planning dept. to inform the employees on semolina receipts and types of semolina. At this area the instruction for truck inspection, sampling, checks at receipt and acceptance criteria is clearly posted at walls (operative instruction “Controllo analitico sfarinati in ingresso con metodo NIR”, dated 19.12.17).

The pictures of most common pests into semolina are also present attached to the instruction. During the site inspection a truck with semolina (SAY internal code) from “Moderne Semolerie” supplier with DDT 7014/00 dated 09.12.19 n° weighs 228878, has been sampled, analysed and accepted according to operative instruction, seen records in IT system regarding to U, proteins, ashes, gluten, gluten index, colour, seal integrity, conformity declaration, cleaning of truck.

NIR analysis is performed for release to unloading of semolina at each delivery, also the certificate of washing of trucks is mandatory for acceptance, together with the declaration of conformity (at any delivery) for compliance with agreed specifications. These documents are checked at receipt and the consigned to the internal lab for storage.

NIR Analysis includes protein, moisture, ash, colour. The results are to be compared with acceptance values reported in the instruction. The NIR software upload automatically the analysis results in the company portal “Gestione Qualità” and are available to be seen by the internal lab. Also visual checks for hygiene and absence of pests is recorded by on NIR and automatically uploaded on Quality portal.

A sample is taken with an aluminium probe at each delivery, sampling from the top of the truck. Some supplier require 4 samples, 2 of which are retained by the company and 2 are given to the truck driver, while for other suppliers 3 samples (2 for the company, 1 to the driver) are prepared.

The samples are identified with a label in which the following data are recorded: barcode (for electronic reading), date of receipt, progressive nr (given by the gate receptionist), ship doc nr, weight (as declared by the ship doc), type of semolina, truck plate. On this label the employee at receipt manually records the number of bin for semolina storage and the hour of start loading. The semolina sample is identified with this label, vacuum packed (a manual machine is present at receipt area) and then transferred to the internal lab for retaining (3 months storage).

**3.5.3 Management of suppliers of services**

Service suppliers are included in the evaluation. External labs, pest control service criteria are defined in the procedure. Pest control, service is based on documentation available by the suppliers and references (pest control companies which worked with mill companies are required). External labs have to be ISO 17025 certified.

**3.5.4 Management of Out sourced processing**

NA

**3.6 Specifications**

The company electronically stores specifications by the suppliers, while for semolina an internal specification is present and agreed with all suppliers. Around 40 finished product specifications, 22 specification for semolina, 3 for other ingredients. Randomly checked

INGREDIENTS all semolina specifications are shared and agreed with relative supplier, seen records regarding to semolina standard SAE rev.2 dated 07.03.19, supplier Candéal Commercio, signed in date 06.05.19. FINAL PRODUCT PTRM018408ae Linguine IGP. PLASTIC PACKAGING MATERIALS are handled by the company, in some cases also paper + plastics is present. Different plastic packaging materials are present:

- BoPP + PP cast for retail products. <sup>[L]</sup><sub>[SEP]</sub>
- paper / PPL coex+PPL cast <sup>[L]</sup><sub>[SEP]</sub>
- LDPE for catering packages <sup>[L]</sup><sub>[SEP]</sub>
- Bags in paper+plastics,
- PP / PE for big bags for loose pasta

supplier “Minini Imballaggi, specifications and food declaration dated <sup>[L]</sup><sub>[SEP]</sub>30.06.17, Rotocalco Mediterranea, specification date 08.07.15, conformity declaration 06.11.18, certificates of conformities are available for each supplier. flexible packaging materials: specifications OPP + CPP dated 08.01.19 from supplier “Nuceria” and

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declaration of conformity dated 04.04.19, certificate BRC IOP site code 2248501, seen migration report n° 0322/FPM/FDC/19 dated 08.04.19

Review every 3 years of all specifications required and performed by the company. All specifications have been included in the company software "Gestione Qualità".

**3.7 Corrective and preventive actions**

The company described into the Quality Manual at par. 3.5 the corrective and preventive actions management. The company included the non-conformity treatment and corrective action management in the Portal for "Quality Management, a dedicated area is present "Non conformity management". For each NC raised during company activities (e.g. during internal audits, during in-process controls, at raw materials inspection for acceptance) a specific nonconformity is opened. The portal includes a column for each activity needed: "Trattamento non conformità" (non conformity treatments), Analisi delle cause" (root cause analysis), azione correttiva" (corrective action) and "verifica" (verification) are included in the NC management.

Seen NC management relative to internal audit and closure on 'gestione qualità' section NC/AC – with cause analyses and corrective action.

**3.8 Control of non-conforming product**

The company described into the Quality Manual at par. 3.4 the non conformities management and consequent actions. The company included the non conformity treatment and corrective action management in the Portal for "Quality Management , a dedicated area is present "Non conformity management". For each NC raised during company activities (e.g. during internal audits, during in-process controls, at raw materials inspection for acceptance) a specific nonconformity is opened. The portal includes a column for each activity needed: "Trattamento non conformità" (non conformity treatments), Analisi delle cause" (root cause analysis), azione correttiva"(corrective action) and "verifica" (verification) are included in the NC management. Final release of potential blocked products is only made by Head of Quality, the task may be operatively conducted by the Head of in process QC for packaging areas when electronic blockage is foreseen (e.g. for finished product in storage areas).

Seen NC management relative to internal audit and closure on 'gestione qualità' section NC/AC – with cause analyses and corrective action.

**3.9 Traceability**

The company described traceability system in a specific procedure "Tracciabilità". Traceability is electronically managed by the use of a dedicated software ("SAP") in charge of recording each product and process movement from raw materials receipt up to delivery to customers or to the external warehouse. The system is allowed for recodeing also process control at production step, while at packaging the packaging orders ("Ordine di confezionamento" are directly printed by this software.

Reworked products are present and traced: dry pasta which is recovered (e.g. curves of spaghetti long pasta), grinded directly on the production line and stored into dedicated bins. A lot is given by the date of collection into a dedicated bin, allowing the identification of semolina suppliers. Traceability on semolina bins is managed according to the loading of the quantities into each bin. At extraction the quantity of semolina is automatically loaded in a way to calculate the exact amount os semolina lot still remaining into each bin.

Traceability test carried out once every 12 months to cover both directions (raw material to finished product and vice versa) per year. Seen records dated 24.06.2019: from RM semolina Candeal used to produce following lot of semi-finished products L709AE52, L707AE52, L202AE52, L200AE52, L440AE52, L487AE52, L426AE52, complete of mass balance and document list. from FP Penne ziti rigate L8335G, production date 30.11.18, pack date 01.12.18 and 30.11.18, seen records complete of mass balance and document list. Reconciliation time < 4 hs

Auditor chose to follow through LINGUINE IGP TRE MULINI 500g packed into flowpack and cardboard cartons 12 x 500 g, L9212, 30.07.2019 packed in date 31.07.19 (L9212) and 01.08.19 (L9213), expiry date 31.07.2021, produced 1326 units (12 x 500 g), all delivered to Eurospin from 09.08.19 to 14.11.19.

From electronic document on SAP the packaging date of this lot has been obtained (31.07.2019). Based on article code (PTRM018408AE) and lot (L9212) the documents "Ordine di lavorazione" (20054686) and "Ordine di confezionamento" (10081411) are obtained.

A total quantity of 1326 cartons is reported for 2 shifts.

A) Packaging order nr 10081411 during the 2<sup>nd</sup> shift (evening shift) started packaging on 31.07.19 at 3:15 p.m. up to 10:00 p.m. (end of shift), employee Mr. Romanelli L. in charge for the packaging.

On this document the following information are present:

- Production order (for traceability aims: **000020054686**)
- Article code PTRM018408AE
- Product code Linguine IGP Tre mulini 12x500g
- Primary packaging material article code (ITRM0014080) and type (film TRM IGP G500 LINGUINE")
- Net weight (500 g)

In the same document the records of metal detector are required to be recorded together with other process controls:

- Article code of primary packaging material
- Mobile data to be printed on packaging (the document reported the following data: 31.07.2021 L9212)
- Correct sealing of packages
- Presence of pasta fragments at packaging sealing
- Coding on secondary packaging (31.07.2021 L9212)
- Average weight are recorded different times: 506 g, 507 g, 504 g, 501 g, 508 g.
- Tare (4 g)

On the back of this document the application of the primary packaging label used is present. Supplier "Roto.Med" ". Lot 0526416644 and 0531617791, production date 18/10/2018 and 03.06.2019, respectively.

At the end of the document the signature for release of the lot is present by the in process QC.

From electronic document "Tracciabilità materie prime" for production order nr **000020054686** the quantity of semolina used and silo for storage (nr. 12), together with supplier name ("Candeal Commercio srl").

From electronic document "Visualizzazione Analisi Materie prime" – 223515, 223515-001, 223604, 223604-001 the receipt of semolina supplier is recorded. Internal analysis performed with NIR which include ash, protein and moisture content, values include target values (in brackets):

- Ash: 0.83% (max 0,86%)
- Protein: 14.32% (min 13.0%)
- Moisture %: 14.69% (max 15,0%)
- Ash: 0.81% (max 0,86%)
- Protein: 13,70% (min 13.0%)
- Moisture %: 15,10% (max 15,0%). Analysis repeated in the laboratory, measured 14,90%.

On the same document the analyses performed by the laboratory on pasta is present.

- Ash 0.86% (max 0,86%)
- Moisture 12.00% (12,5%)
- Protein : 13,69% (min 13%)
- Stability test: 0% (max 3%)

On document "Controllo di processo di produzione pasta lunga" checked for 31.07.2019 "Linguine bronzo IG (corresponding to "Linguine IGP Tre Mulini 12x500 g"). A single process control has been performed according to the internal check frequencies (4 hours and 57 minutes production for this lot).

- Speed of screw
- Screw Pressure
- Temperature of water
- Temperature of cylinders and engine (set point on the PLC of the equipment)
- Temperature and moisture value in the drying and cooling step.

Moisture at exit of predrying (18,40%) and cooling step (12,03%, recorded at 10:00 a.m. of 31th July)

Reconciliation time < 4 hs

### 3.10 Complaint-handling

A specific procedure is present "Gestione reclami" rev 3 dated 31.01.17. The company reports on the printed packages of products a specific e-mail address for consumers complaints. Therefore the company records either consumers and customers complaints.

From consumers a total number of 535 confirmed complaints have been received in 2019, of which 419 for pest infestation, 19 for extraneous matters of which 2 for foreign bodies.

From customers a total number of 147 complaints have been received in 2019, 34 for pest infestation, 2 for extraneous matters.

Seen complaint dated 29.08.19 for presence of glass in traded product Napoletana sauce L168J, seen technical report 19/428A dated 12.09.19 and audit report of supplier in date 17-18.09.19.

3.11 Management of incidents, product withdrawal and product recall

A procedure for emergencies and crisis situations management is defined . “Gestione crisi” rev.5 dated 01.07.19. Information about emergencies are posted at different areas inside and outside . A document “Gestione delle Emergenze” is posted at external areas where electrical power plant (co-generation unit) is present for electrical accidents, flood is also considered. A recall procedure is also present into “Gestione crisi” procedure. The contact names and crisis team (the same of HACCP team) are listed. The evidence of contact of certification body within 3 working days in the event of a recall is present.

During the last year, the Company have carried out n. 1 withdrawal/recall test during the traceability test carried out in date 24.06.2019 from FP Penne ziti rigate L8335G, production date 30.11.18, pack date 01.12.18 and 30.11.18, seen records complete of mass balance and document list.

4. Site standards

4.1 External standards

The company is located in a semi-industrial area close to urban area (Gragnano town). The site is completely fenced, 2 barriers are, the main one (equipped with also a gate) at entrance with 24/7 surveillance presence, while the second one, for trucks access, is monitored by camera and handled with remote control by the receptionist at gate. A new parking area has been obtained externally at a site of the company for employees, which have access by the main gate by the receptionist. No significant risks are present for natural events like flooding, or chemical pollution. All external areas are asphalted and allow movements of vehicles and trucks. Additional buildings present outside are the maintenance workshop (completely separated from the main building), close to the area for water extraction from the well (locked), a main roof where dismantled equipment are stored, the storage area for chemicals (locked), and a new plastic curtain used for plastic packaging materials. Externally at a side of the main building there are also the offices building, while in the same area for the receptionist at the main gate the changing area at first floor is present for packaging area employees.

4.2 Site security and food defence

A Crisis team is defined being the same for Food Defence evaluation. A risk assessment has been performed dated 16.01.19. for each area and production step the potential risks have been listed and an evaluation in terms of Probability and Severity has been done. The company has defined a Food Defence Plan updated 29.11.19, that provide also the security of sensitive and computer-managed data. checked during monthly site inspection: The evaluation led to the identification of no critical area.

The company is equipped with continuous surveillance by internal employees, surveillance for 7 days/24 h of accesses is guaranteed by numerous cameras placed externally. Records are maintained on a disk for at least 3 days. Some cameras are present also internally (no records) for inspection of some equipment (e.g. production areas where wet pasta is laid on frames). All accesses are controlled and locked where restricted access is present (e.g. external lockers for cleaning agents). The company declares that employees have been trained for food defence matters.

Visitors at reception gate are registered for entrance and exit times, identification badge is given to visitor for clear identification, the company contact is also registered on the document “Registro visitatori” In the company rules for visitors instruction for hygiene and security are described, which foresee that a representative of the company for internal visits is present.

Evaluation of food defence updating is on the annual management review. The company is approved (registration nr. 19493040738 dated 2018-10-10) by the FDA for export in the US.

4.3 Layout, product flow and segregation

Maps with flows are present and dated 22.12. 2017 on “Gestione Qualità”. In the HACCP Manual the identification of areas for zoning is present. In the map the well water and distribution plant is also present and used for evaluation of sampling points for water (quarterly). No refurbishments were found during the site inspection. Due to the product rationale and the process (almost an enclosed system) no high care or high risk areas were found. Only at ingredients (concentrated tomato, dried spinaches) production area and in the cleaning and storage area for dies drains are present, suitable for the purpose and routinely cleaned with water at pressure. UTA ventilation systems are present at doughing area to lower ambient temperature, they are periodically maintained and filter systems are routinely inspected/changes as described in the Maintenance plan. An analysis lab is present, placed outside production areas (just before entrance to production areas).

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

The structure was not recently built nevertheless it has been maintained to get acceptable levels for hygiene and to avoid contamination from the building. Floors are in all areas smooth, in some areas (e.g. ingredient preparation area) they are washed with water. Vacuum equipment is used at bin storage areas for floor cleaning. Doors are self closing or vertical sliding doors not openable from the exterior. Lighting units were recently replaced into LED lighting units to reduce risks from breakage. Walls do not allow dirt accumulation and are included in the periodic cleaning and maintenance plan. No false ceilings are present at production or packaging areas.

4.5 Utilities – water, ice, air and other gases

Water comes from a well in the company, 4 tests per year are foreseen in the Analysis Plan. 2 are for “general” evaluation (chemical parameters), other 2 are for “routine” monitoring (microbial and chemical parameters). Furthermore, a control plan is present from the internal lab, which performs every 15 days microbiological tests for TVC and Total Coliforms. Seen internal microbiological analyses (CBT, Coli total). Seen external analysis report according to D.Lgs 31/2001: 19/000462733 dated 12.11.19 process water, 19/00033698 dated 30.01.19 well water, 19/000141362 dated 12.04.19 well water, 19/000280419 dated 15.07.19 well water only microbiology, 19/000266049 dated 05.07.19 well water.

Gas, risk evaluation in Manuale Qualità par.4, low risk because lubricant oil free used in compressors. At least annually the company verify MOSH e MOAH in air food contact, seen report n° 19/000116865 dated 27.03.19, report n° 19/000116868 dated 27.03.19 on flour feed compressors. In special pasta area the air is filtered <0,1 micron.

Compressed-air GHH RAND declaration of conformity from SILU compressors dated 26/05/2015 with oil free compressed air.

4.6 Equipment

Equipment are specific for the process produced. Some new equipment has been bought at doughing area, some new mixers have been placed at production area, checked specification of cup ALTOPACK seen declaration of conformity dated 29.11.18.

Unused equipment (e.g. metal detector which have been replaced by newer ones) have been transferred outside close to workshop area, stored under a roof and covered with plastic protection.

4.7 Maintenance

Maintenance program is present and divided for production and packaging area. An electronic maintenance program is present into an Excel file. Preventive maintenance is performed mostly during the 2 main production stops planned during the year (on August and December, during holidays). All planned activities are performed internally by maintenance personnel available.

Small maintenance activities may be also performed by production employees (e.g. lubrication). When extra-ordinary repairs are needed, they are also recorded in the same excel file. After this repair the cleaning of equipment is made by maintenance personnel while verification for release for further production is given by the employee at production area.

A small area for storage of blades of dies and for small maintenance is available at doughing area. A larger maintenance workshop is present (mostly for packaging area maintenance) outside the main building in a separate area. A contract for intervention on demand is present with external service suppliers. Lubrication in some parts at production areas (e.g. lubrication of transmission chains for short pasta production lines) is done with food grade lubricants, checked “OPTILEB F&D Spray” lubricant appropriately stored, specification available dated Sept 2015 with NSF H1 and “Stac 5” (Saca) specification dated 07.01.16 and into which allergen information is available (no cross contamination described).

Minor 4.7.3 - Some temporary repairs are present, and the company has not defined timescale for permanently reparation.

4.8 Staff facilities

Only male employees are present in production and packaging areas, therefore changing areas are only for men. 2 ladies are present as in process QC responsible and change their clothes in a dedicated room in the internal lab. Production area changing room are close at a side of the internal lab and just before entering into production areas, while packaging area changing room is located over the reception office at main gate. In production area changing facilities lockers by the external cleaning service company are available (AlSCO), separated into production and maintenance personnel. Red lockers are available for male employees (no female in production and packaging areas) with slope on the top. The 2 females present for in QC process control change clothes in a dedicated small room at the internal lab.

Before entering into production area a hand washing station together with dispensers of blue disposable tools are present (overall, headgear and beard covering). Hand washing station is equipped with soap detergent and disposable paper, the correct sequence is posted at walls in a pictogram. Before entering into production areas all visitors must read and sign company hygiene rules at gate reception area. At entrance a microbiological carpet for soles is present.

Close to the changing area a small break area is present for employees where lunch may be consumed. The company hygiene rules (posted in the company showcase) describe that working clothes must be removed before food consumption in break areas. Smoking (included electronic cigarettes) is not allowed all over the company. No catering areas are present in this company.

Minor 4.8.3 - The cleaned clothes are supplied in plastic bag to protect from contamination until use, but during the audit some cleaned clothing were outside the bag and outside the locker.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

Cleaning agents are stored in a locked dedicated room placed externally (keys are owned by the external service provider). Cleaning activities which include the use of chemicals are performed only at the end of the week when no production activities are performed. All cleaning agents are provided with specifications and technical sheets, which are electronically stored by the Head of Quality and are also present in the cleaning agent storage area.

4.9.2 Metal control

Blade policy is present and posted at production area in the employee showcase. Blades to employees are present at packaging, only single blade detectable blades are used. Safe storage (out of production area) of blades used to cut pasta at dies is present. An electronic record of the state of blades of dyes is present on company software at production area where at any change of pasta format either the integrity of sieve present and the integrity of blade is verified and recorded on the system by the employees.

Only detectable pens are allowed at production and packaging area, no staples or pins are allowed by the internal hygiene rules.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Glass and hard plastics risk assessment evaluated in the HACCP study, preventive and control measures have been consequently defined. An list of hard plastics and glass (only at external windows) is present on an excel document "Mappa del vetro e della plastica dura", different colours describe the state of glass and hard plastics (green = OK, yellow = under Maintenance, Red = broken), definite il rischio in funzione del posizionamento (prodotto esposto / non esposto) con frequenza di monitoraggio quotidiana / settimanale / mensile.

Daily inspection of glass and hard plastics is performed by personnel and recorded on appropriate documents, checked into "Ordine di Confezionamento" the request of evaluation of all sources before starting packaging activities.

An instruction is present: "Gestione rottura vetro e plastica dura" dated 28.10.19, it includes also breakage management, cleanliness and inspection of shoes and clothes after cleaning of area, formazione almeno triennale, seen report dated 02.12.19.

No glass or hard plastics breakage claimed since last audit regarding to dried pasta, nor the auditor found signs of breakage during the site inspection.

4.9.4 Products packed into glass or other brittle containers
N/A
4.9.5 Wood
Wood is not present in open product areas. Only wooden pallets are allowed at storage areas for packaging materials and finished product, no risks of contamination of the process is possible.
4.9.6 Other physical contaminants
At the moment the company does not use ingredients for de cartooning. All process is enclosed starting from tanks and pipeline The pens in the production facility are detectable.
4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of foreign-body detection and removal equipment
The HACCP plan includes in the assessment the evaluation of steps in which controls are made possible to identify potential extraneous matters contamination. Steps have been investigated to evaluate process controls. CCPs have been found at both inspection of screens placed at dies in production areas and the verification of effectiveness of metal detector at packaging area. Furthermore, some process controls are present for foreign body detection: the inspections of magnets and planstichers placed after semolina bin storage. Records of these monitoring activities are available. Training has been done to employees for foreign body detection end equipment control, a supervision is routinely made by in-process QC personnel to verify the effective functioning of detectors. Also these records are available and have been inspected during the audit. All detectors are online and recording of rejected packs ia present for each packaging line. The head of in process QC performs daily checks of correspondence between discarded pieces and those effectively available in the rejection box. Those packages are only handled by in process QC, who performs the investigation on the source of contamination of rejected packages. Records of these investigations are on "Rilevamento corpi metallici", where information is sent to Maintenance for detailed investigation on the source and actions.
4.10.2 Filters and sieves
Filters are present at semolina unloading from bins (plansitchers), each of them is equipped by numerous sieves one on each other 0,8 mm each. Inspection and status of cleaning (presence of insect) is verified weekly by the in process QC at production area and recorded on appropriate sheets.
4.10.3 Metal detectors and X-ray equipment
Metal detectors are present at each packaging line and inspect all packed products. New metal detectors have been recently bought and replaced older ones. All metal detectors are equipped with failsafe systems for pressure of ejection and effective discard into the rejection box. Test for effective stop of belt have been tested by the auditor during the site inspection. Record of the effective functioning of failsafe system is made at start of any packaging batch and recorded on packaging record sheet "Ordine di Confezionamento". All detectors are also equipped with locked box and air blow system for rejection, key are owned by in process QC personnel, in charge for routine extraction of testers (placed inside) and consignment to employees for routine testing. A daily test is also performed by in process QC for verification of effective discard for each packaging line and recorded on "Ordine di confezionamento". Testers are present and are the same dimensions for all small packaging lines, while for catering lines (5 – 10 kgs) the are different. CCP1: metal detection on packed product (metallic extraneous matters with testes as follows: (Fe= 1,5 mm; Non Fe = 2,0 mm; SS = 2,0 mm). For catering products (5-10 kg packages) testers are Fe= 2,0 mm; Non Fe = 2,5 mm; SS = 2,5 mm. For industrial finished products (in big-bag) testers are Fe= 2,0 mm; Non Fe = 2,5 mm; SS = 2,5 mm. Effectiveness of detectors is performed at start, with hourly frequency and at end of each packaging batch, recorded on the "Ordine di Confezionamento".
4.10.4 Magnets
Magnets are present at semolina bins unloading, Magnets may be either made by neodymium bars (6.000 Gauss) or Ferrite plates (2,500 Gauss). Inspection and status of cleaning verified weekly by the in process QC at production area and recorded on appropriate sheets. Supplier (Sirgem) declaration is available for testing and verification of effectiveness of strength.

4.10.5 Optical sorting equipment

NA, no optical sorting in use

4.10.6 Container cleanliness – glass jars, cans and other rigid containers

NA, no rigid containers in use

4.11 Housekeeping and hygiene

A detailed cleaning plan is present (rev. 03.17).

The external service company (C&P) is present for overall cleaning of production and storage areas, even though the employees in charge for cleaning purposes are the same of last year. Qualification of the company has been done after evaluation of cleaning performed at another site, a report of this verification before approval is present dated 06.07.17.

Capitolato 01.10.19 which defines the areas and frequencies to be respected.

Istruzioni Operative 01.03.18, defines the methods of execution, the equipment and the products to be used

- instructions for cleaning
- cleaning agent list with characteristics and instructions for use
- instructions for floor cleaning with automatic machine

Electronic records of cleaning are present at doughing on process control computer, while at other areas paper records are posted at walls or on equipment (e.g. packaging machines). An industrial vacuum cleaner is present at semolina bins storage areas for dry cleaning at this area (no other cleaning is performed here).

A list of chemical products including cleaning agents is present in IT system shared with external contractor C&P, available in IT system training records, MSDS, DPI, job description according to competence, quality policy.

Evaluation of effectiveness of cleaning is performed by pre-op inspections, performed by employees and recorded on software (production area) or on paper documents ("Ordine di Confezionamento" at packaging).

Analytical evaluation is also performed by QC personnel through bioluminescence method (Lumitester PD-30), in compliance with an instruction "Test controllo luminescenza". 3 different levels of results in terms of RLU have been defined by the company (<500, 501-1000, > 1000 RLU), a warning is given for intermediate level while for unacceptable results (> 1000 RLU= a re-cleaning of the surface is required. Records are on document "Modulo di registrazione verifica efficacia pulizie - swab". Frequency is defined into 1/month on production areas, while at packaging 1 test/month for each packaging line (for "nidi" pasta frequency is twice/year). Seen records dated 30-31.10.19 and 25-26.11.19.

Minor 4.11.6 - Cleaning tools are identified and coloured, a specific storage area on panel in which dedicated areas for collection of tools is present, but some cleaning equipment are not correctly stored and identified when not in use.

4.11.7 Cleaning in place (CIP)

NA, no CIP in place.

4.11.8 Environmental monitoring

For each phase, the hazards were identified, and the real exposure of the raw material / product to the environment was assessed, assessing the possibility of contamination. Acceptable levels defined Salmonella absent, Staphylococci and E.Coli <100, Enterobacteria <1000, for surfaces in contact dated 06.09.19. Ambient swabs are performed by external laboratory, seen report n° 19/000389368-9 389331-3 389388 dated 30.09.19.

4.12 Waste

Wastes small containers are identified all along the production and packaging areas. Wet pasta discards are collected in to grey large plastic boxes (tanks). Blue bags are for wet pasta discards which need recovery treatment (performed by an external supplier). <sup>SEP</sup>Plastics are collected into transparent bags and daily transferred to a compactor. <sup>SEP</sup>Paper discards are collected into grey boxes and then daily transferred to the external compactor area. Service providers are present for disposal. "SEA" company is for plastics and cartons (recycling company), "Tortota Guido" for plastics, while "Pasquale Saporito" is an authorized feed animal production company in charge for disposing all products and by-products downgraded at animal feed. <sup>SEP</sup>Registers for traceability and records of quantities disposed of these discards are present. <sup>SEP</sup>

**4.13 Management of surplus food and products for animal feed**

Seen contracts with external contractor, waste management for use for animal feed, cat.3, according to legal requirements Reg. 183/2005 registration n° IT/063035/07.

**4.14 Pest management**

A contract with external provider "Anticimex" is present and updated to implement extraordinary monitoring plan for shipping area. Rodents are monitored monthly. A technical project is present by the provider. The company is being transferring the monitoring system into a "safe" system in which no chemicals substances are used externally, and no glue is used internally for rodents. Electronic catch stations are present with "Smart" systems. Electric shock is given to rodents coming into the devices and are automatically transferred into a closed box into the station. Contemporary a signal is generated which sends an email to the company informing about the catch in a specific position. Internally snap traps are placed internally to the stations. A map is present inside the service provider portal updated at any reporting. For each pest the limits of acceptable values are defined as maximum allowable sum in each area. Environmental thermal treatment with hot air (>55°C for > 30 h) has been used for pest control interventions during summertime, checked last intervention performed by "Soges srl" dated 20-22.04.19 and 23-25.08.19. Trends are continuously available on company portal. Last monitoring report dated 3-4.12.2019. Quarterly expert survey available.

**4.15 Storage facilities**

Semolina bins storage are present in an inner part of the company. Bin connections are present outside this area into a controlled external area, inside a room. Cameras for inspections are being including the vision of this area also. <sup>SEP</sup>Metal bins are present for different dimensions and different types of semolina storage (e.g. organic, high protein content, standard, whole grain semolina). At bottom of each bin, before semolina is transferred (by air compressors) into production area, a sieving is present with a battery of plansichters, equipped with sieve 0,8 mm wide. Magnets are also present before plansichters. Instructions are present at this area for daily cleaning with vacuum cleaner (checked "Controlli e pulizia sala silos"), for cleaning of air filter compressor for semolina transferring to production area ("Pulizia filtri compressori", rev. 1). Inspection and cleaning of magnets and plansichters is performed by the employee at bin receipt and storage area at any change of pasta format. A weekly verification is made by the in process QC at production area for the state of cleaning and integrity of sieve and magnets, recorded on "Pulizia filtri e magneti" rev. 1. On this document the extraneous matters rejected by the plasichter and presence of insects is recoded, a limit has been defined by the company (max 10 insects), after which control measures are taken together with the pest control company (e.g. insect treatment of bin when empty). No controlled temperature areas are present for storing raw materials.

Outside storage is linked to cleaning agents, where a dedicated external area is present (locked), the keys are owned by the external service provider and the head of maintenance. <sup>SEP</sup>Finished product storage area completely automated, at the end of palletization (automatic) a barcode is printed for recording of location of the pallets in the finished product warehouse. From them the Head of Logistics unloads a defined product, FIFO rules are automatically applied and have been verified randomly during the site inspection on the company PC.

An external storage is foreseen at an external service provider: "Number One Logistica spa", placed at Marcianise-Caserta, contract dated 16/3/2017 with storage requirements specified. Personnel from the company are routinely sent to the provider for checks and sampling (e.g. outsourced products).

**4.16 Dispatch and transport**

All vehicles are inspected before loading by employee at delivery area. The hygiene and cleaning of trucks and integrity of protection are checked, a printing on the shipping document "Veicolo idoneo al carico". During the audit seen inspection records regarding to DDT n° 100013618 del 11.12.19, destination Number 2, pasta

secca L9344G and L9345G.

**5. Product control**

**5.1 Product design/development**

A dedicated person at QA office is present for supervision and recording of activities related to new product development. NPD activities are supervised by QA with reports which summarize meeting performed with different units participating to NPD (Production, MKTG, Commercial). NPD activity mostly refers to new packaging for dry pasta, even though also fresh pasta produced to outsourcing companies is included. Checked study for new drawing for "Pennoni Garofalo", data collection and start project in date 28.08.19, last verify dated 05.11.19, production validation dated 28.11.19.

**5.2 Product labelling**

Product labelling performed according to national and international rules, where organic production is present preliminary approval by the certification body for compliance is required. Other new labelling are handled by Quality personnel, the Head of Quality in charge for final label approval for company products whereas private labels are approved by the customers. Checked SW Inciflex portal to manage label approval with packaging supplier. seen records regarding to PENNE ZITI rigati approval date 12.07.19.

**5.3 Management of allergens**

The company evaluated in the HACCP study the risk of allergen presence and contamination. Seen 'relazione sulla gestione del rischio di contaminazione da soia' dated 1/07/2016. At section 3 of HACCP it is specified that for AIDEPI line-guide on possible warning for possible traces of soya for accidental contamination during logistic operations, before semolina arrival at premise, for legal protection decided of sharing the policy of inserting an eventual warning on the label 'may contain soy traces' with each client as well as adding warning on own brand label. Allergens handled by the company are gluten and soy. Only semolina from gluten is present as allergen ingredient (declared in all recipes). Regarding soy presence, even though a monthly program is present for routine monitoring of semolina with external accredited lab (ELISA testing method, LoQ at 2,5 ppm), the company is being changing all packaging materials after a study performed by suppliers and the unavoidable declaration recently made by wheat millers from soy into wheat or into the process. No other allergens are present, at staff facilities the risk of potential cross contamination from food with relevant training annually performed on preventive measures (overall required before entering into break areas, hand washing required before re-entering in production areas). A monthly program is present for routine monitoring of semolina with external accredited lab (ELISA testing method, LoQ at 2,5 ppm), no soya >LoQ in last year analyses. <sup>11</sup><sub>SEP</sub>

**5.4 Product authenticity, claims and chain of custody**

The company evaluated product authenticity risks in the HACCP manual, during the raw materials risk assessment. The company received semolina and few ingredients (concentrated tomato, dried spinaches), Conventional semolina is analysed at any receipt, protein content declared in the specification is analysed at any time. Organic production are monitored every week with mass balance. A document is present "Registro generale del biologico" where weekly mass balances are performed by the Head of QA with incoming raw materials, organic pasta produced, conversion into equivalent semolina used and comparison with raw materials used, the percentage of downgraded products (from organic to conventional or discarded for animal feed). Kosher certification is present even though all raw materials are declared Kosher therefore no segregation is required for these products/raw materials. Seen traceability test and mass balance for organic semolina in date 31.10.19 during the CCPB audit, seen analysis report n° 19/000267469 dated 28.06.19. Seen inspection report CSQA for IGP production, dated 30.09.19.

**5.5 Product packaging**

Plastic packaging materials are handled by the company, in some cases also paper + plastics is present. Different plastic packaging materials are present:  
 - BoPP + PP cast for retail products.

- paper / PPL coex+PPL cast
- LDPE for catering packages
- Bags in paper+plastics,
- PP / PE for big bags for loose pasta

supplier "Minini Imballaggi, specifications and food declaration dated 30.06.17, Rotocalco Mediterranea, specification date 08.07.15, conformity declaration 06.11.18, certificates of conformities are available for each supplier.

The following migrations were tested: polyphenylene (Tenax), metal specific migration, aromatic amines specific migration, stimulants specific migration.

## 5.6 Product inspection and laboratory testing

### 5.6.1 Product inspection and testing

An analysis plan is present "Piano della Qualità" (on electronic excel file) into which different items are listed:

- Step of the process
- Process control
- Critical factors
- Responsibility
- Frequency
- Specifications and reference documents
- Record sheets

- Non conformity management In this plan raw materials, finished products, water and surfaces tests are summarized. Raw materials: semolina is tested by the internal lab with a single check/day with official methods of incoming analysis foreseen with NIR at receipt area, seen records in "Controllo analitici sfarinati in ingresso NIR". Protein, ash and moisture content are tested with the official methods by the internal lab, together with granulometry with vibrating screen. All results are transferred on the company portal "Gestione Qualità".

Finished products: tests are conducted for verification of shelf life according to the internal plan. Tests include cooking test performed internally. Process controls of pasta are also performed: pasta dimensions and thickness, texture (a specific instrument is present internally). These process controls are performed to verify the status of consumption of dies. A document is present "Monitor trafilè" in which their results of thickness and dimensions are listed to assess the need of change dies. Cooking tests are also performed at start and end of placement of any die. Thickness is tested with calibres linked to a personal computer for recording data. Water is tested internally by the lab every 15 days for microbiology, while external accredited lab performs quarterly tests for microbiology and chemistry according to national rules. "Legionella pneumophila" is also tested on UTA system for air conditioning at production area for evaluation of presence. The company started an internal project called "Progetto Trasparenza" in which a contract has been agreed with an external accredited lab (Merieux) for sampling of pasta products on retail shelves in Italy. A total amount of 100 samples/year is foreseen. The results of these checks will be published on company website for customers. Tests include furosine, heavy metals (lead and cadmium), soy presence, glyphosate, pesticides content, all mycotoxins, chlormequat. etc.

From electronic document "Tracciabilità materie prime" for production order nr **000020054686** the quantity of semolina used and silo for storage (nr. 12), together with supplier name ("Candeal Commercio srl"). On document "Controllo di processo di produzione pasta lunga" checked for 31.07.2019 "Linguine bronzo IG (corresponding to "Linguine IGP Tre Mulini 12x500 g").

From electronic document "Visualizzazione Analisi Materie prime" – 223515, 223515-001, 223604, 223604-001 the receipt of semolina supplier is recorded. Internal analysis performed with NIR which include ash, protein and moisture content, values include target values (in brackets):

- Ash: 0.83% (max 0,86%)
- Protein: 14.32% (min 13.0%)
- Moisture %: 14.69% (max 15,0%)
- Ash: 0.81% (max 0,86%)
- Protein: 13,70% (min 13.0%)
- Moisture %: 15,10% (max 15,0%). Analysis repeated in the laboratory, measured 14,90%.

On the same document the analyses performed by the laboratory on pasta is present.

- Ash 0.86% (max 0,86%)
- Moisture 12.00% (12,5%)
- Protein : 13,69% (min 13%)

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- Stability test: 0% (max 3%)

5.6.2 Laboratory testing

An internal lab is present even though official analyses for compliance to customer requirements are performed at external accredited laboratories. An internal ring test is performed for moisture, protein and ash content. An instruction has been prepared for this task, "Ring test interno" rev.2. Quarterly tests are conducted between NIR (semolina receipt area, internal lab and thermobalances at production area. A semolina sample is tested internally and acceptance criteria have been defined into the instruction. 3 replicates are performed by each tester and a max acceptable deviation from average results are defined. Checked last results of test conducted on August 2018 on semolina, with good result. External laboratory work according to ISO 17025

5.7 Product release

Finished products are automatically transferred into an automatic warehouse where all pallets are electronically identified with labels for identification of storage. All products are automatically blocked by managing warehouse software "SAP". The result of analyses performed along the process and on loose pasta for protein, ash and moisture are tests for positive release, performed daily by the head of in process QC for packaging area.

5.8 Pet Food

NA, no Pet Food.

6. Process control

6.1 Control of operations

Process controls are present either at production and at packaging departments. At doughing area process controls are mainly related to the process performance, where the PLCs are in charge for automatic setting and control of speed and pressure of screws, temperature of water, temperature of cylinders and engines, moisture at different steps of the production process and at end of production before loading loose pasta into bins. All these are recorded on document "Controllo di processo di produzione pasta corta". Moisture control is performed with 3 thermobalances available at work station into production area, they are calibrated and an internal ring test has been performed for verification of data. At packaging area the process controls are included in the "Ordine di confezionamento" (Packaging order) and include correct usage of packaging material, correctness and readability of lot / expiry date, routine checks for correct weight (with a calibrated offline scale), defects at sealing, lot coding on cardboard cartons, average weight of packages (periodically recorded by the display of the checkweigher). Process controls of pasta are also performed off line by the QC lab : pasta dimensions and thickness, texture are performed to verify the status of consumption of dies. A document is present "Monitor trafilè" in which there results of thickness and dimensions are listed to assess the need of change dies. Cooking tests are also performed at start and end of placement of any die.

6.2 Labelling and pack control

On each packaging order "Ordine di confezionamento" the article code of each packaging material to be used is present. On the label of each packaging material the article code is required to be present. The absence of other packaging on the packing line is recorded on start-up check record. The number of article code and type must also be reported by the employee on the "Ordine di Confezionamento" for confirmation of correct use. Further verification is performed during packaging by in process QC. The labels used for each packaging lot are attached to the Packaging Order for evidence of usage. When change of product is needed, the packaging roll is placed on a pallet and warehouse employee for packaging materials is asked to return in the storage warehouse, where it is replaced in their original plastic bag and appropriately stored. At the audit time randomly checked packaging operation for Linguine "Tre Mulini IGP" L93431A BB 09.12.22, Mafalda corta "Garofalo" L9343H1 BB 09.12.22, Pappardelle "Garofalo"

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L9344G 10.12.22

6.3 Quantity, weight, volume and number control

All packaging lines are equipped with automatic checkweighers for online weight check according to national rules (L. 690/78). Underweight packages are available according to the law requirements and are passed before starting packaging for effective functioning of rejection system. Identification with a red belt of packages is present to avoid accidental use of these packages. Routine monitoring of effective weight by checkweighers is performed by in process QC personnel using calibrated and legally verified offline scales. "Radwag" scale is present on a mobile tray which is transferred at packaging lines and a package is weighed either at checkweigher and then at offline scale. A maximum tolerance range has been defined for acceptance (+-2 g), in the event of deviation line is stopped and maintenance / verification procedure to the checkweigher is required. From traceability test Auditor chose to follow through LINGUINE IGP TRE MULINI 500g packed into flowpack and cardboard cartons 12 x 500 g, L9212, 30.07.2019 packed in date 31.07.19 (L9212) and 01.08.19 (L9213), expiry date 31.07.2021, produced 1326 units (12 x 500 g), all delivered to Eurospin from 09.08.19 to 14.11.19. Average weight is recorded different times: 506 g, 507 g, 504 g, 501 g, 508 g. Tare (4 g)

6.4 Calibration and control of measuring and monitoring devices

A list of equipment under calibration is present and updated. Scales (checkweigher and offline scales), 2 primary probes (used for internal calibration of probes) and thermobalances are present. Primary instruments and working instruments are defined for each area. 2 primary probes are present (calibrated every 3 years), other primary instruments are parallel shapes for micrometers (calibrated every 10 years). A list of scales is present on document "Elenco macchine confezionamento". 20 checkweighers are reported being present, while 3 offline scales are present at packaging area for verification of dynamic weight check. Annual legal verification required. Certificate of calibration for primary probes are present by LAT 141 ("Migliore Russo sas") certificate of calibration nr LAT 141 17-065 and 17-066. Dated 31.03.17 (30-60-90°C the first one and 500-600°C the second one for the mitten at lab). Metal detector are calibrated in date 04.06.19, seen records regarding to matr. 10737523. Scales list is updated to 06.05.18, seen records regarding to L1A, start 08.11.18, last calibration dated 06.06.19, next planned in date 06.06.2020.

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

Training program electronically managed by the software system "Gestione Qualità" on 'piano formazione del personale 2019'. Training is mostly performed for CCPs monitoring and company hygiene rules). Internal training has been also provided for competence of employees in the identification of insects for routine daily internal monitoring of stations available. A record of training is manually performed on "Intervento formativo / informativo", checked training for HACCP dated 21-22.05.19, GMPs and hygiene rules into a refresh training session dated from 25.02.19 to 01.03.19. Signature of employees on the document is present for confirmation of participation. Cleaning workers are trained in feb-jun 2019, receiptment control in date 06.05.19, shipping control (7 points inspection) in date 14.03.19. During the annual management review the results of annual training sessions are discussed and evaluated for compliance.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

A suitable hygiene policy has been defined by the company into "Prescrizioni igieniche per gli ambienti lavorativi". recently updated for the forbidden use of electronic cigarettes, the possibility of usage of glasses, the communication of hand washing pictograms posted at walls. Instruction include no smoking rules (all over the company), the prohibition of any usage of food and drink consumption in production, packaging and storage areas, jewellery policy (no jewels are allowed apart from a plain wedding ring), the exclusive usage of blue plasters (distributed by QA personnel and tested at each new lot under the metal detectors), blade policy (controlled distribution of detectable cutters, single blade). Medicinals are not allowed in the company apart from the changing areas. Clothing rules are also defined and the need of daily change of clothes. Visitors rules include the need of registration at receipt on a register, the receipt of a leaflet for security aims, the need

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to be accompanied by an authorized person in production areas, the signing for acceptance of hygiene and safety rules at receipt. Hand cleaning station is available at entrance of production areas where electronic command for water, blue disposable paper and liquid soap is present. At this station the distribution of disposable clothes (blue overall, headgear) is present. A microbiological carpet at floor is present at entrance for cleaning of foot soles.

7.3 Medical screening

A medical nurse is present in the company twice/week for visits and medical assistance to employees, while once/year a medical doctor is required to come in the company for legal visits according to the national law. Confidential document is given to the company, together with the release for production in food companies. At entrance the auditor has been required to fill a questionnaire for health status declaration.

7.4 Protective clothing: employees or visitors to production areas

Due to the process performed (mostly an enclosed process) and the zoning (no high care or high-risk areas have been identified) the clothing rules foresee only white shirts and trousers, security white shoes and a disposable headgear are worn. Maintenance personnel wear blue clothes while the external cleanin company is identified with a green headgear. A new external service provider is present (AlSCO, certification for biocontamination removal after washing available) for external laundry. Dedicated lockers are present for each employees for clean clothes (which are returned to employees sealed into transparent packaging). No high care or high-risk areas are present therefore no use of gloves is required by the company. No items which cannot be laundered are present.

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones

8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones

Not Applicable, no high care and high risk areas.

8.2 Building fabric in high-risk and high-care zones

Not Applicable, no high care and high risk areas.

8.3 Maintenance in high-risk and high-care zones

Not Applicable, no high care and high risk areas.

8.4 Staff facilities for high-risk and high-care zones

Not Applicable, no high care and high risk areas.

8.5 Housekeeping and hygiene in the high-risk high-care zones

Not Applicable, no high care and high risk areas.

8.6 Waste/Waste disposal in high risk, high care zones

Not Applicable, no high care and high risk areas.

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8.7 Protective clothing in the high-risk high-care zones

Not Applicable, no high care and high risk areas.

Details of non-applicable clauses with justification

Clause/section reference	Justification
3.5.1.5	No agents and brokers is present
3.5.2.3	No live animals are received at this company
3.5.4	No processes are outsourced
4.3.5	No temporary structures are present
4.5.3	No use of non-potable water
4.7.3	No temporary repairs were found during the site inspection
4.9.1.2	No strongly scented materials are present
4.9.4	No products are packed into glass containers
4.10.5	No optical sorting equipment is present
4.10.6	No glass jars or other rigid containers are present in this process
4.11.7	No CIP system is present in this process
4.14.3	No internal pest activity is performed by the company
4.15.4	No controlled atmosphere storage is present
4.16.4	No internal trucks are present
5.6.1.3	Verification of shelf life is performed by PDO Consortium
5.8	No pet food is produced at this site
6.1.3	No in-line monitoring devices in place
6.2.4	No on-line vision equipment used to check product labels and printing
8	No high risk, high care, ambient high care

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**9 - Traded Products**

**9.1 Approval and performance monitoring of manufacturers/packers of traded food products**

Pasta Garofalo brands are also produced by other pasta producer: Gluten free is produced either at “Pasta Lensi” (Verolanuova – BS), an BRC code 1190705; Labor srl certified BRC code 7401572, Newlat SPA certified BRC code 5135442, De Matteis Agroalimentare spa certified BRC code 7051424, La Bolognese Srl certified BRC code 8640686; Wheat flour: “Selezione Casillo srl - Corato via sant’Elia” BRC code 1605047; Special mix flour: Geovita srl - Bruno site FSSC certified expiry date 28/12/2020; extra virgin olive oil: “Manfredi Barbera&Figli” BRC code 6825701; Fresh pasta: filled pasta: “Bertagni 1882 srl” (VI) BRC code 1716913; 'Pastificio Gaetarelli srl' BRC code 1705057; not filled pasta: P.A.C. srl BRC code 5257017; Dumpling/gnocchi: Il pastaio Srl - Torbole site BRC code 7815886;pasta souse: Montanini Conserve alimentari sas BRC code 1139444; La Doria SpA Parma site - BRC code 6398602;dried tomatoes in oil: Fiordelisi srl BRC code 5614174;bulgur, quinoa and cous cous: Geovita srl Villanova Monferrato BRC code 2005023;Tomatoes: suppliers are “Calispa spa”, BRC code 1282243; SICA srl BRC code 1361183; ICAB/La Fiammante SpA BRC code 1154829. The company has defined an agreement with suppliers, seen Bertagni 1882 dated 01.04.19, Selezione Casillo, dated 19.04.19.

**9.2 Specifications**

The specifications are defined according to suppliers, seen Mezzeluna ricotta di bufala con porcini e tartufo dated 27.06.19, Garofalo specification dated 23.07.19 with label approval; Gnocchi farina integrale dated 12.07.19, Garofalo specification dated 12.07.19 with label approval.

**9.3 Product inspection and laboratory testing**

“Piano della Qualità prodotti commercializzati” includes requirement for supplier qualification:  
 - Pre-requisites (GFSI certification)  
 - In coming controls and tests <sup>[1]</sup><sub>SEP</sub>  
 A sampling and testing procedure is also present for products when received at service provider’s finished product warehouse (“Number One Logistica”). Records of inspections and testing are on document “Quantità idonea alla vendita”, a flag for each reference sample by the employee is present for compliance with checks performed. After these checks the document is passed to the Head of in process QC at packaging area for electronic release (products loaded on warehouse software are automatically blocked). <sup>[1]</sup><sub>SEP</sub>

**9.4 Product legality**

All products different from dry pasta are tested for legal compliance according to a sampling plan on shelves at retailers by an external accredited lab (Merieux). <sup>[1]</sup><sub>SEP</sub> For dry pasta all pasta lots are received from outsourcers and are tested at receipt for legal compliance for chemical parameters (ash, protein, moisture content). Piano della qualità prodotti commercializzati dated 14/12/2017 “Controllo analitico prodotti copakers” includes analysed for semolina ash protein and moisture content.

**9.5 Traceability**

All outsourced products are traced with electronic system “SAP”. All products are received at the company, traced on electronic software. Some products may be transferred directly to external warehouse “Number One Logistica” a dedicated unit in charge for checks directly at the storage provider where inspection and sampling are performed. “Modulo ispezione e campionamento prodotti provenienti da copacker” is a document in which the sampling and inspections at receipt or at storage area are performed.  
 Traceability checked during audits, on Mafalda passioni Auchan, lot L8257212, produced 504 kg (14 x 500 g), 72 ct total.  
 During the last year, the Company have carried out n. 1 withdrawal in date 20.08.19, RASFF 2019.2987 for glass presence in traded product.

<b>PRODUCT:</b>	Macaroni Products	<b>PAGE 1 of 35</b>
<b>PLANT NAME:</b>	Pastificio Lucio Garofalo S.p.A.	<b>ISSUE DATE</b> 8/16/2017
<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b> -



STORICO PASTIFICIO

*Garofalo*

**PASTIFICIO LUCIO GAROFALO S.p.A.**

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**Food Safety Plan  
for  
MACARONI PRODUCT**

Developed by: Sergio de Gennaro (PCQI)

Date: August 16, 2017

Approved by: Massimo Menna (CEO - Plant Manager)

Date: August 21, 2017

Food Safety Plan

<b>PRODUCT:</b>	Macaroni Products	<b>PAGE 2 of 35</b>
<b>PLANT NAME:</b>	Pastificio Lucio Garofalo S.p.A.	<b>ISSUE DATE</b> 8/16/2017
<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b>

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## Company Overview

Pastificio Lucio Garofalo is a small business (a business with fewer than 500 full-time equivalent employees) pasta manufacturer. The product variety includes more than 100 different pasta shapes and the possible addition of vitamin and minerals (Enriched Macaroni Product) and vegetable (Tricolor pasta).

FDA Registration Number: 12507415488

DUNS Number 630998235

U.P.C. Company Prefix: 085164

Product is made 7 days a week, 24 hours a day. The site has 8 different production lines, 4 dedicated to short shapes (penne, fusilli or similar), 3 dedicated to long shapes (as spaghetti or vermicelli), 1 dedicated to specialties (lasagna sheets and nested noodles). 14 different packing lines are present.

An internal laboratory is present to check the chemical and microbiological parameters on raw material (durum wheat semolina) and on the finished product (dry pasta). Water comes from an internal well, partially softened and sterilized by UV lamp. An integrated pest control plan is in place.

Members of the Food Safety Team are:

Massimo Menna – C.E.O. – Site Manager

Gianni Schisa – Operation Manager

Sergio De Gennaro – QA Manager – PCQI – Team Leader

Germana Amadoro – QC Manager - PCQI

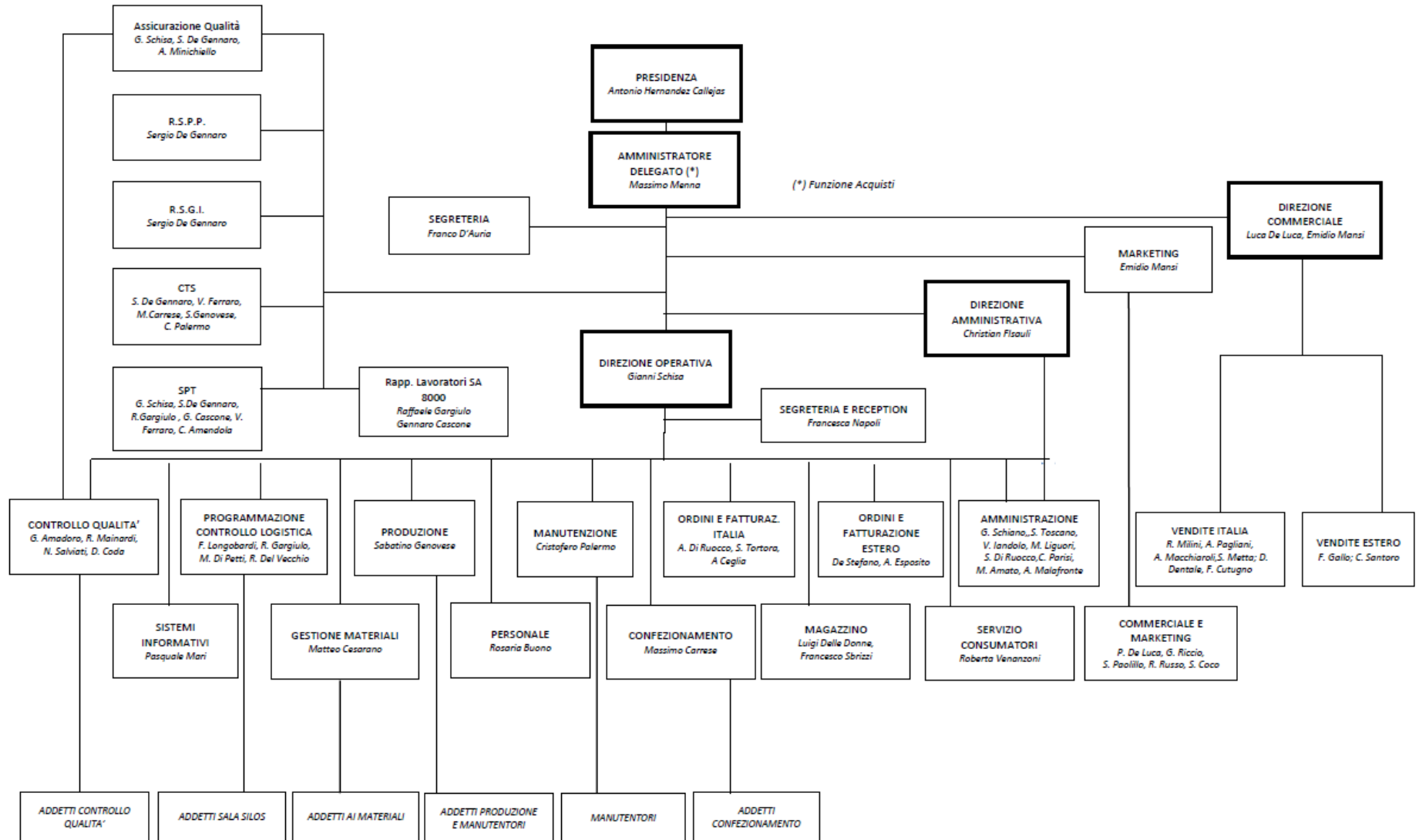
Rosanna Mainardi – QC Manager

Sabato Genovese –Production Manager

Cristofero Palermo – Maintenance Manager

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## ORGANIZATION CHART





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## Product Description

<b>Product Name</b>	<b>Macaroni Product</b>
<b>Product Description, including Important Food Safety Characteristics</b>	Traditional Italian Pasta from durum wheat semolina moisture <12.5% $a_w < 0.60$
<b>Ingredients</b>	Durum wheat semolina
<b>Allergens</b>	Contains wheat
<b>Packaging Used</b>	Plastic bag (Polypropylene or Polyethylene made) thermally sealed, never hermetic in order to permit the pack breathing.
<b>Intended Use</b>	The product needs to be cooked in boiling water for a proper rehydration before being eaten.
<b>Intended Consumers</b>	General public, except for coeliac people.
<b>Shelf Life*</b>	36 months
<b>Labeling Instructions*</b>	None
<b>Storage and Distribution*</b>	Ambient temperature.

*[\*Provide information relevant to food safety]*

<b>Product Name</b>	<b>Whole Wheat Macaroni Product</b>
<b>Product Description, including Important Food Safety Characteristics</b>	Traditional Italian Pasta from whole durum wheat flour moisture <12.5% $a_w < 0.60$
<b>Ingredients</b>	Whole durum wheat flour.
<b>Allergens</b>	Contains wheat
<b>Packaging Used</b>	Plastic bag (Polypropylene or Polyethylene made) thermally sealed, never hermetic in order to permit the pack breathing.
<b>Intended Use</b>	The product needs to be cooked in boiling water for a proper rehydration before being eaten.
<b>Intended Consumers</b>	General public, except for coeliac people.
<b>Shelf Life*</b>	36 months
<b>Labeling Instructions*</b>	None
<b>Storage and Distribution*</b>	Ambient temperature.

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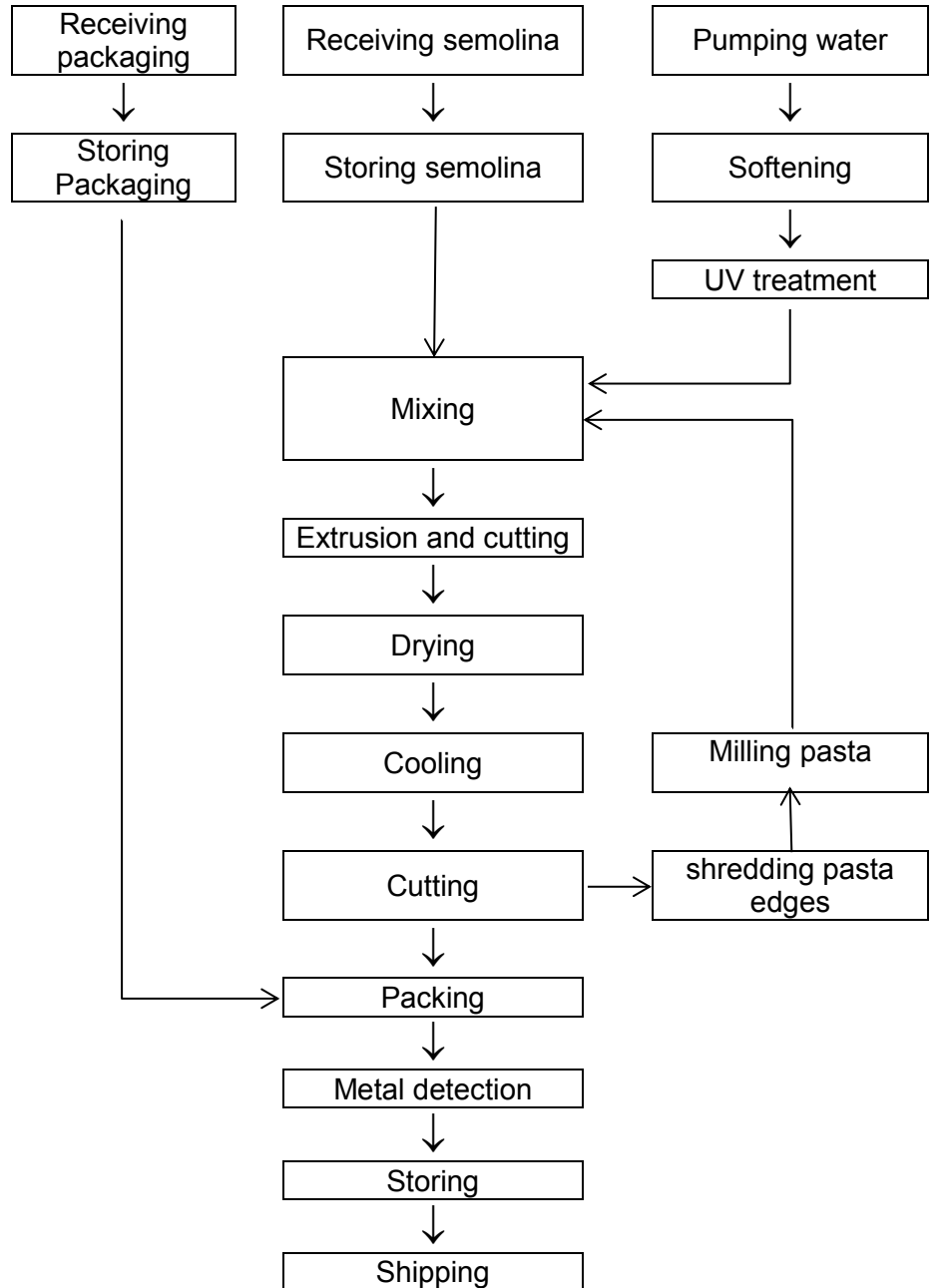
<b>Product Name(s)</b>	<b>Enriched Macaroni Product</b>
<b>Product Description, including Important Food Safety Characteristics</b>	Traditional Italian Pasta enriched with vitamins and iron moisture <12.5% $a_w < 0.60$
<b>Ingredients</b>	Durum wheat semolina, Niacin, Iron Lactate, Thiamine mononitrate, Riboflavin, Folic acid.
<b>Allergens</b>	Contains wheat
<b>Packaging Used</b>	Plastic bag (Polypropylene or Polyethylene made) thermally sealed, never hermetic in order to permit the pack breathing.
<b>Intended Use</b>	The product needs to be cooked in boiling water for a proper rehydration before being eaten.
<b>Intended Consumers</b>	General public, except for coeliac people.
<b>Shelf Life*</b>	36 months
<b>Labeling Instructions*</b>	None
<b>Storage and Distribution*</b>	Ambient temperature.

<b>Product Name(s)</b>	<b>Tricolor pasta</b>
<b>Product Description, including Important Food Safety Characteristics</b>	Traditional Italian Pasta flowered with tomato and spinach moisture <12.5% $a_w < 0.60$
<b>Ingredients</b>	Durum wheat semolina, tomato paste, spinach powder.
<b>Allergens</b>	Contains wheat
<b>Packaging Used</b>	Plastic bag (Polypropylene or Polyethylene made) thermally sealed, never hermetic in order to permit the pack breathing.
<b>Intended Use</b>	The product needs to be cooked in boiling water for a proper rehydration before being eaten.
<b>Intended Consumers</b>	General public, except for coeliac people.
<b>Shelf Life*</b>	36 months
<b>Labeling Instructions*</b>	None
<b>Storage and Distribution*</b>	Ambient temperature.

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## Flow Diagram

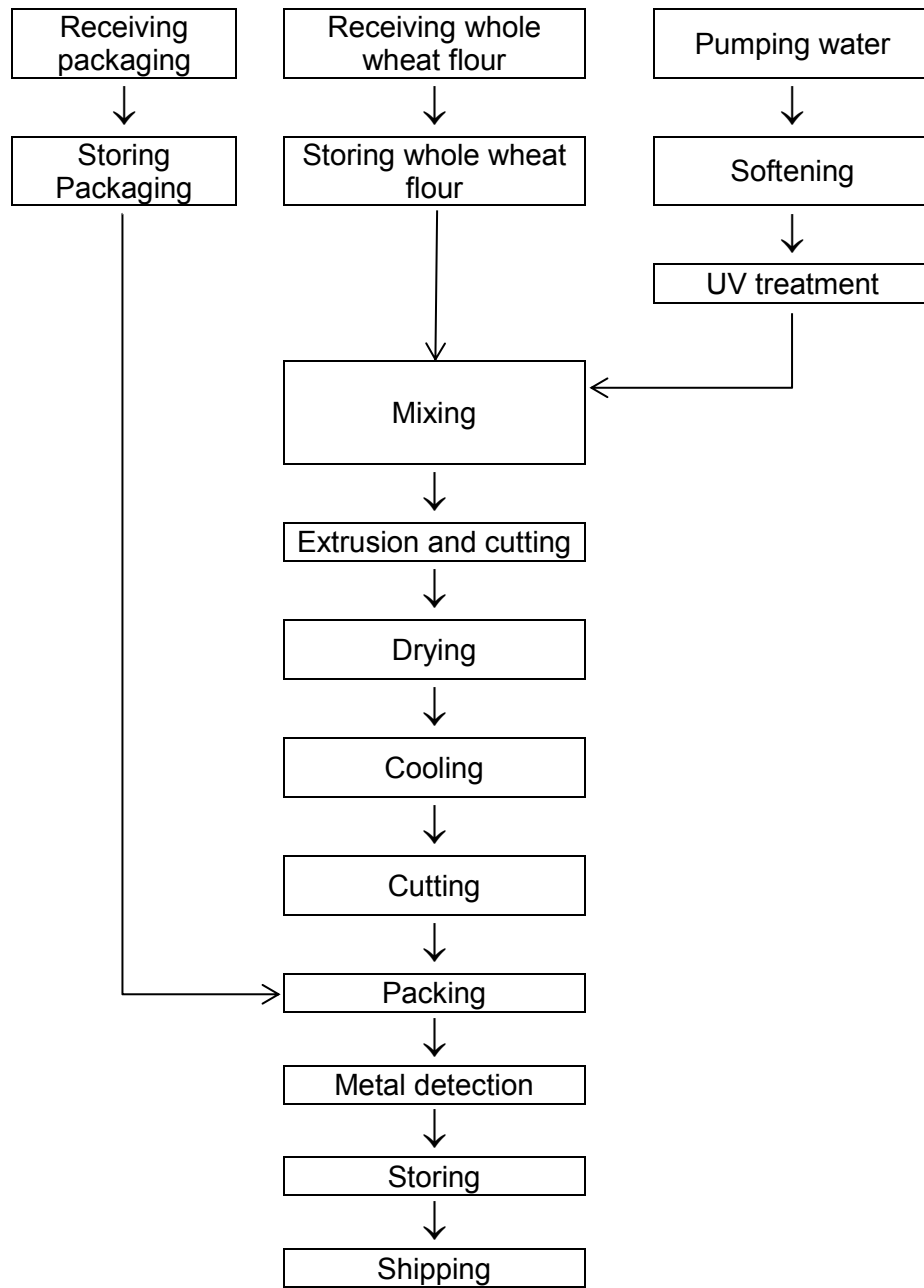
Macaroni Product



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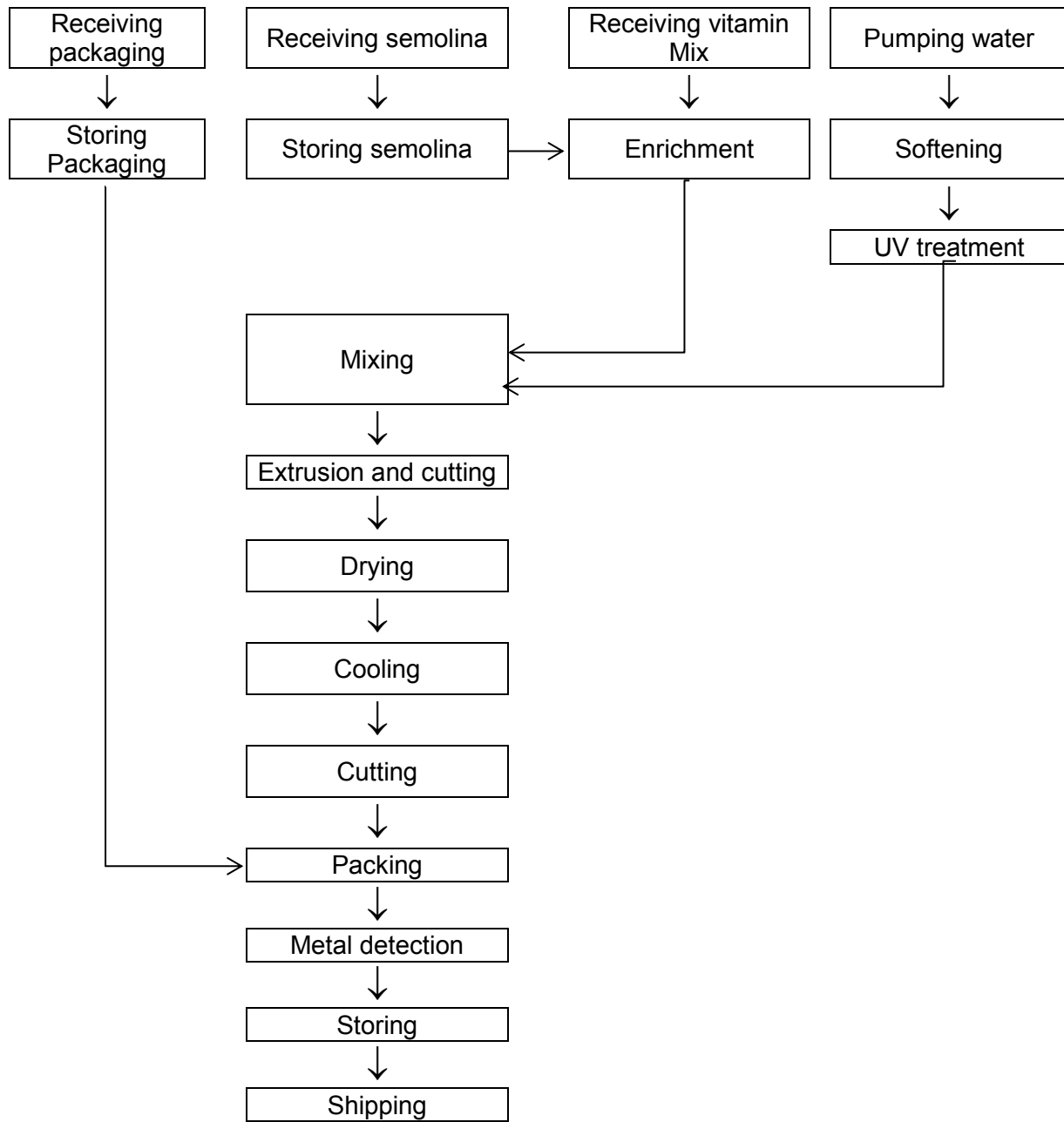
Whole-wheat Macaroni product



Food Safety Plan

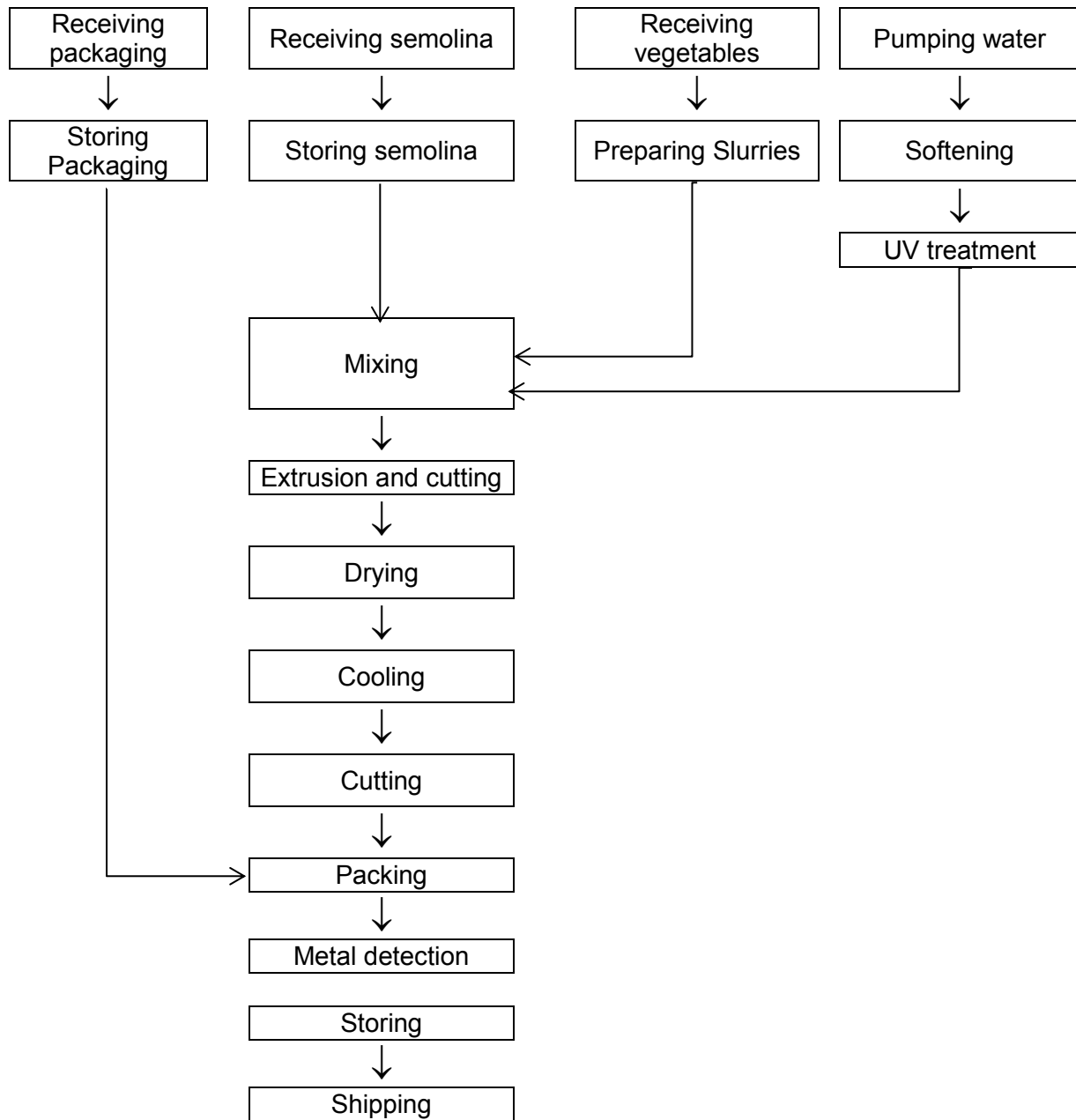
<b>PRODUCT:</b>	Macaroni Product	<b>PAGE 10 of 35</b>
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Enriched Macaroni product



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Tricolor Pasta



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## Process Narrative

Macaroni product and whole-wheat macaroni product

### Receiving packaging

Polypropylene and polyethylene coils are received individually wrapped into a protective bag. Specifications require food grade material for packaging material that is compatible with ambient storage of macaroni product. Vendors provide a certificate of conformance that packaging materials meet safety and regulatory requirements. Corrugated cardboard boxes are received strapped in bundles.

### Receiving semolina and whole-wheat flour

Semolina and flour are received in bulk truck of about 30 tons. Specifications require the chemical and microbiological minimum quality standards. Vendors provide a certificate of conformance that semolina and flour materials meet safety and regulatory requirements. The internal lab confirms the ash, moisture, protein and color value for any delivery. Quarterly the internal lab perform a microbiological survey for any mill. Yearly a complete analytical screening confirms the food safety system of any supplier.

### Pumping water

Processing water comes from an internal well. Its chemical and microbiological quality is monitored quarterly by an external accredited laboratory.

### Storing packaging

Film coils, corrugated shippers and any minor packaging material (stripe, labels and glue) are stored in a dry storage area and segregated by food material. Boxes are ordered and processed according the production schedule while coils are managed with stock and used on a First-In-First-Out basis.

### Storing semolina and whole-wheat flour

Semolina and whole-wheat flour are stored in a dedicated silos room. The total capability is around 950 tons and cover less than 48 production hours. 16 silos are dedicated to the semolina incoming while 11 are dedicated to the line feeding. The raw materials are managed according the quality standards defined with the vendors and can be used individually or according recipes within the following week (usually within the following 36 hours). Any flour pass through magnetic traps and is sieved before the line feeding with a mesh of 800 µm.

### Softening

Water is softened from a native hardness value over 40 °F to 20-25 °F by an ion exchange resins equipment.

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### **UV treatment**

Although the native microbiological quality of the water is confirmed by any checks made in the last 10 years, an UV lamp is present on the piping addressing the water in the production area as precautionary measure.

### **Mixing**

Semolina or whole wheat flour are mixed with water in an approximate rate of 70/30. The dough is processed in about 20 minutes.

### **Extrusion and cutting.**

The fresh dough passes through a vacuum mixer before incoming the die. At this step it has a moisture content of about 30% and suffers a pressure from 50 to 120 bar at a temperature of about 60°C. It is sieved by a 1-2 mm mash to intercept any foreign material. The pasta is cut under the die to give the desired shape.

### **Drying.**

The drying process takes 4-6 hours for the short shape lines and 7-14 hours for the long shapes lines and for the specialties one. The product moisture fall down from 30% to less than 12.5%, according the Italian regulation on pasta. At this content the  $a_w$  value is lower than 0.60 and this is the key for the product stability for so long time.

### **Cooling.**

The cooling step takes less than one hour and let the product go out the line at a temperature lower than 40°C, confirming the vitreous structure of the product and its resistance to the swelling in the cooking before the consumption.

### **Cutting.**

The spaghetti are automatically cut to about 10 inches of length before the packing operation.

### **Shredding pasta.**

The spaghetti edges are grinded in elements smaller than 1 cm by an equipment close to line exit. These fragments are pumped in a holding silo.

### **Milling pasta.**

The spaghetti fragments are milled to grids smaller than 0.6 mm in order to be added once more at the mixing step. The milled pasta passes through magnetic traps, is immediately sieved with a mash of 800  $\mu$ m and is stored into a dedicated silo. Once mixed with the semolina is sieved once more. The reworked rate never exceeds the 10%.

### **Packing.**

The packing operations are totally automatic. Conveyors carry the product to the balance and after the dosage the pasta is closed into a flexible packaging. The bags are never hermetic in order to permit the pack breathing. The bags are closed into cardboard boxes, the boxes are

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carried to a palletizer to build the logistic unit and permit the warehouse handling. A label complying the GS1 standard identifies any logistic unit.

**Metal detection.**

Any packing line is equipped with a metal detector. Any device is tested hourly against 1.5 mm Fe object, 1.5 mm no-Fe and 2.0 mm S/S. Food service packs are tested against 2.0mm Fe, 2.0 mm no-Fe, 2.5 mm S/S. An automatic rejection system ensure that contaminated pack cannot be distributed.

**Storing.**

The logistic units are stored in a dedicated dry warehouse at ambient temperature. A pest control system is in place in order to detect any possible insect infestation.

**Shipping.**

The product is shipped to the USA into containers at ambient temperature, loose on the floor, on pallet or slip-sheet, as agreed with the consignee. The informative system ensure a ready traceability of any product loaded.

Enriched Macaroni product

**Receiving packaging**

Polypropylene and polyethylene coils are received individually wrapped into a protective bag. Specifications require food grade material for packaging material that is compatible with ambient storage of macaroni product. Vendors provide a certificate of conformance that packaging materials meet safety and regulatory requirements. Corrugated cardboard boxes are received strapped in bundles.

**Receiving semolina**

Semolina is received in bulk truck of about 30 tons. Specifications require the chemical and microbiological minimum quality standards. Vendors provide a certificate of conformance that semolina meets safety and regulatory requirements. The internal lab confirms the ash, moisture, protein and color value for any delivery. Quarterly the internal lab perform a microbiological survey for any mill. Yearly a complete analytical screening confirms the food safety system of any supplier.

**Receiving vitamin Mix**

Vitamin Mix is received in sealed bag of about 20 kg each. Specification requires the chemical and microbiological minimum quality standards. Vendor provides a certificate of conformance that the ingredient meets safety and regulatory requirements.

**Pumping water**

Processing water comes from an internal well. Its chemical and microbiological quality is monitored quarterly by an external accredited laboratory.

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### Storing packaging

Film coils, corrugated shippers and any minor packaging material (stripe, labels and glue) are stored in a dry storage area and segregated by food material. Boxes are ordered and processed according the production schedule while coils are managed with stock and used on a First-In-First-Out basis.

### Storing semolina

Semolina is stored in a dedicated silos room. The total capability is around 950 tons and cover less than 48 production hours. 16 silos are dedicated to the semolina incoming while 11 are dedicated to the line feeding. The raw materials are managed according the quality standards defined with the vendors and can be used individually or according recipes within the following week (usually within the following 36 hours). Any flour pass through magnetic traps and is sieved before the line feeding with a mesh of 800 µm.

### Enrichment

Semolina is enriched in a dedicated equipment that add the mix at a rate of 0.12%. The semolina is mixed for a suitable time allowing for proper homogenization and consequently is stored in dedicated silos before feeding the lines. The enriched semolina is processed within 48 hours.

### Softening

Water is softened from a native hardness value over 40 °F to 20-25 °F by an ion exchange resins equipment.

### UV treatment

Although the native microbiological quality of the water is confirmed by any checks made in the last 10 years, an UV lamp is present on the piping addressing the water in the production area as precautionary measure.

### Mixing

Enriched semolina is mixed with water in an approximate rate of 70/30. The dough is processed in about 20 minutes.

### Extrusion and cutting.

The fresh dough passes through a vacuum mixer before incoming the die. At this step it has a moisture content of about 30% and suffers a pressure from 50 to 120 bar at a temperature of about 60°C. It is sieved by a 1-2 mm mesh to intercept any foreign material. The pasta is cut under the die to give the desired shape.

### Drying.

The drying process takes 4-6 hours for the short shape lines and 7-14 hours for the long shapes lines and for the specialties one. The product moisture fall down from 30% to less than 12.5%, according the Italian regulation on pasta. At this content the  $a_w$  value is lower than 0.60 and this is the key for the product stability for so long time.

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### **Cooling.**

The cooling step takes less than one hour and let the product go out the line at a temperature lower than 40°C, confirming the vitreous structure of the product and its resistance to the swelling in the cooking before the consumption.

### **Cutting.**

The spaghetti are automatically cut to about 10 inches of length before the packing operation.

### **Packing.**

The packing operations are totally automatic. Conveyors carry the product to the balance and after the dosage the pasta is closed into a flexible packaging. The bags are never hermetic in order to permit the pack breathing. The bags are closed into cardboard boxes, the boxes are carried to a palletizer to build the logistic unit and permit the warehouse handling. A label complying the GS1 standard identifies any logistic unit.

### **Metal detection.**

Any packing line is equipped with a metal detector. Any device is tested hourly against 1.5 mm Fe object, 1.5 mm no-Fe and 2.0 mm S/S. Food service packs are tested against 2.0mm Fe, 2.0 mm no-Fe, 2.5 mm S/S. An automatic rejection system ensure that contaminated pack cannot be distributed.

### **Storing.**

The logistic units are stored in a dedicated dry warehouse at ambient temperature. A pest control system is in place in order to detect any possible insect infestation.

### **Shipping.**

The product is shipped to the USA into containers at ambient temperature, loose on the floor, on pallet or slip-sheet, as agreed with the consignee. The informative system ensure a ready traceability of any product loaded.

Tricolor pasta

### **Receiving packaging**

Polypropylene and polyethylene coils are received individually wrapped into a protective bag. Specifications require food grade material for packaging material that is compatible with ambient storage of macaroni product. Vendors provide a certificate of conformance that packaging materials meet safety and regulatory requirements. Corrugated cardboard boxes are received strapped in bundles.

### **Receiving semolina**

Semolina is received in bulk truck of about 30 tons. Specifications require the chemical and microbiological minimum quality standards. Vendors provide a certificate of conformance that

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semolina meets safety and regulatory requirements. The internal lab confirms the ash, moisture, protein and color value for any delivery. Quarterly the internal lab perform a microbiological survey for any mill. Yearly a complete analytical screening confirms the food safety system of any supplier.

### Receiving vegetables

Vegetables added to tricolor pasta are Spinach and Tomato. Spinach is used ad dry powder, with a moisture content lower than 6%. It is delivered in sealed plastic bag of 20 kg. Tomato is purchased as Tomato paste at 28-30 °Bx, packed in aseptic drums of about 220 kg.

### Pumping water

Processing water comes from an internal well. Its chemical and microbiological quality is monitored quarterly by an external accredited laboratory.

### Storing packaging

Film coils, corrugated shippers and any minor packaging material (stripe, labels and glue) are stored in a dry storage area and segregated by food material. Boxes are ordered and processed according the production schedule while coils are managed with stock and used on a First-In-First-Out basis.

### Storing semolina

Semolina is stored in a dedicated silos room. The total capability is around 950 tons and cover less than 48 production hours. 16 silos are dedicated to the semolina incoming while 11 are dedicated to the line feeding. The raw materials ae managed according the quality standards defined with the vendors and can be used individually or according recipes within the following week (usually within the following 36 hours). Any flour pass though magnetic traps and is sieved before the line feeding with a mash of 800 µm.

### Preparing slurries

Vegetables (tomato paste and spinach powder) are dissolved in fresh water into dedicated tanks at defined concentration. The slurries are processed within 8 hours with two different piping equipments.

### Softening

Water is softened from a native hardness value over 40 °F to 20-25 °F by an ion exchange resins equipment.

### UV treatment

Although the native microbiological quality of the water is confirmed by any checks made in the last 10 years an UV lamp is present on the piping addressing the water in the production area as precautionary measure.

### Mixing

Enriched semolina is mixed with water in an approximate rate of 70/30. The dough in processed in about 20 minutes.

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### **Extrusion and cutting.**

The fresh dough passes through a vacuum mixer before incoming the die. At this step it has a moisture content of about 30% and suffers a pressure from 50 to 120 bar at a temperature of about 60°C. It is sieved by a 1-2 mm mash to intercept any foreign material. The pasta is cut under the die to give the desired shape.

### **Drying.**

The drying process takes 4-6 hours for the shirt shape lines and 7-14 hours for the long shapes lines and for the specialties one. The product moisture fall down from 30% to less than 12.5%, according the Italian regulation on pasta. At this content the  $a_w$  value is lower than 0.60 and this is the key for the product stability for so long time.

### **Cooling.**

The cooling step takes less than one hour and let the product go out the line at a temperature lower than 40°C, confirming the vitreous structure of the product and its resistance to the swelling in the cooking before the consumption.

### **Cutting.**

The spaghetti are automatically cut to about 10 inches of length before the packing operation.

### **Packing.**

The packing operations are totally automatic. Conveyors carry the product to the balance and after the dosage the pasta is closed into a flexible packaging. The bags are never hermetic in order to permit the pack breathing. The bags are closed into cardboard boxes, the boxes are carried to a palletizer to build the logistic unit and permit the warehouse handling. A label complying the GS1 standard identifies any logistic unit.

### **Metal detection.**

Any packing line is equipped with a metal detector. Any device is tested hourly against 1.5 mm Fe object, 1.5 mm no-Fe and 2.0 mm S/S. Food service packs are tested against 2.0mm Fe, 2.0 mm no-Fe, 2.5 mm S/S. An automatic rejection system ensure that contaminated pack cannot be distributed.

### **Storing.**

The logistic units are stored in a dedicated dry warehouse at ambient temperature. A pest control system is in place in order to detect any possible insect infestation.

### **Shipping.**

The product is shipped to the USA into containers at ambient temperature, loose on the floor, on pallet or slip-sheet, as agreed with the consignee. The informative system ensure a ready traceability of any product loaded.

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## Hazard Analysis

Hazard identification (column 2) considers known or reasonably foreseeable hazards (i.e., potential hazards) 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 hazards, 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

### Macaroni Product

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving packaging	B None						
	C Residue releasing to the product	X		Plastic materials and inks have a history of contamination of foodstuff, although the dry pasta was never involved.	Supply-chain control Verification of the supplier "Declaration of Conformity"	X	
	P None						
Receiving semolina	B None						
	C Mycotoxins						
	Unapproved pesticides	X		Durum wheat semolina has an history of pesticide content (Pirimiphos-methyl) not approved by EPA	Supply-chain control Verification of the supplier "Declaration of Conformity"	X	
	Undeclared allergen (soybeans)	X		Cereal products have a history of presence of soybeans trace due to post harvesting operation and storing.	Supply-chain control Verification of the supplier "Declaration of Conformity"	X	
	Lead						
P None							
Pumping water	B Environmental pathogens such as <i>Salmonella</i> or pathogenic <i>E. Coli</i>		X	Historical facility data confirm the microbiological quality of the water coming from the internal well. A preventive sanitizer equipment is present at a following step			
	C Metal such as Lead Arsenic or Chromium		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	Unapproved pesticides due to the anthropic activity		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	P None						

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?  <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Storing Packaging	B None						
	C None						
	P None						
Storing semolina	B None						
	C None						
	P None						
Softening	B None						
	C None						
	P None						
UV treatment	B None						
	C None						
	P None						
Mixing	B None						
	C None						
	P None						
Extrusion and cutting	B None						
	C None						
	P None			Possible metallic foreign matter is detected at the metal detection step			
Drying	B None						
	C None						
	P None						
Cooling	B None						
	C None						
	P None						
Cutting	B None						
	C None						
	P None			Possible metallic foreign matter is detected at the metal detection step			
Shredding pasta edges	B None						
	C None						
	P None			Possible metallic foreign matter is detected at the metal detection step			
Milling pasta	B None						
	C None						
	P None			Possible metallic foreign matter is detected at the metal detection step			
Packing	B None						
	C None						
	P None						

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Metal detection	B None						
	C None						
	P Foreign bodies presence	X		Potential equipment failure against the detection of foreign material present in the packed product, generated by the equipment or introduced by the employees	Process control Metal detection		
storing	B None						
	C None						
	P None						
Shipping	B None						
	C None						
	P None						

#### Whole wheat Macaroni product

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving packaging	B None						
	C Residue releasing to the product	X		Plastic materials and inks have a history of contamination of foodstuff, although the dry pasta was never involved.	Supply-chain control Verification of the supplier "Declaration of Conformity"	X	
	P None						
Receiving whole wheat flour	B None						
	C Mycotoxins						
	C Unapproved pesticides	X		Durum wheat flour has an history of pesticide content (Pirimiphos-methyl) not approved by EPA	Supply-chain control Verification of the supplier "Declaration of Conformity"	X	
	C Undeclared allergen (soybeans)	X		Cereal products have a history of presence of soybeans trace due to post harvesting operation and storing.	Supply-chain control Verification of the supplier "Declaration of Conformity"	X	
	P Lead						
P None							

#### Food Safety Plan

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?  <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Pumping water	B Environmental pathogens such as <i>Salmonella</i> or pathogenic <i>E. Coli</i>		X	Historical facility data confirm the microbiological quality of the water coming from the internal well. A preventive sanitizer equipment is present at a following step			
	C Metal such as Lead Arsenic or Chromium		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	Unapproved pesticides due to the anthropic activity		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	P None						
Storing Packagin	B None						
	C None						
	P None						
Storing whole wheat flour	B None						
	C None						
	P None						
Softening	B None						
	C None						
	P None						
UV treatment	B None						
	C None						
	P None						
Mixing	B None						
	C None						
	P None						
Extrusion and cutting	B None						
	C None						
	P None			Possible metallic foreign matter is detected at the metal detection step			
Drying	B None						
	C None						
	P None						
Cooling	B None						
	C None						
	P None						
Cutting	B None						
	C None						

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<b>ADDRESS:</b>	via dei pastai, 42 – 80054 Gragnano (NA) Italy	<b>SUPERSEDES</b> -

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
	P None			Possible metallic foreign matter is detected at the metal detection step			
Packing	B None						
	C None						
	P None						
Metal detection	B None						
	C None						
	P Foreign bodies presence	X		Potential equipment failure against the detection of foreign material present in the packed product, generated by the equipment or introduced by the employees	<i>Process control</i> Metal detection		
storing	B None						
	C None						
	P None						
Shipping	B None						
	C None						
	P None						

### Enriched Macaroni product

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving packaging	B None						
	C Residue releasing to the product	X		Plastic materials and inks have a history of contamination of foodstuff, although the dry pasta was never involved.	<i>Supply-chain control</i> Verification of the supplier "Declaration of Conformity"	X	
	P None						
Receiving semolina	B None						
	C Mycotoxins Unapproved pesticides	X		Durum wheat semolina has an history of pesticide content	<i>Supply-chain control</i>	X	

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
				(Pirimiphos-methyl) not approved by EPA	Verification of the supplier "Declaration of Conformity"		
	Undeclared allergen (soybeans)	X		Cereal products have a history of presence of soybeans trace due to post harvesting operation and storing.	Supply-chain control Verification of the supplier "Declaration of Conformity"	X	
	Lead						
	P None						
Receiving vitamin mix	B None						
	C None						
	P None						
Pumping water	B Environmental pathogens such as <i>Salmonella</i> or pathogenic <i>E. Coli</i>		X	Historical facility data confirm the microbiological quality of the water coming from the internal well. A preventive sanitizer equipment is present at a following step			
	C Metal such as Lead Arsenic or Chromium		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	Unapproved pesticides due to the anthropic activity		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	P None						
Storing Packagin	B None						
	C None						
	P None						
Storing semolina	B None						
	C None						
	P None						
Enrichment	B None						
	C None						
	P None						
Softening	B None						
	C None						
	P None						
UV treatment	B None						
	C None						
	P None						
Mixing	B None						
	C None						
	P None						

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?  <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Extrusion and cutting	B None						
	C None						
	P None			Possible metallic foreign matter is detected at the metal detection step			
Drying	B None						
	C None						
	P None						
Cooling	B None						
	C None						
	P None						
Cutting	B None						
	C None						
	P None			Possible metallic foreign matter is detected at the metal detection step			
Packing	B None						
	C None						
	P None						
Metal detection	B None						
	C None						
	P Foreign bodies presence		X	Potential equipment failure against the detection of foreign material present in the packed product, generated by the equipment or introduced by the employees	<i>Process control</i> Metal detection		
storing	B None						
	C None						
	P None						
Shipping	B None						
	C None						
	P None						

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Tricolor pasta

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving packaging	B None						
	C Residue releasing to the product	X		Plastic materials and inks have a history of contamination of foodstuff, although the dry pasta was never involved.	Supply-chain control Verification of the supplier "Declaration of Conformity"	X	
	P None						
Receiving semolina	B None						
	C Mycotoxins						
	Unapproved pesticides	X		Durum wheat semolina has an history of pesticide content (Pirimiphos-methyl) not approved by EPA	Supply-chain control Verification of the supplier "Declaration of Conformity"	X	
	Undeclared allergen (soybeans)	X		Cereal products have a history of presence of soybeans trace due to post harvesting operation and storing.	Supply-chain control Verification of the supplier "Declaration of Conformity"	X	
	Lead						
P None							
Receiving vegetables	B None						
	C None						
	P None						
Pumping water	B Environmental pathogens such as <i>Salmonella</i> or pathogenic <i>E. Coli</i>		X	Historical facility data confirm the microbiological quality of the water coming from the internal well. A preventive sanitizer equipment is present at a following step			
	C Metal such as Lead Arsenic or Chromium		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	Unapproved pesticides due to the anthropic activity		X	Historical facility data confirm the chemical quality of the water coming from the internal well.			
	P None						
Storing Packagin	B None						
	C None						
	P None						
Storing semolina	B None						
	C None						
	P None						
	B None						

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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?  <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Preparing slurries	C None						
	P None						
Softening	B None						
	C None						
UV treatment	P None						
	B None						
	C None						
Mixing	P None						
	B None						
	C None						
Extrusion and cutting	P None						
	C None						
	B None			Possible metallic foreign matter is detected at the metal detection step			
Drying	P None						
	C None						
	B None						
Cooling	P None						
	C None						
	B None						
Cutting	P None						
	C None						
	B None			Possible metallic foreign matter is detected at the metal detection step			
Packing	P None						
	C None						
	B None						
Metal detection	P Foreign bodies presence	X		Potential equipment failure against the detection of foreign material present in the packed product, generated by the equipment or introduced by the employees	<i>Process control</i> Metal detection		
	C None						
	B None						
storing	P None						
	C None						
	B None						
Shipping	P None						
	C None						
	B None						

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## Process Preventive Controls

### Macaroni Product

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal detection	Foreign bodies presence	2.0mm Fe 2.0mm no-Fe 2.5mm S/S	Testing the detection equipment	Challenging the detector with calibrated testers	Hourly	Packing line operator.	In case of failing the product packed after the latest complete control is on hold and re-tested through a metal detector	The QC manager verify the automatic logs related to the metal detection, including the working data and the testing results	The testing operations are automatically logged on the company server. The CQ manager signs the paper sheets by the operators.

### Whole-wheat macaroni product

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal detection	Foreign bodies presence	2.0mm Fe 2.0mm no-Fe 2.5mm S/S	Testing the detection equipment	Challenging the detector with calibrated testers	Hourly	Packing line operator.	In case of failing the product packed after the latest complete control is on hold and re-tested through a metal detector	The QC manager verify the automatic logs related to the metal detection, including the working data and the testing results	The testing operations are automatically logged on the company server. The CQ manager signs the paper sheets by the operators.

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Enriched Macaroni Product

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal detection	Foreign bodies presence	2.0mm Fe 2.0mm no-Fe 2.5mm S/S	Testing the detection equipment	Challenging the detector with calibrated testers	Hourly	Packing line operator.	In case of failing the product packed after the latest complete control is on hold and re-tested through a metal detector	The QC manager verify the automatic logs related to the metal detection, including the working data and the testing results	The testing operations are automatically logged on the company server. The CQ manager signs the paper sheets by the operators.

Tricolor Pasta

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal detection	Foreign bodies presence	2.0mm Fe 2.0mm no-Fe 2.5mm S/S	Testing the detection equipment	Challenging the detector with calibrated testers	Hourly	Packing line operator.	In case of failing the product packed after the latest complete control is on hold and re-tested through a metal detector	The QC manager verify the automatic logs related to the metal detection, including the working data and the testing results	The testing operations are automatically logged on the company server. The CQ manager signs the paper sheets by the operators.

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## Food Allergen Preventive Controls

### Food Allergen Ingredient Analysis

#### Macaroni Product

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation								Allergens in Supplier's Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	
Durum wheat semolina	All the approved mills	NO	NO	NO	Yes	NO	NO	NO	NO	Wheat presence in the product is well reported in the ingredient list and in other claims on the label

#### Whole-wheat Macaroni Product

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation								Allergens in Supplier's Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	
Durum whole-wheat flour	All the approved mills	NO	NO	NO	Yes	NO	NO	NO	NO	Wheat presence in the product is well reported in the ingredient list and in other claims on the label

#### Enriched Macaroni Product

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation								Allergens in Supplier's Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	
Durum wheat semolina	All the approved mills	NO	NO	NO	Yes	NO	NO	NO	NO	Wheat presence in the product is well reported in the ingredient list and in

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										other claims on the label
Vitamin Mix	Stern Vitamin	NO	NO	NO	NO	NO	NO	NO	NO	

Tricolor pasta

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation								Allergens in Supplier's Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	
Durum wheat semolina	All the approved mills	NO	NO	NO	Yes	NO	NO	NO	NO	Wheat presence in the product is well reported in the ingredient list and in other claims on the label
Tomato Paste	Rodolfi Mansueto spa	NO	NO	NO	NO	NO	NO	NO	NO	
Spinach Powder	New foods spa	NO	NO	NO	NO	NO	NO	NO	NO	

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### Allergen Verification Listing

Product	Allergen Statement	Label Number
Macaroni Product	Wheat presence	all
Whole wheat macaroni product	Wheat presence	all
Enriched Macaroni product	Wheat presence	all
Tricolor pasta	Wheat presence	all

### Allergen Scheduling and Cleaning Implications

#### Production Line Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)
Macaroni Product	all	NO	NO	NO	Yes	NO	NO	NO	NO
Whole wheat macaroni product	all	NO	NO	NO	Yes	NO	NO	NO	NO
Enriched Macaroni product	all	NO	NO	NO	Yes	NO	NO	NO	NO
Tricolor pasta	all	NO	NO	NO	Yes	NO	NO	NO	NO

**Scheduling Implications:** None

**Allergen Cleaning Implications:** None

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## Sanitation Preventive Controls

### Cleaning and Sanitizing Procedure

<b>Location</b>	Production department
<b>Purpose</b>	Limiting the mold growth in the mixing tank
<b>Frequency</b>	At least once a week
<b>Who</b>	Production personnel or contractor personnel
<b>Procedure</b>	As described in the document "Piano di pulizie"
<b>Monitoring</b>	By bioluminescence swab-test
<b>Corrections</b>	New cleaning activity/frequency review
<b>Records</b>	"Modulo di registrazione Verifica efficacia pulizie (SWAB)"
<b>Verification activities</b>	By quality control manager.

### Hygienic Zoning

*[Insert simple facility layout, indicating flow of material to aid common understanding and visualization.]*

<b>Location</b>	Internal and external areas
<b>Purpose</b>	Pest control
<b>Frequency</b>	15 days
<b>Who</b>	Contractor
<b>Procedure</b>	As described in the document "Procedura pest control"
<b>Monitoring</b>	By specific traps
<b>Corrections</b>	Extraordinary cleaning – increased monitoring – extraordinary treatment
<b>Records</b>	Contractor web portal
<b>Verification activities</b>	Quarterly audit on pest control system

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## Supply-chain-applied Preventive Controls Program

### Verification Procedures for Supply-Chain-Applied Control Ingredients

Primary packaging:

<b>Hazards requiring a supply-chain-applied control</b>	Residue releasing from packaging to the product
<b>Preventive controls applied by the supplier</b>	Periodical migration test in order to validate the material and its suitability for a defined product.
<b>Verification activities and procedures</b>	Check on the “conformity declaration” attached to any packaging delivery
<b>Records</b>	archiving documents

Ingredient Semolina/whole-wheat flour:

<b>Hazards requiring a supply-chain-applied control</b>	Unapproved pesticides in semolina/whole-wheat flour
<b>Preventive controls applied by the supplier</b>	Analytical check on wheat batch.
<b>Verification activities and procedures</b>	Check on the “conformity declaration” attached to any semolina/whole-wheat flour delivery
<b>Records</b>	archiving documents

<b>Hazards requiring a supply-chain-applied control</b>	Undeclared allergen (soybeans)
<b>Preventive controls applied by the supplier</b>	Analytical check on the milling batch.
<b>Verification activities and procedures</b>	Check on the “conformity declaration” attached to any semolina/whole-wheat flour delivery
<b>Records</b>	archiving documents

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### Approved Suppliers for Ingredients Requiring a Supply-chain-applied Control

Ingredient (requiring supply-chain- applied control)	Approved Supplier	Hazard(s) requiring supply-chain- applied control	Date of Approval	Verification method	Verification records
Primary packaging	Rotomed Polifilm Polipack Icimen Maca Nuovaerreplast De Lucia Cielle Anico Masterpack	Residue releasing from packaging to the product	16 <sup>th</sup> August 2017	Migration test	Analytical reports
Durum wheat semolina	Casillo Moramarco Candeal Ferro	Unauthorized pesticide	16 <sup>th</sup> August 2017	Pesticides analysis	Analytical reports
Durum wheat semolina	Casillo Moramarco Candeal Ferro	Undeclared allergen (soybeans)	16 <sup>th</sup> August 2017	Soy trace analysis	Analytical reports

### Receiving Procedure for Ingredients Requiring a Supply-chain-applied Control

Primary packaging

**Istruzione:** Controllo packaging in ingresso.

Durum wheat semolina/Whole-wheat flour

**Istruzione:** Controllo sfarinati in ingresso.

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FSVP DOC 021920 03 ILB

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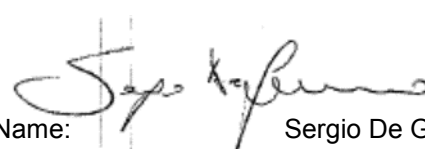


## Ingredient Testing Plan

<b>Testing (specify hazard)</b>	Heavy metals	Pesticides	Mycotoxins	Soybean trace
<b>Testing Frequency</b>	Yearly by mill	Yearly by mill	Yearly by mill	Monthly by mill
<b>Testing Criteria</b>	Regulation (CE) 1881/2006  Cadmium < 0.2 ppm Lead < 0.2 ppm	Regulation (CE) 396/2005	Regulation (CE) 1881/2006  OTA < 3.0 ppb DON < 750 ppb ZEA < 75 ppb Afla B1 < 2.0ppb Afla tot < 4.0 ppb	Regulation (UE) 1169/2011  <2.5 ppm
<b>Corrective Actions if Requirements are not met</b>	Product recall, supplier suspension	Product recall, supplier suspension	Product recall, supplier suspension	Product recall, supplier suspension

## Product Testing Plan

<b>Testing (specify hazard)</b>	Moisture (Hazard: microbiological decay)	Ash (Hazard: product conformity)	Protein (Hazard: product conformity)
<b>Testing Frequency</b>	Each lot	Each lot	Each lot
<b>Testing Criteria</b>	< 12.5%	< 0.90 % (on d.m.)	> 10.5% (Nx5.70 on d.m.)
<b>Corrective Actions if Requirements are not met</b>	Product not released and addressed as animal feed	Product not released and addressed as animal feed or to market with different product regulation	Product not released and addressed as animal feed

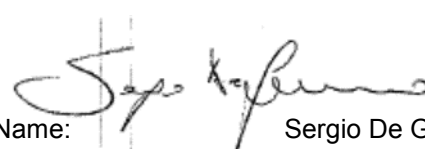
  
 Name: Sergio De Gennaro  
 Title/Position: Quality System Manager  
 Name of Company: Pastificio Lucio Garofalo Spa  
 Phone Number: (+39) 081 801 1002 ext. 441  
 Email Address: [degennaro@pastagarofalo.it](mailto:degennaro@pastagarofalo.it)  
 Date: 300/07/2018

## Environ. Sampling/Monitoring Plan

Testing (specify hazard)	Total Viable Count (Hazard: Environ hygiene)	S. Aureus (Hazard: Environ hygiene)	Total Coliforms (Hazard: Environ hygiene))	Mould and yeast (Hazard: Environ hygiene)
Testing Frequency	4/years	4/years	4/years	4/years
Testing Criteria	< 10 <sup>3</sup> c.f.u./g	< 10 <sup>3</sup> c.f.u./g	< 10 <sup>3</sup> c.f.u./g	< 10 <sup>3</sup> c.f.u./g
Corrective Actions if Requirements are not met	Product recall, extraordinary cleaning and cleaning plan review.	Product recall, extraordinary cleaning and cleaning plan review.	Product recall, extraordinary cleaning and cleaning plan review.	Product recall, extraordinary cleaning and cleaning plan review.

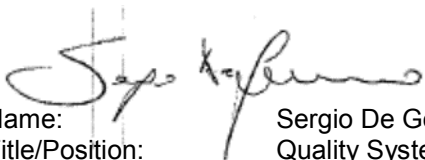
## Supplier Qualification Program

Food Safety Audit Requirements - recognized audit supplier certification	GFSI certification (BRC, IFS, ISO 22000) BRC IOP		
Transportation Requirements - Incoming shipment inspection procedure etc.	Incoming semolina Truck dedicated to cereal derivatives Cleaning certification at any arrival Seals integrity at any arrival		
Corrective Actions if Requirements are not met - Escalation process, conditions for supplier contract termination etc.	Certification absence	Contract termination	
	Delivery NC (broken seal, cleaning certificate absence)	Rejection	
	Routine analysis NC (protein, moisture, ash, gluten)	Rejection	
	Monitoring analysis NC (pesticides, Mycotoxins, heavy metals)	Contract termination	

  
 Name: Sergio De Gennaro  
 Title/Position: Quality System Manager  
 Name of Company: Pastificio Lucio Garofalo Spa  
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 Email Address: [degennaro@pastagarofalo.it](mailto:degennaro@pastagarofalo.it)  
 Date: 300/07/2018

### Hazard Analysis (HACCP)

HACCP prerequisite program	Pest control program	24 inspection by year specific traps for cereal infesting insects flying and crumbling insects rodents  2 preventive heat treatments by year of the whole site
	Plansichters and magnets inspection	weekly
	Cleaning program	Daily dry cleaning weekly mixer sanitation Swab monitoring program
	GMP	Monthly formal audits

  
 Name: Sergio De Gennaro  
 Title/Position: Quality System Manager  
 Name of Company: Pastificio Lucio Garofalo Spa  
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 Date: 300/07/2018

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FSVP DOC 021920 03 ILB

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220

SPAGHETTI



SPAGHETTI

**COOKING SUGGESTIONS**  
ADD PASTA AND A PINCH OF SALT  
TO BOILING WATER.  
COOK FOR 11 MINUTES.  
TAKE YOUR TIME. GOOD ITALIAN  
PASTA TAKES LONGER TO COOK.  
BUT YOU WILL ENJOY A UNIQUE  
FLAVOR WHEN EATING!



**ORGANIC**  
MADE IN ITALY

**COOKING  
TIME**



**MINUTES**

PRODUCT OF ITALY  
CERTIFIED ORGANIC BY CCPB SRL  
IMPORTED IN USA BY:  
P&L IMPORTS  
85262 SCOTTSDALE, AZ  
WWW.P&LIMPORTS.COM  
MAIL TO: INFO@P&LIMPORTS.COM



BEST WHEN USED BY:

1 220 H330  
P&L IMPORTS  
PALM BEACH, FL



MADE FROM 100%  
DURUM WHEAT SEMOLINA  
INGREDIENTS:  
ORGANIC DURUM WHEAT  
SEMOLINA  
STORE IN A COOL DRY PLACE.  
NET WT 500g (17.6 oz)



**Nutrition Facts**

9 servings per container  
Serving size 1/9 package (56g/2oz) dry

Amount per serving  
**Calories 210**

	% Daily Value*
<b>Total Fat</b> 1g	1%
Saturated Fat 0g	0%
Trans Fat 0g	0%
Cholesterol 0mg	0%
Sodium 0mg	0%
<b>Total Carbohydrate</b> 43g	16%
Dietary Fiber 2g	7%
Total Sugars 2g	0%
Includes 0g Added Sugars	0%
<b>Protein</b> 6g	
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0.6mg	4%
Potassium 115mg	2%

\*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. A diet of 2,000 calories a day is used for general nutrition advice.

**AUTHENTIC ITALIAN LIFESTYLE**

WE HAVE MADE OUR PASTA FOR  
OVER 200 YEARS IN THE TOWN  
OF GRAGNANO. THE TOWN WAS  
NAMED AFTER WHEAT (GRANO).  
THE PASTA IS MADE USING THE  
WEATHER AND THE NEARBY SEA  
TO MAKE THIS THE PERFECT  
AREA IN ALL OF ITALY FOR  
MAKING PASTA. WE KNOW YOU  
OF COURSE, PASTA IS KNOW THAT  
YOU WILL ENJOY IT.



MADE FROM 100%  
DURUM WHEAT SEMOLINA



ORGANIC MACARONI PRODUCT  
NET WEIGHT 500 G (17.6 OZ)

PASTA DI SEMOLA DI GRANO DURO

47.5

95

47.5

15

*Claudio Innocenti*

300.0

CASARECCE



COOKING SUGGESTIONS  
ADD PASTA AND A PINCH OF SALT  
TO BOILING WATER.  
COOK FOR 13 MINUTES.  
TAKE YOUR TIME. GOOD ITALIAN  
PASTA TAKES LONGER TO COOK.  
BUT YOU WILL ENJOY A UNIQUE  
FLAVOR WHEN EATING!

ORGANIC  
MADE IN ITALY

PRODUCT OF ITALY  
CERTIFIED ORGANIC BY CCPB S&L  
IMPORTED IN USA BY:  
PAL IMPORTS  
85262 SCOTTSDALE, AZ  
WWW.PALIMPORTS.COM  
MAIL TO: INFO@PASTAGAROFALO.IT



BEST WHEN USED BY:

CASARECCE



Garofalo

ORGANIC  
MADE IN ITALY

STORICO PASTIFICIO GAROFALO  
GRAGNANO - NAPLES



MADE FROM 100%  
DURUM WHEAT SEMOLINA  
ORGANIC MACARONI PRODUCT  
NET WEIGHT 500 G (17.6 OZ)



CASARECCE



Garofalo

ORGANIC  
MADE IN ITALY

STORICO PASTIFICIO GAROFALO  
GRAGNANO - NAPLES

CASARECCE



Garofalo

ORGANIC  
MADE IN ITALY

STORICO PASTIFICIO GAROFALO  
GRAGNANO - NAPLES

AUTHENTIC ITALIAN LIFESTYLE

WE HAVE MADE OUR PASTA FOR  
OVER 200 YEARS IN THE TOWN  
OF GRAGNANO. THE TOWN WAS  
NAMED AFTER WHEAT (GRANO).  
FRESH SPRING WATER, SUNNY  
WEATHER AND THE NEARBY SEA  
MAKE THIS HILL THE PERFECT  
AREA IN ALL OF ITALY FOR  
MAKING PASTA. WE ARE PROUD  
OF OUR PASTA AND KNOW THAT  
YOU WILL ENJOY IT.



MADE FROM 100%  
DURUM WHEAT SEMOLINA  
INGREDIENTS:  
ORGANIC DURUM WHEAT  
SEMOLINA.

STORE IN A COOL DRY PLACE.

**Nutrition Facts**

9 servings per container

Serving size 55g (1 1/2 cups)

**Calories 210**

Amount per serving		% Daily Value*
<b>Total Fat</b> 1g		1%
Saturated Fat 0g		0%
Trans Fat 0g		0%
Cholesterol 0mg		0%
Sodium 0mg		0%
<b>Total Carbohydrate</b> 43g		16%
Dietary Fiber 2g		7%
Total Sugars 3g		6%
Includes 0g Added Sugars		0%
<b>Protein</b> 5g		
Vitamin D 0mcg		0%
Calcium 0mg		0%
Iron 4mg		4%
Potassium 115mg		2%

\*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a diet of 2,000 calories. A diet is based on general nutrition advice.

PASTA DI SEMOLA DI GRANO DURO

IMPORTED IN THE USA BY: PAL IMPORT  
85262 SCOTTSDALE, ARIZONA - www.palimports.com

Claudio Innocenti

21

17

20

32.5

180

32.5

320

PENNE ZITI RIGATE



COOKING SUGGESTIONS  
ADD PASTA AND A PINCH OF SALT  
TO BOILING WATER.  
COOK FOR 11 MINUTES.  
TAKE YOUR TIME. GOOD ITALIAN  
PASTA TAKES LONGER TO COOK,  
BUT YOU WILL ENJOY A UNIQUE  
FLAVOR WHEN EATING!

**ORGANIC**  
MADE IN ITALY

PRODUCT OF ITALY  
CERTIFIED ORGANIC BY CCPB SBL  
IMPORTED BY USA BY:  
PAL IMPORTS  
8546A SCOTTSDALE, AZ  
WWW.PALIMPORTS.COM  
MAIL TO: INFO@PASTAGAROFALO.IT



BEST WHEN USED BY:

PENNE ZITI RIGATE



*Garofalo*  
**ORGANIC**  
MADE IN ITALY

STORICO PASTIFICIO GAROFALO  
GRAGNANO - NAPLES



PENNE ZITI RIGATE



*Garofalo*

**ORGANIC**  
MADE IN ITALY



PENNE ZITI RIGATE



*Garofalo*  
**ORGANIC**  
MADE IN ITALY

STORICO PASTIFICIO GAROFALO  
GRAGNANO - NAPLES

**AUTHENTIC ITALIAN LIFESTYLE**

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OVER 200 YEARS IN THE TOWN  
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MAKING PASTA. WE ARE PROUD  
OF OUR PASTA AND KNOW THAT  
YOU WILL ENJOY IT.

**COTTURA**  
**11'**  
**MINUTI**

MADE FROM 100%  
DURUM WHEAT SEMOLINA



**ORGANIC MACARONI PRODUCT**  
**NET WEIGHT 500 G (17.6 OZ)**

**PASTA DI SEMOLA DI GRANO DURO**  
IMPORTED IN THE USA BY: PAL IMPORT  
8546A SCOTTSDALE, ARIZONA - www.palimports.com

**STP**  
MADE FROM 100%  
DURUM WHEAT SEMOLINA  
INGREDIENTS:  
ORGANIC DURUM WHEAT  
SEMOLINA.  
STORE IN A COOL DRY PLACE.  
**NT WT 500g (17.6 oz)**

**Nutrition Facts**  
9 servings per container  
Serving size 50g (1.76oz)

Amount per serving	
<b>Calories</b>	<b>210</b>
<b>% Daily Value*</b>	
<b>Total Fat</b> 1g	2%
<b>Saturated Fat</b> 0g	0%
<b>Trans Fat</b> 0g	0%
<b>Cholesterol</b> 0mg	0%
<b>Sodium</b> 0mg	0%
<b>Total Carb</b> 42g	84%
<b>Dietary Fiber</b> 3g	6%
<b>Total Sugars</b> 2g	4%
<b>Protein</b> 8g	16%
<b>Vitamin D</b> 0mcg	0%
<b>Calcium</b> 0mg	0%
<b>Iron</b> 4mg	4%
<b>Potassium</b> 110mg	22%

\*Percent Daily Values are based on a diet of other people's secrets.

*Claudio Innocenti*

14

6

42.5

60

110

60

42.5

20

GEMELLI



COOKING SUGGESTIONS  
ADD PASTA AND A PINCH OF SALT  
TO BOILING WATER.  
COOK FOR 9 MINUTES.  
TAKE YOUR TIME. GOOD ITALIAN  
PASTA TAKES LONGER TO COOK.  
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GEMELLI



GEMELLI



*Garofalo*

GEMELLI



STP

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DURUM WHEAT SEMOLINA  
INGREDIENTS:  
ORGANIC DURUM WHEAT  
SEMOLINA

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**Nutrition Facts**

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Amount per serving

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	% Daily Value*
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Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 43g	16%
Dietary Fiber 2g	7%
Total Sugars 0g	
Includes Gg Added Sugars	0%
Protein 0g	
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 115mg	2%

\*% Daily Value is based on a diet of pasta.  
A serving of food contributes to a diet. Only 100% of the  
data is used for general nutrition advice.

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BEST WHEN USED BY:

*Garofalo*  
**ORGANIC**  
MADE IN ITALY

STORICO PASTIFICIO GAROFALO  
GRAGNANO - NAPLES



*Garofalo*  
**ORGANIC**  
MADE IN ITALY

STORICO PASTIFICIO GAROFALO  
GRAGNANO - NAPLES

COTTURA



MINUTI

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