



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

FUSION GOURMET INCORPORATED

*Name of FSVP Importer*

GR.A.M.M. S.R.L. | GRUPPO ALIMENTARE MEDITERRANEO MILO S.R.L.

*Name of Foreign Supplier*

DOLCETTO TUSCAN CRISPS & TOSCANA CRACKERS - [SEVERAL FLAVORS]

*Name of Product*

JULY 30, 2022

*Date of Initial Verification / Reverification*

JULY 31, 2023

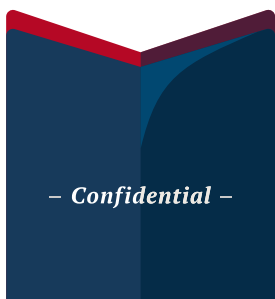
*Date of FSVP Plan Expiration*

VERIFICATION COMPLETE | APPROVED FOR IMPORT

*Result of Verification*

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 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 within 24 hours of FDA’s request. Electronic records are considered to be on-site if they are accessible from an on-site location. Records obtained by FDA are subject to the disclosure requirements found under Part 20. **Please contact USA immediately** to report a change in a foreign supplier’s processes or status, upon contact by FDA, or with any questions that you may have by email at [info@unitedsafetyagents.com](mailto:info@unitedsafetyagents.com), or by telephone at +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 on-site 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 on-site 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.

*Continued onto next page.*

## FOREIGN SUPPLIER VERIFICATION PROCEDURES

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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 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 page eleven, Ongoing Document Requirements found on page twelve, and Ongoing Verification Activities & Frequency of Ongoing Verification Activities found on page fourteen.

### 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: GR.A.M.M. S.r.l.

Product: Dolcetto Tuscan Crisps & Crackers (Baked)

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

Review Start: June 29, 2022 Review End: July 30, 2022

## 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: GR.A.M.M. S.r.l.

Product: Dolcetto Tuscan Crisps & Crackers (Baked)

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

Review Start: June 29, 2022 Review End: July 30, 2022

## 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 twenty-eight through thirty-six for substantiation of the FSVP QI's / PCQI's credentials.

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

## 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: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI, Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

**DESIGNATION of ROLES & SUMMARY of REVIEW**

**FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER**

Company Name: Fusion Gourmet, Incorporated FDA FEI: 3012239442

Physical Address: 690 W. Manville Street DUNS No.: 12-319-1194

City: Compton/Rancho State: California Country: United States

Mailing Address: 690 W. Manville Street

City: Compton/Rancho State: California Country: United States

Phone Number: +1 (310) 898-2180 Email Address: steveliaw@fusiongourmet.com

Name of Representative(s): Mr. Steve Liaw Title: Commercial Rep.

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

Company Name: GR.A.M.M. S.r.l. FDA FFR: 16111067886

Manufacturing Address: Strada Statale 96 km 113,200 FDA FEI: 3013416475

City: Palo del Colle Province/Territory: Bari, 70027 Country: Italy

Office Address: Palombaio, via Teologo Valente, s.n.c.

City: Bitonto Province/Territory: Bari Country: Italy

Phone Number: +390803735950 Email Address: qualita@gruppomilo.it

Name of Representative(s): Mr. Francesco Garofalo Title: Tech. Rep.

**QUALIFIED INDIVIDUAL(s) & AGENT(s)**

Agent/QI Name: Claudio Innocenti Signature: 

Title: Partner & Preventive Controls Qualified Individual. Date: July 30, 2022

Support PCQI: William J. Barber Signature: 

Title: Preventive Controls Qualified Individual.

**SUMMARY of REVIEW**

Details of Product(s)	Is foreign supplier expected to implement controls for			Comments
	Biological Hazards	Chemical Hazards	Physical Hazards	
Dolcetto Tuscan Crisps and Toscana Crackers (Olive Oil & Sea Salt, Italian Cheese, Rosemary & Olive Oil, Parmesan Garlic & Herb, Sour Cream & Onion).	<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 & Approved.
	<input 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	See Addendum.
	<input type="checkbox"/> Customer	<input type="checkbox"/> Customer	<input type="checkbox"/> Customer	

Preventive Control or Disclosure Req.: 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: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

## REGISTER of SUBSTANTIATING DOCUMENTS



### HAZARD ANALYSIS

Requested  Required  Received  Reviewed

NOTES GR.A.M.M. S.r.l.'s (Brand: Casa Milo) HACCP Plan received.  
Dated:  
Plan Entitled: Food Safety Plan for Oven Baked Products.  
Version: No. 20220412.  
Plant FDA: 16111067886



### ON-SITE AUDIT

Requested  Required  Received  Reviewed

NOTES GR.A.M.M. S.r.l.'s Full BRC Audit Report received.  
Dated: May 2021.  
Re-audit Due Date: July 2022.  
Audit Grade: A+.  
Number of Minor Non-conformities: 8. All with corresponding corrective actions.  
Previous Audit Grade: A.



### SAMPLING OR TESTING RESULTS

Requested  Required  Received  Reviewed

NOTES Several Certificates of Analysis received from supplier.  
Dated: March 2022.  
Tested for: Biological hazards such as Salmonella.  
Laboratory: Food Safety Lab.



### OTHER FOOD SAFETY RECORDS

Requested  Required  Received  Reviewed

NOTES Completed Foreign Supplier FSVP Questionnaire received.  
Dated: June 16, 2022.  
Completed by: Mr. Francesco Garofalo.

Several PCQI Certificates received.

Note: No substantiating information provided by the supplier.



### PRODUCT LABELING

Requested  Required  Received  Reviewed

NOTES Product Label received. Label clearly identifies all present allergens. Labeling is in compliance with Part 403(w) of the Federal Food, Drug, and Cosmetic Act in so far as it is not misbranded with respect to the presence of food allergens. See Analysis & Determination of Allergenic Hazard(s) for details.

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.

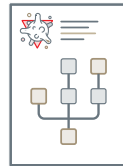
**VERIFICATION FREQUENCY for UPDATED DOCUMENTS**

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 accord 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: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

## INITIAL VERIFICATION ACTIVITIES

To confirm that all relevant or identified food safety hazards requiring a control have been significantly minimized or prevented, the below enumerated activities were used to initially verify Baked Crackers & Cubetti Products (“product” or “imported product”), supplied by Gr.a.m.m. srl (“supplier” or “foreign supplier”), imported by Fusion Gourmet (“importer” or “FSVP importer”):

RELEVANT FOOD SAFETY RECORDS, including a review of the foreign supplier’s relevant food safety records, including Gr.a.m.m. srl’s Hazard Analysis and Critical Control Plan (“HACCP Plan”); food safety plan/program; implementation records; and internal monitoring procedures. Per §1.506(d)(1)(ii)(C) and (e)(1)(iii), documentation of each record, including the dates of review, the general nature of the records reviewed, the conclusions of the review, and documentation that the review was conducted by a FSVP qualified individual were completed.

SAMPLING AND/OR TESTING of the imported product, including the assessment of one or more certificates of analysis – for testing conducted to determine the presence or absence of all relevant or identified hazards requiring a control. Per §1.506(d)(1)(ii)(B) and (e)(1)(ii), documentation of the report or reports, the number of samples tested, the tests conducted, the date(s) on which the tests were conducted and the date(s) of the report(s) of the testing, the results of the testing, information identifying the laboratory or laboratories conducting the testing, and documentation that the review was conducted by a qualified individual (ISO 17025-accreditation requested) were completed.

THIRD-PARTY ON-SITE AUDIT REPORT, including the assessment of Gr.a.m.m. srl’s on-site audit report. Per (e)(1)(i)(B) Gr.a.m.m. srl’s on-site audit report was not relied upon to approve the supplier because United Safety Agents (“USA”) could not definitively confirm – or rule out – that the report considered FDA food safety regulations.

FOREIGN SUPPLIER FSVP QUESTIONNAIRE, including a review and assessment of the Gr.a.m.m. srl’s reported critical/process/supply-chain controls for biological, chemical, environmental, allergenic, and physical hazards; facility cleaning information; staff hygiene details; pest control procedures; HACCP, TACCP, and VACCP; traceability procedures; release procedures; packaging format; customer complaint handling procedures; and plans/information relating to a recall and/or food safety issue. Per §1.506(d)(1)(ii)(D) and (e)(1)(iv)(B), documentation of each activity conducted in accordance with paragraph (e)(1)(iv), including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a FSVP qualified individual (“QI”) were completed.

OTHER APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES, including a review of Gr.a.m.m. srl’s compliance history, including whether Gr.a.m.m. srl is the subject of an FDA Warning Letters; Import Alerts; or other FDA compliance actions related to food safety. Per §1.506(d)(1)(ii)(D) and (e)(1)(iv)(B), documentation of each activity conducted in accordance with paragraph (e)(1)(iv), including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a FSVP QI were completed.

### NOTE

Per §1.506(d)(3), Fusion Gourmet relied on the determination of appropriate foreign supplier verification activities made by an entity other than the foreign supplier (USA) and reviewed and assessed whether the determination was appropriate. Fusion Gourmet has documented its review and assessment, including documenting that the determination of appropriate verification activities was made by a FSVP QI. Fusion Gourmet’s attestation of review and assessment can be found on page number nine of this FSVP. USA’s certifications and qualifications can be found on page numbers twenty-eight through thirty-six of this FSVP.

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

## ONGOING VERIFICATION ACTIVITIES

To confirm that all relevant or identified food safety hazards requiring a control, for Baked Crackers & Cubetti Products (“product” or “imported product”), supplied by Gr.a.m.m. srl (“supplier” or “foreign supplier”), continue to be significantly minimized or prevented prior to public distribution, up-to-date versions of all documents used during the initial FSVP verification and approval processes will be re-acquired at least once every three years – or sooner, per the following document-specific requirements:

An updated version of Gr.a.m.m. srl's FOOD SAFETY PLAN will be required if any change or update occurs. Gr.a.m.m. srl has been informed of this ongoing requirement and USA will confirm annually that the version on file remains current and faithfully illustrates all processes, monitoring procedures, etc., or acquire and review Gr.a.m.m. srl's most up-to-date copy.

An updated version of Gr.a.m.m. srl's HACCP PLAN will be required if any change or update occurs. Gr.a.m.m. srl has been informed of this ongoing requirement and USA will confirm annually that the HACCP Plan on file remains current and faithfully illustrates all supply chain controls and/or process/critical control procedures, or acquire and review Gr.a.m.m. srl's most up-to-date copy.

An updated version of Gr.a.m.m. srl's ON-SITE AUDIT REPORT will be requested annually, or if any change or update occurs prior to year's end. Gr.a.m.m. srl has been informed of this ongoing request and USA will acquire and review the updated Report from the supplier annually, or sooner if a change has been made.

Updated LABORATORY TESTING RESULTS for all relevant biological and chemical hazards will be required if a positive result is returned, recall or import refusal occurs, facility inspection takes place, or – at minimum – on an annual basis. Gr.a.m.m. srl has been informed of this ongoing requirement and USA will acquire the results from the supplier annually.

Updated substantiation of Gr.a.m.m. srl's QUALIFIED INDIVIDUAL'S CREDENTIALS will be required if any change or update occurs. USA will confirm annually that the certificate(s) on file remain current.

An updated copy of USA's FSVP SUPPLIER QUESTIONNAIRE will be required if any change or update occurs. Gr.a.m.m. srl has been informed of this ongoing requirement and USA will confirm annually that the details relayed via the questionnaire on file remain current or acquire a newly completed version.

The supplier's COMPLIANCE STANDING/HISTORY will be checked by USA via FDA's Data Dashboard annually – at a minimum – or sooner in the event that USA is made aware of new information.

An updated version of the product's LABELING will be required if any change or update occurs. Gr.a.m.m. srl has been informed of this ongoing requirement and USA will confirm annually that the label on file remains current.

### NOTE

USA's assessment of the product's labeling is restricted to the label's allergen disclosure statement and should not be interpreted to mean that the label meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or all other applicable sections of 21 CFR Part 101. It shall remain Fusion Gourmet's responsibility to independently confirm that the product label follows all regulations prior to import.

## FREQUENCY of VERIFICATION ACTIVITIES

All Ongoing Verification Activities will be conducted and re-conducted at their individually noted frequency, as appropriate to confirm that each hazards requiring a control continues to be significantly minimized or prevented by the supplier. Or, if not controlled by the supplier, is properly disclosed to the appropriate party. Document frequency-specific determinations can be found on page number twelve of FSVP.

*Note: It is understood that the above actions are applicable only if USA continues to serve as the FSVP QI.*

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

### 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
Sept. 25, 2018.	<p>FDA FACILITY INSPECTION Inspection Id: 1070412 Project Area: Food Composition, Standards, Labeling and Econ, and Foodborne Biological Hazards. Classification: No Action Indicated.</p> <p>FDA Data Dashboard search results indicate that supplier's compliance history does not include FDA Warning Letters, Import Alerts, or other applicable compliance actions.</p> <p>Covers: GR.A.M.M. S.r.l. FEI: 3013416475 Date: July 30, 2022</p>

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

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

**REVISION LOG for FSVP PLAN**

Version No.	Date of Change	Description of Revision
No. 01	July 30, 2022	Product and supplier underwent initial FSVP verification.

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

**ANALYSIS & DETERMINATION of BIOLOGICAL HAZARDS**

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input 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 checked="" type="checkbox"/> <i>Pathogenic E. coli</i> <input checked="" type="checkbox"/> <i>Salmonella spp.</i> <input 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 Heat Application (thermal kill step) to control hazards posed by biological agents.</p> <p>Details: 150°C for 10+ minutes.</p> <p>02. Supplier utilizes laboratory testing of finished product to verify that biological hazards have been effectively controlled.</p> <p>Details: Several Certificates of Analysis received. Dated: March 2022. Tested for: Biological hazards such as Salmonella. Laboratory: Food Safety Lab.</p> <p>03. All staff undergoes formal food hygiene training.</p> <p>04. All staff issued protective clothing.</p> <p>05. All production operatives are required to cover head/facial hair within the processing/manufacturing area.</p> <p>06. Adequate toilet and hand washing facilities provided.</p> <p>07. Product is positively released.</p> <p>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> <hr/> <p>----- HAZARD PROFILE ----- ----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables) Category: Baked. Category No.: 2. Subcategory: Bread snacks, Seasoned. 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: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

**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 type="checkbox"/> <i>Mycotoxins/Toxins</i> <input type="checkbox"/> <i>Radiological</i> <input checked="" type="checkbox"/> <i>Unapproved colors &amp; additives</i> <input checked="" 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 style="text-align: center;">———— 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 style="padding-left: 40px;">Details: Raw material approval before being used in the production. Raw material spec, label and ingredient list verification and approval before being used in the production.</p> <p>02. Product's formulation is closely monitored by PCQI.</p> <p>03. Product is positively released.</p> <p>-----</p> <p>Product is not in Ready-to-Eat form upon arrival to FSVP Importer and will undergo further processing by FSVP Importer or FSVP Importer's customer. FSVP Disclosure is required (see Addendum).</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>----- HAZARD PROFILE -----</p> <p>----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables)            Category: Baked.            Category No.: 2.            Subcategory: Bread snacks, Seasoned.            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)

**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 checked="" 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:</p> <p>A) Milk and Wheat are present in products.</p> <p>B) a documented allergen control program is in use.</p> <p>C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination.</p> <p>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>----- Labeling Requirements -----</p> <p>- Food Allergen Labeling and Consumer Protection Act -</p> <p>-----</p> <ul style="list-style-type: none"> <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 mean 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: Baked.            Category No.: 2.            Subcategory: Bread snacks, Seasoned.            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)  
 \*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: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

**ANALYSIS & DETERMINATION of ENVIRONMENTAL HAZARDS**

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input checked="" 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>_____ 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. Efficacy of kill step monitored by PCQI. Laboratory testing of finished product used as validation.</p> <p>04. All product is positively released and hermetically sealed within plastic.</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>----- HAZARD PROFILE -----            ----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables)            Category: Baked.            Category No.: 2.            Subcategory: Bread snacks,                              Seasoned.            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: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

### ANALYSIS & DETERMINATION of PHYSICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<p><input checked="" type="checkbox"/> <b>Metal</b></p> <p><input type="checkbox"/> <b>Glass</b></p> <p><input type="checkbox"/> <b>Extraneous Matter</b></p> <p><input type="checkbox"/> <b>Plastics</b></p> <p><input type="checkbox"/> <b>Stones</b></p> <p><input type="checkbox"/> <b>Wood</b></p> <p><input type="checkbox"/> <b>Natural Component of Food</b></p> <p><input type="checkbox"/> <b>Other</b></p>	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 style="text-align: center;">———— SUPPLIER CONTROL MEASURES ————</p> <p>01. Supplier utilizes an operational and calibrated metal detector to control hazards posed by physical agents.</p> <p>Critical Limits: In-line Metal Detector. Ferrous: 2.5 mm. Non Ferrous: X2.5 mm. Stainless Steel: 2.5 mm.</p> <p>02. Glass and Breakable Plastic Program in use.</p> <p>03. Supplier sieves incoming ingredients and finished products.</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 style="text-align: center;">----- HAZARD PROFILE ----- ----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables) Category: Baked. Category No.: 2. Subcategory: Bread snacks, Seasoned. 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: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

## ASSESSMENT of FOREIGN SUPPLIER

### 1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: GR.A.M.M. S.r.l. 1.2. Supplier country: Italy

1.3. Products manufactured/supplied: Dolcetto Tuscan Crisps & Crackers (Baked)

1.4. Is the supplier certified to a Global Food Safety Standard and audited annually?  Yes  No  N/A

Standard: BRC, ISO 9001, ISO 14001.

### 2.0 SUPPLIER PROCEDURES, PROCESSES & PRACTICES

2.1. Does supplier follow current GMPs?  Yes  No

2.2. Does the supplier have SOPs in place?  Yes  No  N/A

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

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

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

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

### 3.0 SUPPLIER PERFORMANCE HISTORY

3.1. 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.

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

Yes  No

Description: \_\_\_\_\_

### 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 activitie(s) 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 FSVP  Yes  No

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

## REVIEW of GENERAL FOOD SAFETY PROGRAM

### Claims Made Against Product

No claims have been made against the raw material / product type.

### Overview of Foreign Supplier's Commercial Operation

Production (mixing, forming, boiling (possible), rising (possible), baking, toasting (possible) and packaging of dry and/or flavoured bakery products, enveloped in heat-sealed polypropylene bags or in polypropylene buckets and packaged in cardboard boxes or in polypropylene buckets.

### Testing Program & Accreditation

Microbiological flour, filth test, mycotoxins and pesticides 3 times a year; physical chemical and heavy metals twice a year, with rotation plan for suppliers. EVO oil, acidity, peroxides and spectrophotometry 1 time / year, heavy and multiresidual metals 1 every 2 years; Spices, 3 times a year microbiology (CBT, coliforms, E. coli, Salmonella, molds and yeasts), filth test, pesticides and heavy metals); finished products: a microbiological-chemical-physical analysis is carried out monthly, 4 times / year filth test, 2 times / year mycotoxins, heavy metals and pesticides, 1 time / year allergens (soy).

Several Certificates of Analysis received from supplier.

Dated: March 2022. Tested for: Biological hazards such as Salmonella. Laboratory: Food Safety Lab.

### Supplier & Product Allergen Information

Supplier certifies that: A) Milk and wheat are 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.

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

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

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

## 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.

GR.A.M.M. S.r.l.'s Full BRC Audit Report received.

Dated: May 2021. Re-audit Due Date: July 2022. Audit Grade: A+.

Number of Minor Non-conformities: 8. All with corresponding corrective actions.

Previous Audit Grade: A.

### Close Supplier Monitoring

No. 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.

### 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.

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

## 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.

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

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Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

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**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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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  
  
Certificate # 223faa17

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


Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

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**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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**Foreign Supplier Verification Programs**  
delivered by Lead Instructor  
**Bob Bauer**  
completed on  
**09/14/2018**

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

*Gerald Wojtals*  
Gerald Wojtals, Executive Director  
International Food Protection Training Institute

*Joseph Corby*  
Joseph Corby, Executive Director  
Association of Food and Drug Officials

**IFSH** INSTITUTE FOR FOOD SAFETY AND HEALTH  
ILLINOIS INSTITUTE OF TECHNOLOGY

**ifpti** INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

**AFDO**

Certificate # d2e9c287

**Produce Safety ALLIANCE**



ASSOCIATION OF FOOD & DRUG OFFICIALS  
SINCE 1898

## 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**



*Joseph Corby*  
Joseph Corby  
Executive Director, AFDO

*Elizabeth A. Bihn*  
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: GR.A.M.M. S.r.l.

Product: Dolcetto Tuscan Crisps & Crackers (Baked)

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

Review Start: June 29, 2022    Review End: July 30, 2022

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05/31/2018

  
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 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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 Gerald Wojtala, Executive Director  
 International Food Protection Training Institute

  
 Joseph Corby, Executive Director  
 Association of Food and Drug Officials





Certificate # d2e9c287

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

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

*Gerald Wojtala*  
Gerald Wojtala, Executive Director  
International Food Protection Training Institute

*Joseph Corby*  
Joseph Corby, Executive Director  
Association of Food and Drug Officials

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ILLINOIS INSTITUTE OF TECHNOLOGY

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Certificate # 2d697331

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

**QUALIFICATIONS of SUPPORTING QI**

  
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

  
Gerald Wojtala, Executive Director  
International Food Protection Training Institute

  
Steve Mandernach, Executive Director  
Association of Food and Drug Officials

  
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AND HEALTH  
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ifpti  
Certificate # ed6f0b58

  
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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

  
Gerald Wojtala, Executive Director  
International Food Protection Training Institute

  
Joseph Corby, Executive Director  
Association of Food and Drug Officials

  
IFSH INSTITUTE FOR  
FOOD SAFETY  
AND HEALTH  
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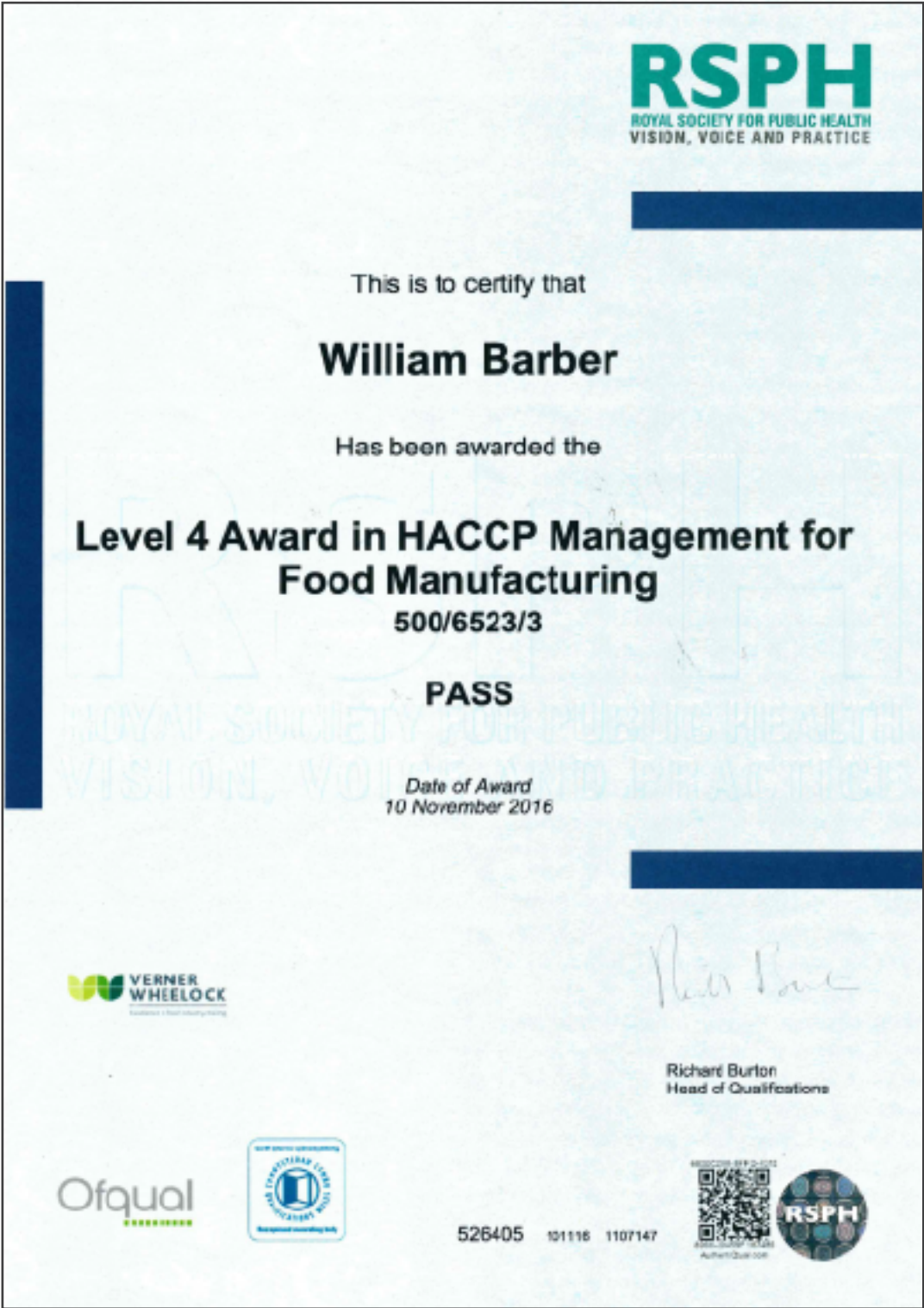
  
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Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

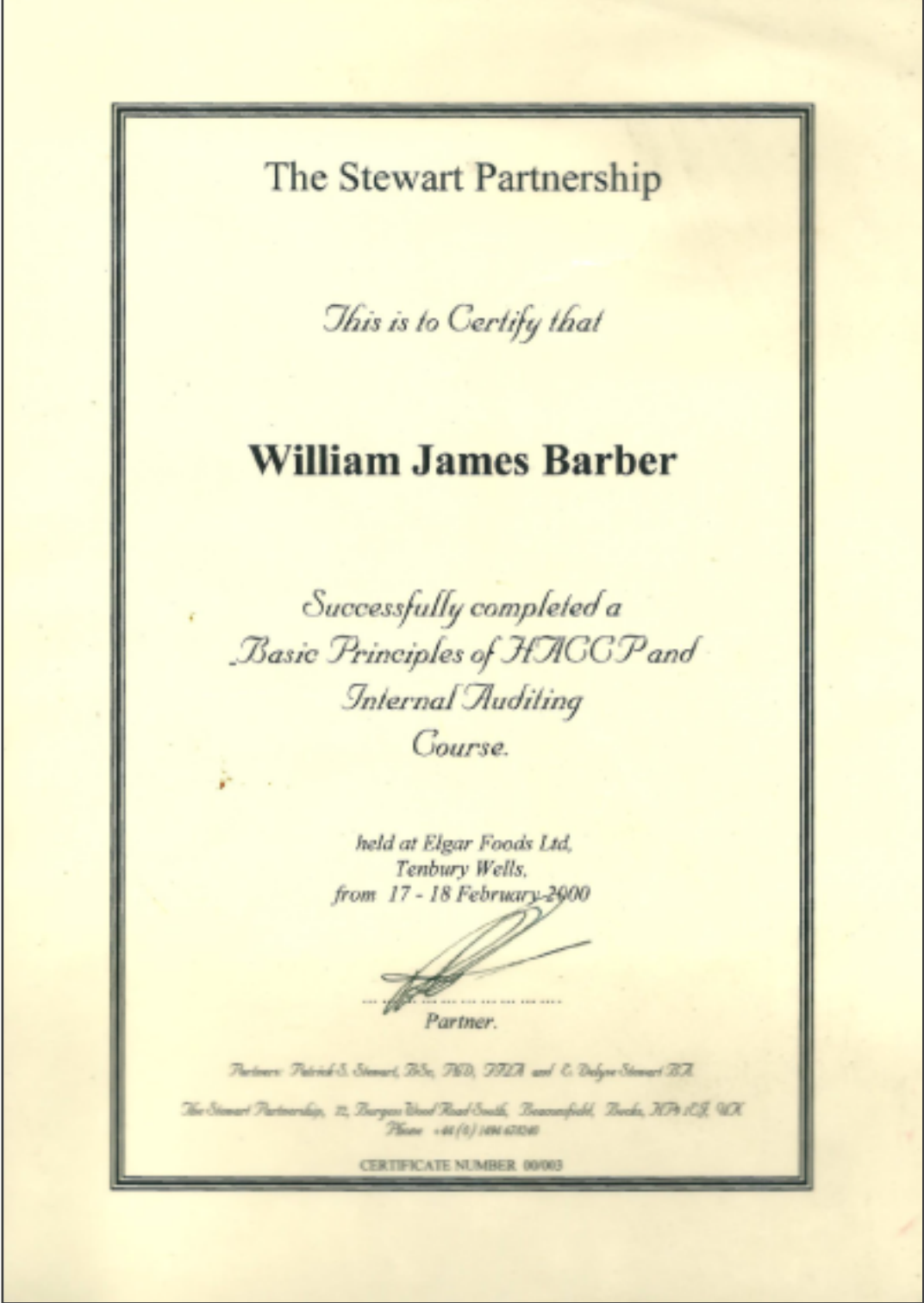
**QUALIFICATIONS of SUPPORTING QI**



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QUALIFICATIONS of SUPPORTING QI



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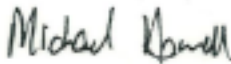



**NATIONAL VOCATIONAL QUALIFICATION**  
**LEVEL 3 NVQ IN FOOD AND DRINK MANUFACTURING OPERATIONS**  
(Q1054402)


**IS AWARDED TO**  
**WILLIAM BARBER**


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


AWARDED SEPTEMBER 2007 0719/024307 A/1 24203/PXC4025/1/1 3103/64

  
M Rowell  
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 1996.  
The City & Guilds Group comprises City & Guilds, C&G, City & Guilds NVQs and City & Guilds iC&G.

Supplier: GR.A.M.M. S.r.l. Product: Dolcetto Tuscan Crisps & Crackers (Baked)

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 29, 2022 Review End: July 30, 2022

**QUALIFICATIONS of SUPPORTING QI**



**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** 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.



# FSP COVER SHEET

Bakery FSP rev 20220412

# Food Safety Plan for Oven Baked Products

DUNS® number: 63-085-0709

Plant FDA Registration # 16111067886 Renewed date: 2020-10-01 / Expiration date: 2022-12-31

Reviewed by: Francesco Garofalo PCQI Date: April 12th 2022

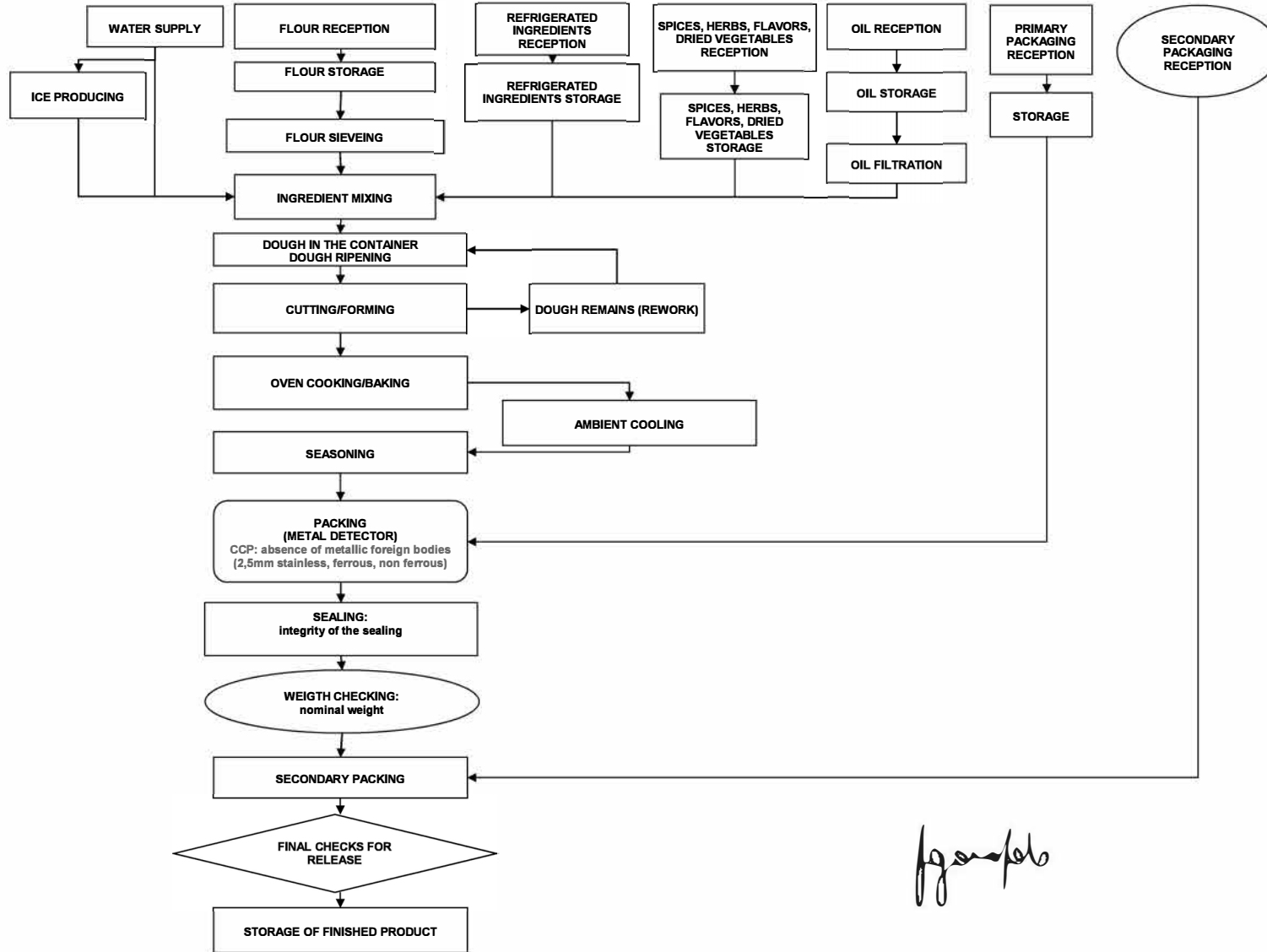
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**GR.A.M.M. Gruppo Alimentare Mediterraneo Milo Srl** is a company located in Italy, Bitonto (BA) Fraz. Palombaio, via Teologo Valente. The manufacturing factory of Oven Baked Products is located in Italy, Palo del Colle (BA), SS 96 km 113,200. This area is free from industrial activities and/or any other activity that could be a source of contamination for the products.

The factory produce oven baked products obtained by mixing the main ingredient wheat flour with water, oil and yeast. Other special ingredients can be added: dried vegetables, dried spices, seeds, flavors, etc. Production steps are: ingredient are mixed to obtain the dough, then the dough is pressed and/or laminated to obtain the shape of the product, the product can be leavened, then there is the oven baking. After baking and ambient cooling the product is usually seasoned with oil. At this step some products are seasoned/dusted with flavors, dried vegetables, dried spices, etc. At the end the product is packed in polypropylene bags.

The company and the manufacturing plant is certified according to BRC Global Standard For food Safety, IFS International Food Standard, ISO 9001, ISO 14001, Organic.



*fgarofalo*



**CRITERIA TEMPLATE**

Severity of injury S		
Score	Severity	Description
0 < S < 1	little serious damage	Damage limited in time, without consequences
1 ≤ S < 2	serious harm	Damage with consequences that extend over time
≤ 2 S ≤ 3	very serious damage	Damage associated with possible fatal outcome

Probability of injury P		
Score	Chance	Description
0 < P < 1	Damage unlikely	<ul style="list-style-type: none"> <li>It occurred very rarely;</li> <li>corporate hygienic conditions are such as to be thought unlikely the occurrence of the damage;</li> <li>according to the characteristics of perishability of the product, it is considered unlikely the occurrence of the damage.</li> </ul>
1 ≤ P < 2	Damage likely	<ul style="list-style-type: none"> <li>You may occur during the manufacturing process;</li> <li>the perishability characteristics of the product and / or raw materials are such as to consider the likely occurrence of the damage.</li> </ul>
2 ≤ P ≤ 3	very likely Damage	<ul style="list-style-type: none"> <li>It occurred frequently;</li> <li>the applicable preventive measures are not sufficient to reduce the probability of occurrence of damage to an acceptable level.</li> </ul>

Probability of injury P	3	3	6	9
	2	2	4	6
	1	1	2	3
		1	2	3
Severity of injury S				

Severity of hazard SxP
high
Average
Modesta

Multiplying the value attributed to GD for the value attributed to P you get a number which can vary from 0 to 9  
 And the following risk severity scale was used:

Severity of hazard SxP		
Score	Severity	Prevention System
0 ≤ SxP < 3	Modesta. The danger is not significant.	Unnecessary
≤ 3 SxP < 6	Average. The danger is significant.	necessary
≤ 6 SxP ≤ 9	High. The danger is particularly significant.	Essential;



### Hazard Analysis

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
1	Water reception	B	//	N	- only town supply water used in the factory; - adequate plumbing design.			0		
1	Water reception	C	//	N	- only town supply water used in the factory.			0		
1	Water reception	P	//	N	- only town supply water used in the factory; - adequate plumbing design.			0		
2	Producing of ICE and COLD WATER	B	//	N	- only town supply water used in the factory; - GHP to prevent contamination; - personnel trained on hygiene and safety			0		
2	Producing of ICE and COLD WATER	C	//	N	- only town supply water used in the factory.			0		
2	Producing of ICE and COLD WATER	P	//	N	- GHP to prevent contamination; - personnel trained on hygiene and safety			0		
3	Receive ingredients: flour	B	//	N	dry ingredients, shelf stable, no risk of microbiological growth at this step			0		
3	Receive ingredients: flour	C	pesticides, micotoxins, heavy metals	N	GAP adopted at the crop step and during wheat storage are enough to prevent chemical contamination	2	1	2		
3	Receive ingredients: flour	C	allergens	Y	wheat flour is an allergen	3	1	3	allergen preventive control: raw material risk analysis to identify allergens (in ingredient formulation and precautionary labelled); supply chain preventive control: PRP 2 RAW MATERIAL RECEIVING (checks at the arriving of raw material: allergen labelling, pack integrity, hygiene checks, sensory evaluation)	Y
3	Receive ingredients: flour	P	foreign bodies	Y	presence of foreign bodies may occur. This step is followed by a process preventive control for this hazard	2	2	4	process preventive control: sieve integrity check	N



### Hazard Analysis

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
4	Receive ingredients: spices, herbs, flavors, dired vegetables	B	//	N	dry ingredients, shelf stable, no risk of microbiological growth at this step			0		
4	Receive ingredients: spices, herbs, flavors, dired vegetables	C	pesticides, micotoxins, heavy metals	N	GAP adopted at the crop step and during wheat storage are enough to prevent chemical contamination	2	1	2		
4	Receive ingredients: spices, herbs, flavors, dired vegetables	C	allergens	Y	some ingredients have allergens in formulation, some other ingredients have precautionary labelling for other allergens handled at supplier step	3	1	3	allergen preventive control: raw material risk analysis to identify allergens (in ingredient formulation and precautionary labelled); supply chain preventive control: PRP 2 RAW MATERIAL RECEIVING (checks at the arriving of raw material: allergen labelling, pack integrity, hygiene checks, sensory evaluation)	Y
4	Receive ingredients: spices, herbs, flavors, dired vegetables	P	//	N	no physical risks for these ingredients			0		
5	Receive ingredients: oils	B	//	N	no microbiological risk for this ingredient			0		
5	Receive ingredients: oils	C	pesticides	N	GAP adopted at the crop step are enough to prevent chemical contamination	2	1	2		
5	Receive ingredients: oils	P	//	N	no physical risks for these ingredients			0		
6	Receive refrigerated ingredients: yeast, cheese	B	- Microbiological (Enterobacteria, salmonella, staphylococcus aureus, mould, yeast)	N	refrigerated transport is enough to prevent microbial growth and product safety along the entire shelf-life	2	1	2		



## Hazard Analysis

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
6	Receive refrigerated ingredients: yeast, cheese	C	allergens	Y	- cheese is an allergen (milk);	3	1	3	allergen preventive control: raw material risk analysis to identify allergens (in ingredient formulation and precautionary labelled); supply chain preventive control: PRP 2 RAW MATERIAL RECEIVING (checks at the arriving of raw material: allergen labelling, pack integrity, hygiene checks, sensory evaluation)	Y
6	Receive refrigerated ingredients: yeast, cheese	P	//	N	these ingredients arrive packaged, no risks of foreign bodies			0		
7	Receive primary packaging	B	//	N	no microbiological risk for this subject			0		
7	Receive primary packaging	C	//	N	Substances used in the manufacture of plastic layers in plastic materials and articles is of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition is known. Supplier makes periodically migration test and declare the conformity to food			0		
7	Receive primary packaging	P	//	N	packaging is protected, no physical for this subject			0		
8	Receive labels and /or printed primary packaging	B	//	N	no microbiological risk for this subject			0		
8	Receive labels and /or printed primary packaging	C	Undeclared Allergens	Y	Printing errors can occur and a correct allergen statement is essential for safety. Packaging line operators check the label but not necessarily the allergen information.	2	3	6	allergen preventive control: labels when received by the printer are sampled and checked to verify if allergens are correctly declared.	Y
8	Receive labels and /or printed primary packaging	P	//	N	packaging is protected, no physical for this subject			0		



## Hazard Analysis

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
9	Ingredients storage: flour, spices, herbs, flavors, dried vegetables	B	Pests	N	GHP and GMP are in place: cleaning procedure; pest monitoring procedure; personell training	2	1	2		
9	Ingredients storage: flour, spices, herbs, flavors, dried vegetables	C	Allergen cross contact	N	personnel trained in allergen management: ingredients containing allergens are clearly identified and kept in closed containers.	3	1	3		
9	Ingredients storage: flour, spices, herbs, flavors, dried vegetables	P	//	N	no physical risk: ingredients are stored in closed container			0		
10	Ingredients storage: oils	B	//	N	no microbiological Irisk for these ingredients			0		
10	Ingredients storage: oils	C	//	N	no chemical risk: ingredients are stored in closed container			0		
10	Ingredients storage: oils	P	//	N	no physical risk; ingredients are stored in closed container			0		
11	Refrigerated ingredient (yeast, cheese) storage	B	Pests	N	GHP and GMP are enough to prevent this hazard: cleaning procedure; pest monitoring procedure; personell training	1	2	2		
11	Refrigerated ingredient (yeast, cheese) storage	B	Microbiological (Enterobacteria, Staphylococcus aureus, moulds)	Y	- refrigerated products are subject to rapid deterioration if not properly stored and must be consumed by the expiry date;	2	2	4	process preventive control: PRP 5 REFRIGERATION CHECK	Y
11	Refrigerated ingredient (yeast, cheese) storage	C	Allergen cross contact	Y	personnel trained in allergen management: ingredients containing allergens are clearly identified and kept in closed containers.	3	1	3		
11	Refrigerated ingredient (yeast, cheese) storage	P	//	N	- no risks as ingredients are packaged in primary and secondary packaging; - personnel trained in GHP during package opening			0		
12	Packaging storage	B	Pests	N	GHP and GMP are enough to prevent this hazard: cleaning procedure; pest monitoring procedure; personell training	1	2	2		

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
12	Packaging storage	C	//	N	- GHP during the handling of packaging and when the packaging is stored; - personnel training.			0		
12	Packaging storage	P	//	N	- GHP during the handling of packaging and when the packaging is stored; - personnel training.			0		
13	Flour sieving	B	//	N	this step specific to prevent foreign bodies			0		
13	Flour sieving	C	//	N	this step specific to prevent foreign bodies			0		
13	Flour sieving	P	foreign bodies	N	presence of foreign bodies may occur	2	2	4	- process preventive control: sieve integrity check; - sanitation preventive control: sieve cleaning; - personnel training;	Y
14	Oil filtration	B	//	N	no microbiological risk for this ingredient			0		
14	Oil filtration	C	//	N	no chemical risks for this ingredient at this step			0		
14	Oil filtration	P	//	N	filtration as GMP, not a significant risk of foreign bodies	1	1	1		
15	Ingredient mixing	B	Microbiological (Enterobacteria, Staphylococcus aureus, moulds, yeasts)	N	GHP and GMP are enough to avoid hazard to a unacceptable level: hygiene procedures; pest monitoring procedure; sanitation preventive control: cleaning and sanitizing procedure; personnel training. This step is followed by a letality step (baking).	2	1	2		
15	Ingredient mixing	C	sanitizing residues	N	- personnel trained in GHP and GMP; - periodic quality inspections to verify cleaning procedure carried-out correctly.	2	1	2		

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
15	Ingredient mixing	C	allergens cross contact	Y	- ingredients containing allergens are handled in the same environment.	3	2	6	- process preventive control: scheduled production (product containing allergens to be produced at the end of production run); - sanitation preventive control: checks after cleaning to assess the absence of residue of previous production; - process preventive control: checks of equipment before a new production run; - personnel training on cleaning and sanitizing procedures;	Y
15	Ingredient mixing	P	foreign bodies (equipment, personnel)	Y	- GHP and GMP are in place to prevent this hazard; - breakage can occur on equipment: scheduled maintenance, GMP and pre-operative checks are in place to prevent this hazard.	2	1	2		
16	Dough in the container	B	Microbiological (Enterobacteria, Staphylococcus aureus, moulds, yeasts)	N	GHP and GMP are enough to avoid hazard to an unacceptable level: hygiene procedures; pest monitoring procedure; sanitation preventive control: cleaning and sanitizing procedure; personnel training. This step is followed by a lethality step (baking).	2	1	2		
16	Dough in the container	C	sanitizing residues	N	- personnel trained in GHP and GMP; - periodic quality inspections to verify cleaning procedure carried-out correctly.	2	1	2		

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
16	Dough in the container	C	allergens cross contact	Y	- ingredients containing allergens are handled in the same environment.	3	2	6	- process preventive control: scheduled production (product containing allergens to be produced at the end of production run); - sanitation preventive control: checks after cleaning to assess the absence of residue of previous production; - process preventive control: checks of equipment before a new production run; - personnel training on cleaning and sanitizing procedures;	Y
16	Dough in the container	P	foreign bodies (equipment, personnel)	Y	- GHP and GMP are in place to prevent this hazard; - breakage can occur on equipment: scheduled maintenance, GMP and pre-operative checks are in place to prevent this hazard.	2	1	2		
17	Dough remains (rework)	B	Microbiological (Enterobacteria, Staphylococcus aureus, moulds, yeasts)	N	GHP and GMP are enough to avoid hazard to a unacceptable level: hygiene procedures; pest monitoring procedure; sanitation preventive control: cleaning and sanitizing procedure; personnel training. This step is followed by a lethality step (baking).	2	1	2		

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
17	Dough remains (rework)	C	allergens cross contact	Y	- ingredients containing allergens are handled in the same environment.	3	2	6	- process preventive control: scheduled production (product containing allergens to be produced at the end of production run); - sanitation preventive control: checks after cleaning to assess the absence of residue of previous production; - process preventive control: checks of equipment before a new production run; - personnel training on cleaning and sanitizing procedures;	Y
17	Dough remains (rework)	P	foreign bodies (equipment, personnel)	Y	- GHP and GMP are in place to prevent this hazard; - breakage can occur on equipment: scheduled maintenance, GMP and pre-operative checks are in place to prevent this hazard.	2	1	2		
18	LAMINATING / CUTTING / FORMING	B	- Microbiological (Enterobacteria, Staphylococcus aureus, mould, yeasts) - Pests	N	GHP and GMP are enough to avoid hazard to an unacceptable level: hygiene procedures; pest monitoring procedure; sanitation preventive control: cleaning and sanitizing procedure; personnel training.	1	2	2		
18	LAMINATING / CUTTING / FORMING	C	sanitizing residues	N	- personnel trained in GHP and GMP; - periodic quality inspections to verify cleaning procedure carried-out correctly.	2	1	2		

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
18	LAMINATING / CUTTING / FORMING	C	allergens cross contact	Y	- ingredients containing allergens are handled in the same environment.	3	2	6	- process preventive control: scheduled production (product containing allergens to be produced at the end of production run); - sanitation preventive control: checks after cleaning to assess the absence of residue of previous production; - process preventive control: checks of equipment before a new production run; - personnel training on cleaning and sanitizing procedures;	Y
18	LAMINATING / CUTTING / FORMING	P	foreign bodies (equipment, personnel)	Y	- GHP in place to prevent foreign bodies carried-out from personnel; - breakage can occur on equipment: scheduled maintenance, GMP and pre-operative checks in place to prevent this hazard.	2	1	2		
19	LEAVENING	B	//	N	no microbiological risk for this ingredient			0		
19	LEAVENING	C	//	N	no chemical risks at this step			0		
19	LEAVENING	P	//	N	no physical risks at this step			0		
20	OVEN BAKING	B	- Microbiological (Enterobacteria, Staphylococcus aureus, mould, yeasts)	Y	microbial growth is possible if baking not managed at appropriate conditions and final product not dry enough	3	2	6	process preventive control: baking temperature monitoring;	Y
20	OVEN BAKING	C	acrylamide	N	- low level of acrylamide avoiding burnt product: personnel trained on this risk and on GMP; - low level of acrylamide avoiding the use of ammonium bicarbonate and fructose in the recipe; if required sugars in the recipe, fructose shall be avoided and glucose or non-reducing sugars such as sucrose will be preferred	3	1	3		

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
20	OVEN BAKING	P	foreign bodies (metal fragments from trays and tunnel belt)	N	- breakage can occur on equipment: scheduled maintenance in place to prevent this hazard; - GMP and pre-operative checks in place to prevent this hazard	2	1	2		
21	AMBIENT COOLING	B	Microbiological (mould)	N	GMP are in place: ambient cooling in an aerated area to avoid condense on the product that is responsible of mould growth	2	1	2		
21	AMBIENT COOLING	C	//	N	no chemical risks at this step			0		
21	AMBIENT COOLING	P	foreign bodies (personnel)	N	GHP and trained personnel in place to prevent foreign bodies carried-out from personnel;	1	2	2		
22	SEASONING	B	//	N	dry ingredients, shelf stable, no risk of microbiological growth at this step			0		
22	SEASONING	C	sanitizing residues	N	- personnel trained in GHP and GMP; - periodic quality inspections to verify cleaning procedure carried-out correctly.	2	1	2		
22	SEASONING	C	allergens cross contact	Y	- ingredients containing allergens are handled in the same environment.	3	2	6	- process preventive control: scheduled production (product containing allergens to be produced at the end of production run); - sanitation preventive control: checks after cleaning to asses the absence of residue of previous production; - process preventive control: checks of equipment before a new production run; - personnel training on cleaning and sanitizing procedures;	Y
22	SEASONING	P	//	N	no risks of foreign bodies at this step			0		
23	PACKING (filling, metal detector, labelling, sealing)	B	//	N	no microbiological risk for this ingredient			0		

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
23	PACKING (filling, metal detector, labelling, sealing)	C	- allergens cross contact; - allergens delcaration.	Y	- ingredients containing allergens are handled in the same environment; - errors in labelling can occur.	3	2	6	- process preventive control: scheduled production (product containing allergens to be produced at the end of production run); - sanitation preventive control: checks after cleaning to asses the absence of residue of previous production; - process preventive control: checks of equipment before a new production run; - personnel training on cleaning and sanitazing procedures; allergen preventive control: label verification on the product: declared allergen verification; personnel training.	Y
23	PACKING (filling, metal detector, labelling, sealing)	P	metal foreign bodies	Y	breakage can occur on equipment. This step specifically designed to eliminate this hazard	3	3	9	- hygiene procedures; - checks on the equipment to asses the integrity and the absence of breakage; - audit/site inspection to check personnel hygiene;	Y
24	WEIGHT CHECKING	B	//	N	product packed: no microbiological risk at this step			0		
24	WEIGHT CHECKING	C	//	N	product packed: no chemical risks at this this step			0		
24	WEIGHT CHECKING	P	//	N	product packed: no physical risks at this this step			0		
25	SECONDARY PACKING	B	//	N	product packed: no microbiological risk at this step			0		
25	SECONDARY PACKING	C	//	N	product packed: no chemical risks at this this step			0		
25	SECONDARY PACKING	P	//	N	product packed: no physical risks at this this step			0		



## Hazard Analysis

Step	(1) Ingredient/ Processing Step	Hazard class	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards requiring a preventive control? Y/N	(4) Justify your decision for column 3	Severity (S)	Probability (P)	SxP	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control	(6) Is the preventive control applied at this step? Y/N
26	FINAL CHECKS FOR THE RELEASE OF THE FINISHED PRODUCT	B	//	N	this is not a production step			0		
26	FINAL CHECKS FOR THE RELEASE OF THE FINISHED PRODUCT	C	Allergens	Y	this is not a production step: quality/label check on batch sample	3	2	6	allergen preventive control: - label verification on the product; declared allergen verification; - personnel training	Y
26	FINAL CHECKS FOR THE RELEASE OF THE FINISHED PRODUCT	P	//	N	this is not a production step			0		
27	STORAGE OF FINISHED PRODUCT	B	//	N	shelf stable product, no risk of microbial growth			0		
27	STORAGE OF FINISHED PRODUCT	C	//	N	product is packed at this step, no chemicals risk			0		
27	STORAGE OF FINISHED PRODUCT	P	//	N	product is packed at this step, no physical risk			0		

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(1) Ingredient/ Processing Step	CCP PRP PRPo CP	Identification of procedure or operative instruction	Specific hazard to be addressed	Critical limit(s)	MONITORING				Corrective Action	Verification and Records	Validation and Records
					WHAT	HOW	FREQUENCY	WHO			
Receive ingredients: flour	PRPo	PRG 5 SUPPLIER APPROVAL PRP 2 RAW MATERIAL RECEIVING	allergens	- correct allergen declaration; - absence of undeclared allergens.	a) ingredient and supplier approval; b) ingredient receiving.	a) ingredient risk analysis, supplier HACCP procedures, audit; b) checks at the arrival	a) yearly b) ingredient arrival	a) quality assurance b) warehouse employee	- ingredient refusal; - ingredient quarantine; - supplier decay; renew of supplier approval after CA evidences.	- supplier specs with allergen grid declaration - raw material hazard analysis; - MOD PRP 2.1	- yearly analysis on supplied batches; - report of analysis
Receive ingredients: spices, herbs, flavors, dried vegetables	PRPo	PRG 5 SUPPLIER APPROVAL PRP 2 RAW MATERIAL RECEIVING	allergens	- correct allergen declaration; - absence of undeclared allergens.	a) ingredient and supplier approval; b) ingredient receiving.	a) ingredient risk analysis, supplier HACCP procedures, audit; b) checks at the arrival	a) yearly b) ingredient arrival	a) quality assurance b) warehouse employee	- ingredient refusal; - ingredient quarantine; - supplier decay; renew of supplier approval after CA evidences.	- supplier specs with allergen grid declaration - raw material hazard analysis; - MOD PRP 2.1	- yearly analysis on supplied batches; - report of analysis
Receive refrigerated ingredients: yeast, cheese	PRPo	PRG 5 SUPPLIER APPROVAL PRP 2 RAW MATERIAL RECEIVING	allergens	- correct allergen declaration; - absence of undeclared allergens.	a) ingredient and supplier approval; b) ingredient receiving.	a) ingredient risk analysis, supplier HACCP procedures, audit; b) checks at the arrival	a) yearly b) ingredient arrival	a) quality assurance b) warehouse employee	- ingredient refusal; - ingredient quarantine; - supplier decay; renew of supplier approval after CA evidences.	- supplier specs with allergen grid declaration - raw material hazard analysis; - MOD PRP 2.1	- yearly analysis on supplied batches; - report of analysis
Receive labels and/or printed primary packaging	PRPo	PRP 2 RAW MATERIAL RECEIVING	correct allergen declaration	undeclared allergen	labelling (allergen declaration)	PRP 2 PACKAGING AND RAW MATERIAL RECEIVING the operator takes a sample of the arrived label and compares it with the technical data sheet dated and signed by the PCQL. The allergens declared on the label must correspond to those established in the technical data sheet. The sample of the label is kept.	every time a label is received	warehouse worker	refuse the arriving labels, inform the quality manager. A non conformance to the supplier will be issued by the Quality Manager	MOD PRP 2.2 PACKAGING AND LABELS RECEIVING	Quality Manager will periodically carry-out inspections to verify and validate these activities
Refrigerated ingredient (yeast, cheese) storage	PRPo	PRP 5 REFRIGERATION CHECK	microbiological growth	a) +6°C b) expiry date > day to use the ingredient	a) temperature b) expiry date	a) visual inspection of the display b) visual check of expiry date	a) daily b) weekly	warehouse worker	a) immediate control of the temperature at the heart of the raw material using the data logger. If the temperature is above 8 ° C, a sample must be taken for a microbiological check to be carried out before the raw material is used; investigate on causes of the temperature increasing; retrain personnel if necessary; store raw materials in an additional chiller; b) remove the ingredients with expired date to avoid unintentionally use; retrain personnel and review the quantity of ingredients to be periodically purchased	PRP 5 a) MOD PRP 5.2 b) MOD PRP 5.1	a) yearly verification of chiller probe; list of verified instruments; b) site inspection by the quality manager; inspection records;
Flour sieving	PRPo	PRP 1 CLEANING AND SANITIZING PRG 16 RECRUITING AND TRAINING OF PERSONNEL	foreign bodies	- absence of foreign bodies; - absence of filter damages	sieve integrity check and sieve cleaning	- visual inspection of the sieve: open the equipment, check the integrity; inform the quality dept if foreign bodies or sieve brackage found; - dry cleaning: open the equipment, remove residual with vacuum cleaner, close the equipment	weekly	cleaning staff	- if foreign bodies retained at the filter: collect, investigate and communicate a non conformance to the flour supplier; - if filter brackage occurred: verify if pieces of filter missing; investigate and re-discuss about the filter maintenance; quarantine products and investigate about metal detector records	MOD PRP 1.3.1 cleaning records MOD PRP 1.3.2 filter check	site inspection by the quality manager; inspection records;
Ingredient mixing	PRPo	PRP 1 CLEANING AND SANITIZING PRG 16 RECRUITING AND TRAINING OF PERSONNEL MOD LG 6.2 PRE-OPERATIVE CHECKS	allergens residues of previous production	absence of residues of previous production on the equipment	check cleaning and absence of previous product residues	- visual inspection of equipment	a) weekly at the end of cleaning and after a production containing undeclared allergen; b) daily, before a new production run	a) cleaning supervisor; b) production and packaging employees	- repeat cleaning and check after cleaning; - refresh training for cleaning staff; - activate quality inspections to verify the cleaning procedure; if necessary update the cleaning procedure (cleaning operations, frequency, ...)	- MOD PRP 1.3.1 cleaning records; - MOD LG 6.2 PRE-OPERATIVE CHECKS	- periodic swab test results; - site inspection by the quality manager; - inspection records;

(1) Ingredient/ Processing Step	CCP PRP PRPo CP	Identification of procedure or operative instruction	Specific hazard to be addressed	Critical limit(s)	MONITORING				Corrective Action	Verification and Records	Validation and Records
					WHAT	HOW	FREQUENCY	WHO			
Dough in the container	PRPo	PRP 1 CLEANING AND SANITIZING PRG 16 RECRUITING AND TRAINING OF PERSONNEL MOD LG 6.2 PRE-OPERATIVE CHECKS	allergens residues of previous production	absence of residues of previous production on the equipment	check cleaning and absence of previous product residues	- visual inspection of equipment	a) weekly at the end of cleaning and after a production containing undeclared allergen; b) daily, before a new production run	a) cleaning supervisor; b) production and packaging employees	- repeat cleaning and check after cleaning; - refresh training for cleaning staff; - activate quality inspections to verify the cleaning procedure; if necessary update the cleaning procedure (cleaning operations, frequency, ...)	- MOD PRP 1.3.1 cleaning records; - MOD LG 6.2 PRE-OPERATIVE CHECKS	- periodic swab test results; - site inspection by the quality manager; - inspection records;
Dough remains (rework)	PRPo	PRP 1 CLEANING AND SANITIZING PRG 16 RECRUITING AND TRAINING OF PERSONNEL MOD LG 6.2 PRE-OPERATIVE CHECKS	allergens residues of previous production	absence of residues of previous production on the equipment	check cleaning and absence of previous product residues	- visual inspection of equipment	a) weekly at the end of cleaning and after a production containing undeclared allergen; b) daily, before a new production run	a) cleaning supervisor; b) production and packaging employees	- repeat cleaning and check after cleaning; - refresh training for cleaning staff; - activate quality inspections to verify the cleaning procedure; if necessary update the cleaning procedure (cleaning operations, frequency, ...)	- MOD PRP 1.3.1 cleaning records; - MOD LG 6.2 PRE-OPERATIVE CHECKS	- periodic swab test results; - site inspection by the quality manager; - inspection records;
LAMINATING / CUTTING / FORMING	PRPo	PRP 1 CLEANING AND SANITIZING PRG 16 RECRUITING AND TRAINING OF PERSONNEL MOD LG 6.2 PRE-OPERATIVE CHECKS	allergens residues of previous production	absence of residues of previous production on the equipment	check cleaning and absence of previous product residues	- visual inspection of equipment	a) weekly at the end of cleaning and after a production containing undeclared allergen; b) daily, before a new production run	a) cleaning supervisor; b) production and packaging employees	- repeat cleaning and check after cleaning; - refresh training for cleaning staff; - activate quality inspections to verify the cleaning procedure; if necessary update the cleaning procedure (cleaning operations, frequency, ...)	- MOD PRP 1.3.1 cleaning records; - MOD LG 6.2 PRE-OPERATIVE CHECKS	- periodic swab test results; - site inspection by the quality manager; - inspection records;
OVEN BAKING	PRP PRPo	PRP 3 OVEN BAKING PROCEDURE	Microbiological (Enterobacteria, Staphylococcus aureus)	- T°C ≥ 150 - moisture of baked product max 8% p/p	- temperature - moisture of the baked product	- visual check of oven display; - thermobalance	each batch	employee (baker)	Quality manager will be informed to decide actions. Possible actions: - bake the product again or destroy if a rework is not safe; - identify the oven if not working correctly and inform the maintenance to be repaired; - repeat quality checks: moisture content of the baked product; - re-train employee (baker) if the issue is related to a wrong setting of the oven;	PRP 3 OVEN BAKING PROCEDURE MOD PRP 6.2	site inspection by the quality manager; inspection records;
SEASONING	PRPo	PRP 1 CLEANING AND SANITIZING PRG 16 RECRUITING AND TRAINING OF PERSONNEL MOD LG 6.2 PRE-OPERATIVE CHECKS	allergens residues of previous production	absence of residues of previous production on the equipment	check cleaning and absence of previous product residues	- visual inspection of equipment	a) weekly at the end of cleaning and after a production containing undeclared allergen; b) daily, before a new production run	a) cleaning supervisor; b) production and packaging employees	- repeat cleaning and check after cleaning; - refresh training for cleaning staff; - activate quality inspections to verify the cleaning procedure; if necessary update the cleaning procedure (cleaning operations, frequency, ...)	- MOD PRP 1.3.1 cleaning records; - MOD LG 6.2 PRE-OPERATIVE CHECKS	- periodic swab test results; - site inspection by the quality manager; - inspection records;
PACKING (filling, metal detector, labelling, sealing)	PRPo	PRP 1 CLEANING AND SANITIZING PRG 16 RECRUITING AND TRAINING OF PERSONNEL MOD LG 6.2 PRE-OPERATIVE CHECKS PRP 4 Confezionamento	- cross contact: allergens residues of previous production - allergen declaration	- cross contact: absence of residues of previous production on the equipment - allergen declaration: a) undeclared allergen; b) incorrect allergen declaration; c) incorrect product label / printed primary packing	- cross contact: check cleaning and absence of previous product residues - allergen declaration: check of label / printed primary packaging used during packing	- cross contact: visual inspection of equipment - allergen declaration: visual inspection of label / printed primary packaging	- cross contact: a) weekly at the end of cleaning and after a production containing undeclared allergen; b) daily, before a new production run  - allergen declaration: at the beginning; every two hours during the packing	- cross contact: a) cleaning supervisor; b) production and packaging employees  - allergen declaration: packaging employee	- cross contact: - repeat cleaning and check after cleaning; - refresh training for cleaning staff; - activate quality inspections to verify the cleaning procedure; if necessary update the cleaning procedure (cleaning operations, frequency, ...)  - allergen declaration: a) quarantine product; b) inform the quality assurance; c) repeat labelling / packaging with correct label / printed package d) plan a new training for personnel in the packaging dept	- cross contact: - MOD PRP 1.3.1 cleaning records; - MOD LG 6.2 PRE-OPERATIVE CHECKS  - allergen declaration: MOD PRP 4.1 PACKING CHECKS	- cross contact: a) periodic swab test results; b) site inspection by the quality manager; c) inspection records;  - allergen declaration: periodical audit by the quality assurance.



Process Preventive Control

(1) Ingredient/ Processing Step	CCP PRP PRPo CP	Identification of procedure or operative instruction	Specific hazard to be addressed	Critical limit(s)	MONITORING				Corrective Action	Verification and Records	Validation and Records
					WHAT	HOW	FREQUENCY	WHO			
PACKING (filling, metal detector, labelling, sealing)	CCP	PRP 4 Confezionamento	metal foreign body	2,5mm ferrous 2,5mm non ferrous 2,5mm stainless	check of metal detector	let the sample going throw the MD and verify the alarm and identification of polluted bag	at the beginning; every two hours during the packing	employee on the packing line	- product identification and isolation; - MD maintenance	MOD PRP 4.1 PACKING CHECKS	- inspection by the quality manager (simulate the contamination with possible contaminant, verify how the employee react to the contamination) - yearly verification of metal detector by external company
FINAL CHECKS FOR THE RELEASE OF THE FINISHED PRODUCT	PRPo	PRP 4 Confezionamento	allergen declaration	a) undeclared allergen; b) incorrect allergen declaration; c) incorrect product label / printed primary packing	check of label / printed primary packaging on the packed product	visual inspection of label / printed primary packaging	batch release	quality assurance	a) quarantine product; b) inform the packaging dept and repeat training; c) repeat labelling / packaging with correct label / pnted package	MOD PRP 4.1 PACKING CHECKS (RQ signed)	periodical audit

Allergen Preventive Control

Introduction

In recent years the phenomenon of food allergies and intolerances has been growing in importance. The number of people affected by this type of ailment, is growing in the same manner.

The taking of allergens by an intolerant person can even have lethal effects.

By means of Directive 2003/89/CE of 10 November 2003, which amends Directive 2000/13/CE, and with EU Regulation 1169/2011 the ingredients have been identified that, if found in products, can cause food intolerances or allergies.

One must also taken all the norms from outside Europe into account, in relation to allergens, especially for the countries to which the products are exported, especially the USA and Canada.

The purpose of this procedure is to ensure correct management of allergen materials, with the aim of reducing the risk of contamination of products by allergens, and in order to satisfy legal labelling requirements.

Assessment of suppliers and raw materials

A thorough assessment is made of all raw materials used within the site, in order to evaluate the presence and probability of contamination by allergens. This action is taken by asking suppliers for detailed specifications for the raw materials. The suppliers are sent forms / questionnaires to complete, in order to assess the status of the allergens in the raw materials supplied, and the potential sources of cross contamination.

The reference documents are:

- FORM PRG 5.2 RAW MATERIALS SUPPLIERS ASSESSMENT QUESTIONNAIRE

As an alternative the supplier's technical documents are also deemed to be valid.

Based on the information contained in the questionnaire and technical schedules, a risk assessment is done for the supplier, and the allergens present and potentially present in the raw materials are identified. The outcome of this assessment gives rise to the form: MOD. PRG 5.6 RAW MATERIALS RISK ASSESSMENT

Positive list of materials that contain allergens

Based on the assessment done on the suppliers, a list is drawn up of all the raw materials and allergens to be found, or that are potentially present, on the production site.

Based on the information gathered, one finds that the following allergens are present on the site:

- ▣ Cereals that contain gluten and derived products. Wheat flour
- ▣ Milk and milk-based products. cheese, cheese flavor
- ▣ Sesame seeds

All these raw materials are indicated on the label, if the product contains them.

The only danger that remains is that of crossing-contamination, in relation to products that not contain one of the above allergens.

In addition (for wheat flour) there is a risk of primary contamination with the soya allergen.

There is also a risk of crossing contamination with Egg allergen in products containing the ingredient "LIEVITO MADRE AUTOLIEVITANTE IN POLVERE" (powdered sordough yeast).



Allergen Preventive Control

Risk assessment for contamination during the production process

As far as gluten is concerned, this allergen is present in all products. Consumers are adequately informed by means of the list of ingredients. In order to reduce the danger of cross-contamination to a minimum, suitable preventive measures have been taken:

- ▣ personnel is trained in specific procedures related to the allergen management;
- ▣ storage of ingredients containing allergens is clearly identified; ingredients containing allergens are handled with specific tools of specific color;
- ▣ Production processes that involve using cheese product (milk based products) and sesame seeds must preferably be done last.
- ▣ After each production process for products that contain allergens, the line must be washed completely with detergent, and sanitised, in accordance with the operating instructions.
- ▣ From time to time analytical tests must be done to check the efficacy of the preventive measures (e.g. qualitative analysis of rinse water in equipment previously used for products containing allergens to check for the presence of any allergens and demonstrate the efficacy and efficiency of cleaning procedures).

Indication of allergens on the label

Information related to the presence of allergens is given in the list of ingredients, which must be complete, detailed, and true to the product's contents.

As regards allergens potentially present due to their use on the production site, or due to them possibly arising from cross-contamination in the phases prior to out processes, the consumer is informed by means of an indication at the bottom of the list of ingredients.

The phrase used can be one of the following:

May contain traces of ... list of allergens ...

Made at a plant that also uses ... list of allergens ...

In accordance with the EU's legislative provisions, allergens are to be highlighted by means of a type of character clearly different from the other ingredients listed, in the form of size, style, or background colour for example. The methods may be one or a combination of the following:

- Underlining
- Bold print
- CAPITALS

For products exported outside the EU, allergens are indicated taking the local law in force.





Allergen Preventive Control

Preventive Measures

Prevention of cross-contamination by allergens during the production process, is done by means of a series of actions described below:

Training of personnel involved: all operators have received adequate training on the danger of contamination by allergens, and the measures and procedures to be adopted to prevent cross-contamination. Personnel are also instructed and trained on the operating procedures for cleaning the plants. From time to time checks / inspections are carried out to make sure that the operators carry out the procedures defined, correctly.

Identification of raw materials that contain allergens:

In the raw materials stores, the presence of raw materials that contain allergens has been indicated, by means of signage with wording in red. The tools and containers used for those substances are of a different colour, specifically to avoid the same tools and container being used for raw materials that do not contain allergens.

Adequate hygienic procedures in production plans:

Processing of products that contain allergenic raw materials is planned at the end of the working day. Production processes involving allergens are planned at the end of the week (on Fridays), dedicating entire working days (time separation). On completion of these processes all the plant and equipment is cleaned thoroughly and carefully. The operating instructions for correct cleaning are as described and detailed in MOD PRP 1.1 CLEANING INSTRUCTIONS. Images and/or photos are also used to help personnel understanding how to carry-out the cleaning. Further detail of materials to be used (indicating concentrations and application times), the equipment to be used, and the operating instructions.

Plant inspections:

Before beginning a new production process, and on completion of cleaning and sanitising operations, the shift boss carry-out an inspection of the plants and equipment to ensure they are thoroughly clean and there is no residue from previous production. If any hygienic shortcoming is found, cleaning and sanitising of the plant/equipment/tool/container/belt is done again, and steps are taken to prevent the shortcoming repeating itself.



Allergen Preventive Control

Designing of Labels and Packaging:

All designing of labels or packaging follows a precise formula. Both for making labels for new products and for modifying or revising all products, the Quality Manager sends to the Packaging Manager the technical schedule for the product, for a mock up to be produced. Once the graphics have been done in pdf format, it is sent to the Quality Manager by e-mail, for them to check the correctness of the information on the label. If any incorrect information is found, the Quality Manager adds comments in the same pdf, and sends all the graphics back for correction. Finally, before proceeding with printing, the graphic artist sends the Quality Manager the final pdf for approval. The Quality Manager approves the graphics, by replying by e-mail.

Checking packaging when receiving:

Should any packaging commissioned arrive with incorrect information and allergens not declared, this can only be avoided by checking the packaging when it is received by the company. When receiving primary packaging, the Stores Manager informs the Quality Manager or their delegate, for preliminary checking of the correctness of the label's information (by comparing it with the technical schedule or label schedule). After this check the packaging can be stored and released for production. If there is incorrect information, the packaging is contested and sent back to the supplier to be destroyed. The supplier will be asked to analyse the causes and corrective actions proposed, to prevent such an event in the future.

Label checking during packing:

The operator of the packing area is required to check that the label conforms at the time of packing: correctness of the film and/or label for the product being produced. The operator records the outcome of the check on the record form. If the label is incorrect, the operator informs the production and/or quality manager, so they can deal with any product not labelled correctly.

Label checking when releasing the finished product:

Before they release the product, the quality control worker does a final check of the label. They take samples of the packaged product, and carefully examine the label, comparing it to an approved master. On completion of the check, they sign the release on the production report. If any discrepancies and/or errors are found, the product is quarantined and the non-conformity is dealt with by the quality manager.



## Allergen Preventive Controls

**Ingredient Allergen Ident.**

Raw Material Name	Supplier	Intentional Allergen									Allergen Preventive Label	Other Allergens
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Sesame		
wheat flour	approved suppliers	no	no	no	yes	no	no	no	no	no	soy	
oregano	approved suppliers	no	no	no	no	no	no	no	no	no		
dehydrated tomato	approved suppliers	no	no	no	no	no	no	no	no	no		
dehydrated rosemary	approved suppliers	no	no	no	no	no	no	no	no	no		
dehydrated basil	approved suppliers	no	no	no	no	no	no	no	no	no		
dehydrated garlic	approved suppliers	no	no	no	no	no	no	no	no	no		sulphites
cheese	approved suppliers	no	yes	no	no	no	no	no	no	no		
cheese flavor	approved suppliers	no	yes	no	no	no	no	no	no	no		
tomato chilli flavor	approved suppliers	no	no	no	no	no	no	no	no	no	milk	
rice flour	approved suppliers	no	no	no	no	no	no	no	no	no		
brewer's yeast	approved suppliers	no	no	no	no	no	no	no	no	no		
powdered sordough starter	approved suppliers	no	no	no	yes	no	no	no	no	no	soy, egg, milk, sesame	
malted wheat flour	approved suppliers	no	no	no	yes	no	no	no	no	no	soy	
olive oil	approved suppliers	no	no	no	no	no	no	no	no	no		
olive pomace oil	approved suppliers	no	no	no	no	no	no	no	no	no		
extra virgin olive oil	approved suppliers	no	no	no	no	no	no	no	no	no		
dehydrated onion	approved suppliers	no	no	no	no	no	no	no	no	no		sulphites
salt	approved suppliers	no	no	no	no	no	no	no	no	no		
chiasseeds	approved suppliers	no	no	no	no	no	no	no	no	no		
sunflower oil	approved suppliers	no	no	no	no	no	no	no	no	no		
green olives	approved suppliers	no	no	no	no	no	no	no	no	no		
black olives	approved suppliers	no	no	no	no	no	no	no	no	no		
Ginger & Lemon flavouring	approved suppliers	no	no	no	no	no	no	no	no	no		
sesame seeds	approved suppliers	no	no	no	no	no	no	no	no	yes		
turmeric	approved suppliers	no	no	no	no	no	no	no	no	no		

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Product Allergen Assessment

Product Name	Brand Name	Production	Intentional Allergens									Allergen Preventive Label	Other Allergens	
			no	yes	no	yes	no	yes	no	yes	no			
Dolcetto Italian Cheese Blend Tuscan Crisps	DOLCETTO - FUSION GOURMET	laminated	no	yes	no	yes	no	no	no	no	no	no	egg, soy, peanuts, tree nuts	
Dolcetto Olive Oil & Sea Salt Tuscan Crisps	DOLCETTO - FUSION GOURMET	laminated	no	no	no	yes	no	no	no	no	no	no	milk, egg, soy, peanuts, tree nuts	
Dolcetto Parmesan Garlic & Herb Tuscan Crisps	DOLCETTO - FUSION GOURMET	laminated	no	yes	no	yes	no	no	no	no	no	no	egg, soy, peanuts, tree nuts	
Dolcetto Rosemary & Olive Oil Tuscan Crisps	DOLCETTO - FUSION GOURMET	laminated	no	no	no	yes	no	no	no	no	no	no	milk, egg, soy, peanuts, tree nuts	
Dolcetto Sour Cream & Spring Onion Tuscan Crisps	DOLCETTO - FUSION GOURMET	laminated	no	yes	no	yes	no	no	no	no	no	no	egg, soy, peanuts, tree nuts	
Toscana Cracker Formaggio	TOSCANA - ASA FOODS - FUSION GOURMET	laminated	no	yes	no	yes	no	no	no	no	no	no	egg, soy, peanuts, tree nuts	
Toscana Cracker Rosmarino	TOSCANA - ASA FOODS - FUSION GOURMET	laminated	no	no	no	yes	no	no	no	no	no	no	milk, egg, soy, peanuts, tree nuts	
Toscana Cracker Tradizionale	TOSCANA - ASA FOODS - FUSION GOURMET	laminated	no	no	no	yes	no	no	no	no	no	no	milk, egg, soy, peanuts, tree nuts	
Toscana Cracker SourCream&Onion	TOSCANA - ASA FOODS - FUSION GOURMET	laminated	no	yes	no	yes	no	no	no	no	no	no	egg, soy, peanuts, tree nuts	

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Allergen Preventive Controls

Allergen Label Verification

Allergen control	Hazard(s)	Criteria	Monitoring			Corrective Action	Verification	Records	
			What	How	Frequency				Who
Receiving labels	Undeclared allergens	Product label shall declare the allergen in the ingredient list and as a allergen statement at the end of ingredient list	Statement of Ingredients and allergen statement match the product to be packed with the label	Visual exam of label arrived compared with approved product description template	Each receipt	Packaging Manager and Quality manager	- refuse the label; return to supplier or destroy; - investigate and conduct a root cause analysis; - conduct training if needed; - communicate the non conformance to the supplier and discuss actions to prevent the recurrence	QA manager	Allergen Label Verification at Receipt; Record of Non conformance and Corrective actions Internal Audit records
labelling of product	Undeclared allergens	Appropriate Label of the packed product	Confirm that label used match the packed product	employee of the packing area check if the label on the product is correct and correspond to the packed product, as foreseen on the production sheet;	- beginning and end of packing; - when label stock is changed	Packing employee	- product in quarantine; - investigate about the issue to understand why was occurred; - re-label the product or destroy if is not possible to re-label; - train personnel;	- site inspection by the quality manager; - verification of records;	MOD. PRP 4.1
Allergen change over procedures, including clean following the use of other allergenic material on equipment	Cross-contact with allergens not present in the recipe	No residual allergenic material from previous production run	- full cleaning and sanitation; - checks/inspection prior the beginning of a new production to verify the effectiveness of cleaning	Cleaning and verification as outlined in PRP 1 Cleaning and sanitation procedure	After products containing allergens not contained in the product	Sanitation employee Quality dept	- Re-clean line; - plan a new training in cleaning and allergen management;	- Hygiene audit; - Visual inspection of equipment;	- MOD PRP 1.1 Sanitation and verification record; - Corrections actions records - cleaning validation with allergen swab

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*Claudio Innocenti*

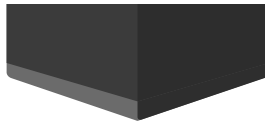


# SUPPLIER QUESTIONNAIRE

*for*

U.S. IMPORT ENTRY  
UNDER FSVP

- Confidential -



## OVERVIEW of REGULATIONS

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.

## INSTRUCTIONS

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

## CONFIDENTIALITY

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.

## CONTACT

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: Gr.a.m.m. srl Today's Date: June 16th 2022  
Factory Address: SS 96 km 113,200  
City: Palo del Colle Province: BA Country: Italy  
Office Address: Palombaio, via Teologo Valente, s.n.c.  
City: Bitonto Province: BA Country: Italy  
FDA Registration No.: 16111067886 DUNS No.: \_\_\_\_\_  
FDA Establishment Id.: UFI 439804945 Phone No.: +390803735950  
QC/QA's Name: MR FRANCESCO GAROFALO E-mail: qualita@gruppomilo.it

## SUPPLIER CLASS

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

Manufacturer (*Raw Material*)       Processor       Packer       Re-Packer  
 Manufacturer (*Finished Product*)       Distributor       Shipper       Warehouse  
 Importer (*US-based*)       Exporter (*Non US-based*)       Broker       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: Dolcetto Tuscan Crisps (Olive Oil & Sea Salt, Italian) Product Code: \_\_\_\_\_  
No. 02, Product Name: Toscana Crackers (Olive Oil & Sea Salt, Italian Chees Product Code: \_\_\_\_\_  
No. 03, Product Name: \_\_\_\_\_ Product Code: \_\_\_\_\_  
No. 04, Product Name: \_\_\_\_\_ Product Code: \_\_\_\_\_  
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 type="checkbox"/> Bacillus cereus    | <input type="checkbox"/> Clostridium botulinum         | <input 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 type="checkbox"/> S. aureus     |
| <input 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**

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START:  
 GMPs: Written Sanitation Operating Procedures are in place to prevent contamination or adulteration of product. Personnel trained on Hygiene. Regular cleaning and maintenance of equipment.  
 Heat: Product is baked at a temperature not below than 150°C for a minimum time of 10 minutes  
 Testing: Periodical analysis are carried-out on site environment, raw materials and finished products.

**FREQUENCY of VALIDATION**

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START: annually

**U. S. FDA HAZARD PROFILE**

Category Name: Baked  
 Category Number: 2  
 Subcategory Name: Bread snacks, Seasoned  
 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

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START: Raw material approval before being used in the production. Raw material spec, label and ingredient list verification and approval before being used in the production.

### FREQUENCY of VALIDATION

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START: annually and/or if a change occur in the recipe

### U. S. FDA HAZARD PROFILE

Category Name: Baked  
Category Number: 2  
Subcategory Name: Bread snacks, Seasoned  
Storage Type: shelf-stable

Resource

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

**FDA – IDENTIFIED ENVIROMENTAL / PROCESS HAZARDS**

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

- Recontamination with environmental pathogens.
- Bacterial pathogen survival of a lethal treatment.
- Bacterial growth and/or toxin formation due to lack of time / temperature control.
- Recontamination due to lack of container integrity.
- Bacterial growth and/or toxin formation due to reduced oxygen packaging.
- Bacterial growth and/or toxin formation due to formulation control.



**CRITICAL CONTROLS for ENVIROMENTAL 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**

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START:  
 GMPs: Written Sanitation Operating Procedures are in place to prevent contamination or adulteration of product. Personnel trained on Hygiene. Regular cleaning and maintenance of equipment.  
 Testing: Periodical analysis are carried-out on site environment and finished products.

**FREQUENCY of VALIDATION**

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START: annually

**U. S. FDA HAZARD PROFILE**

Category Name: Baked  
 Category Number: 2  
 Subcategory Name: Bread snacks, Seasoned  
 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    |

<b>Resources</b>	Appendix 1	Description of Hazard	Bad Bug Book
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**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**

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START:  
 GMPs: Personnel trained on physical hazard prevention. Regular maintenance of equipment.  
 Metal detector: product at the packing step go through the metal detector to ensure absence foreign bodies. Alarm and segregation if foreign bodie detected. Metal detector is checked with tests (ferrous. non ferrous, stainless steel) at the beginnig, every two hours and at the end of production to guarantee that is working correctly.

**FREQUENCY of VALIDATION**

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START: annually

**U. S. FDA HAZARD PROFILE**

Category Name: Baked  
 Category Number: 2  
 Subcategory Name: Bread snacks, Seasoned  
 Storage Type: shelf-stable

<b>Metal detection standards</b>	Ferrous: <u>2.5</u> mm
	Non-Ferrous: <u>2.5</u> mm
	Stainless Steel: <u>2.5</u> mm

<b>Resource</b>	U.S. FDA
	Hazard Profile – Appendix 1

*Claudio Innocenti*

**ALLERGEN & CROSS-CONTAMINATION CONTROLS**

<b>Component or Ingredient</b>	<b>Present in product?</b>	<b>Present on same equipment?</b>	<b>Present in same facility?</b>
<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 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>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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input 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 type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>ALL ALLERGENS</b>	<input type="checkbox"/> <b>Absent</b>	<input type="checkbox"/> <b>Absent</b>	<input type="checkbox"/> <b>Absent</b>

**DESCRIPTION of ALLERGENIC CONTROLS**

**Assessment of suppliers and raw materials**

A thorough assessment is made of all raw materials used within the site, in order to evaluate the presence and probability of contamination by allergens. This action is taken by asking suppliers for detailed specifications for the raw materials.

**Preventive Measures**

Prevention of cross-contamination by allergens during the production process, is done by means of a series of actions described below:

Training of personnel involved: all operators have received adequate training on the danger of contamination by allergens, and the measures and procedures to be adopted to prevent cross-contamination. Personnel are also instructed and trained on the operating procedures for cleaning equipment. Periodical checks / inspections are carried-out to verify the efficiency and efficacy of cleaning activities.

**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 and IFS

**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:

detergents and sanitizers

**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? 7

## PEST CONTROL

Is a pest control contractor employed?  Yes  No

If yes, please provide: Name of contractor used: NATURA AMBIENTE SRLS \_\_\_\_\_

Number of yearly visits: 12 \_\_\_\_\_

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

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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: pre-operative checks on the equipment to ensure the absence of metal*

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

*Please provide details: tests are carried-out to verify the ability to detect a threat. for example in the past it was tested*

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

*Please provide details: Food defense plan is in force in the site, videocamera, personnel training, etc*

## 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: L YYJJJ - L= lot; YY= last two digits

**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:

periodical analysis on raw materials, audits and/or GFSI certification, checks on raw materials at the arrival

**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:

periodical analysis carried-out on the finished product: microbiological (salmonella, e. coli, staphilococcus aureus), chemical (aflatoxins, heavy metals, pesticides residue)

**CUSTOMER COMPLAINTS**

Does a formal customer complaint procedure exist?  Yes  No

Please describe your customer complaint procedure.

there is a recordsheet for all compliants. the procedure require to verify the cause of the compliant, the treatment and, if reured, the corrective action. There is always a feedback to the customer. Compliants are reviewed yearly during the management review and actions are taken for improvement.

**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.

**CERTIFICATION**

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.

**CONFIRMATION - REQUIRED**

**Representative's Name:** Mr Francesco Garofalo \_\_\_\_\_

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

**Today's Date:** 6/16/22 \_\_\_\_\_





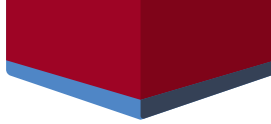
# SUPPLIER QUESTIONNAIRE

*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: Gr.a.m.m. srl Today's Date: June 16th 2022  
Factory Address: SS 96 km 113,200  
City: Palo del Colle Province: BA Country: Italy  
Office Address: Palombaio, via Teologo Valente, s.n.c.  
City: Bitonto Province: BA Country: Italy  
FDA Registration No.: 16111067886 DUNS No.: \_\_\_\_\_  
FDA Establishment Id.: UFI 439804945 Phone No.: +390803735950  
QC/QA's Name: MR FRANCESCO GAROFALO E-mail: qualita@gruppomilo.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: Dolcetto Tuscan Crisps (Olive Oil & Sea Salt, Italian) Product Code: \_\_\_\_\_  
No. 02, Product Name: Toscana Crackers (Olive Oil & Sea Salt, Italian Chees Product Code: \_\_\_\_\_  
No. 03, Product Name: \_\_\_\_\_ Product Code: \_\_\_\_\_  
No. 04, Product Name: \_\_\_\_\_ Product Code: \_\_\_\_\_  
No. 05, Product Name: \_\_\_\_\_ Product Code: \_\_\_\_\_  
No. 06, Product Name: \_\_\_\_\_ Product Code: \_\_\_\_\_

Resources

FDA Product Codes and Product Code Builder

## F D A - I D E N T I F I E D B I O L O G I C A L H A Z A R D S

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

- |   |  |   |  |
|---|--|---|--|
| <input type="checkbox"/> Bacillus cereus    | <input type="checkbox"/> Clostridium botulinum         | <input 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 type="checkbox"/> S. aureus     |
| <input 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

## C R I T I C A L C O N T R O L S *f o r* B I O L O G I C A L H A Z A R D S

*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

### D E S C R I P T I O N *o f* C R I T I C A L C O N T R O L S

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START:  
 GMPs: Written Sanitation Operating Procedures are in place to prevent contamination or adulteration of product. Personnel trained on Hygiene. Regular cleaning and maintenance of equipment.  
 Heat: Product is baked at a temperature not below than 150°C for a minimum time of 10 minutes  
 Testing: Periodical analysis are carried-out on site environment, raw materials and finished products.

### F R E Q U E N C Y *o f* V A L I D A T I O N

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START: annually

### U . S . F D A H A Z A R D P R O F I L E

Category Name: Baked  
 Category Number: 2  
 Subcategory Name: Bread snacks, Seasoned  
 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

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START: Raw material approval before being used in the production. Raw material spec, label and ingredient list verification and approval before being used in the production.

### FREQUENCY of VALIDATION

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START: annually and/or if a change occur in the recipe

### U. S. FDA HAZARD PROFILE

Category Name: Baked  
Category Number: 2  
Subcategory Name: Bread snacks, Seasoned  
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 type="checkbox"/> Recontamination with environmental pathogens.                                      | <input 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. |

Resources



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

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START:  
 GMPs: Written Sanitation Operating Procedures are in place to prevent contamination or adulteration of product. Personnel trained on Hygiene. Regular cleaning and maintenance of equipment.  
 Testing: Periodical analysis are carried-out on site environment and finished products.

### FREQUENCY of VALIDATION

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START: annually

### U. S. FDA HAZARD PROFILE

Category Name: Baked  
 Category Number: 2  
 Subcategory Name: Bread snacks, Seasoned  
 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

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START:  
 GMPs: Personnel trained on physical hazard prevention. Regular maintenance of equipment.  
 Metal detector: product at the packing step go through the metal detector to ensure absence foreign bodies. Alarm and segregation if foreign bodie detected. Metal detector is checked with tests (ferrous. non ferrous, stainless steel) at the beginnig, every two hours and at the end of production to guarantee that is working correctly.

### FREQUENCY of VALIDATION

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START: annually

### U. S. FDA HAZARD PROFILE

Category Name: Baked  
 Category Number: 2  
 Subcategory Name: Bread snacks, Seasoned  
 Storage Type: shelf-stable

Metal detection standards

Ferrous:	<u>2.5</u> mm
Non-Ferrous:	<u>2.5</u> mm
Stainless Steel:	<u>2.5</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 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>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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input 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**

**Assessment of suppliers and raw materials**

A thorough assessment is made of all raw materials used within the site, in order to evaluate the presence and probability of contamination by allergens. This action is taken by asking suppliers for detailed specifications for the raw materials.

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Prevention of cross-contamination by allergens during the production process, is done by means of a series of actions described below:

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## 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 and IFS

**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:

detergents and sanitizers

## 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? 7

## PEST CONTROL

Is a pest control contractor employed?  Yes  No

If yes, please provide: Name of contractor used: NATURA AMBIENTE SRLS

Number of yearly visits: 12

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

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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: pre-operative checks on the equipment to ensure the absence*

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

*Please provide details: tests are carried-out to verify the ability to detect a threat. for example in the past it was tested*

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

*Please provide details: Food defense plan is in force in the site, videocamera, personnel training, etc*

## 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: L YYJJJ - L= lot; YY= last two digits of

## 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:

periodical analysis on raw materials, audits and/or GFSI certification, checks on raw materials at the arrival

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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:

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Please describe your customer complaint procedure.

there is a recordsheet for all compliants. the procedure require to verify the cause of the compliant, the treatment and, if reuired, the corrective action. There is always a feedback to the customer.  
Compliants are reviewed yearly during the management review and actions are taken for improvement.

## 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.

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

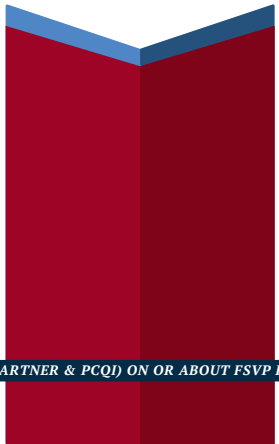
I certify that the information I provided on and in connection with this form is true, accurate and complete. I also understand that any false statements or deliberate omissions on this document or any other document I file with United Safety Agents, LLC may be grounds for disqualification from successful 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:** Mr Francesco Garofalo \_\_\_\_\_

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

**Today's Date:** 6/16/22 \_\_\_\_\_



## Audit Report

1. Audit Summary			
Company name	GR.A.M.M. srl	Site Code	2077210
Site name	GR.A.M.M. srl		
Scope of audit	Production (mixing, forming, boiling (possible), rising (possible), baking, toasting (possible) and packaging of dry and/or flavoured bakery products, enveloped in heat-sealed polypropylene bags or in polypropylene buckets and packaged in cardboard boxes or in polypropylene buckets.		
Exclusions from scope	None		
Justification for exclusion	None		
Audit Start Date	2021-05-10	Audit Finish Date	2021-05-11
Re-audit due date	2022-07-17	Head Office	No

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	A+	Audit type	Unannounced
Previous audit grade	A		Previous audit date	2020-07-23	
Certificate issue date	2021-07-05		Certificate expiry date	2022-08-28	
Number of non-conformities			Fundamental	0	
			Critical	0	
			Major	0	

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2. Audit Results		
	Minor	8

3. Company Details			
Address	SS 96 km 113,200 - 70027 PALO DEL COLLE (BA)		
Country	Italy	Site Telephone Number	+39 080625662
Commercial representative Name	Peppino Milo Milo	Email	g.milo@gruppomilo.it
Technical representative Name	Francesco Garofalo	Email	qualita@gruppomilo.it

4. Company Profile					
Plant size (metres square)	<10K sq.m	No. of employees	1-50	No. of HACCP plans	1-3
Shift Pattern	2				
Subcontracted processes	No				
Other certificates held	ISO 9001, ISO 14001, organic, Kosher, Halal				
Regions exported to	Asia South America North America Europe Oceania Other				
Company registration number	na.				
Major changes since last BRCGS audit	None				

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**4. Company Profile**

The Palo del Colle site produces bakery products. It is part of the Gruppo Alimentare Mediterraneo Milo srl, owner of other two pasta production sites: fresh pasta and special pasta at the Palombaio site (Bitonto, head office and registered office), and dried pasta in different formats at another site in Palo del Colle. The audited site, renovated in 2014, has a total covered surface area of 2700 square metres. At the Palombaio site, common requirements such as logistics, sales, purchasing, IT services, accounting, human resources management, etc. are verified. No significant changes or investments since the last audit. Salted and/or flavoured bakery products with different ingredients are produced and packaged in polypropylene bags or buckets. Processing steps: receiving of flours and other ingredients, storage of raw materials (refrigerated storage for yeast and milk-based spices), production through the steps of mixing, forming/cutting, boiling (only for taralli), rising (bruschetta), baking, toasting (bruschetta), flavouring or seasoning, cooling to room temperature, packaging. There are 16 full-time workers in two shifts. There are no seasonal workers. Emergency Manager Francesco Garofalo +39 3356100724. There are no outsourced or marketed activities. No cases of recall/withdrawal during the last year. The GFSI logo is used according to the contractual regulation. During the audit saw the production and packaging processes of: rosemary Bruschetta, Vegè brand, production batch 21130, pack of 100 g, in polypropylene bags and packaging in cardboard boxes of 8 pcs; traditional large taralli, batch 21130, Casa Milo 250 g production batch 21130, expiry date 28.05.2022, packaging in polypropylene bags and packaging in cardboard boxes of 8 pcs. The audit time was respected. The company is certified IFS, ISO 9001, ISO 14001, organic, Vegan OK, Kosher and Halal.

Nel sito di Palo del Colle si producono prodotti da forno. Fa parte del Gruppo Alimentare Mediterraneo Milo srl, proprietario di altri due siti di produzione pasta: paste fresche e paste speciali presso il sito di Palombaio (Bitonto, sede centrale e legale), e pasta secca in diversi formati presso altro sito di Palo del Colle. Il sito oggetto di audit, ristrutturato nel 2014, ha una superficie totale di 2700 mq coperti. Nel sito di Palombaio sono verificati i requisiti comuni come logistica, vendite, acquisti, servizi IT, contabilità, gestione delle risorse umane, ecc. Nessun cambiamento significativo né investimento dall'ultimo audit. Si producono prodotti da forno salati e/o aromatizzati con diversi ingredienti e confezionati in sacchetti o secchi di polipropilene. Fasi del processo: ricevimento di farine e altri ingredienti stoccaggio materie prime (stoccaggio refrigerato per lievito e spezie a base di latte, produzione attraverso le fasi di miscelazione, formatura/taglio, bollitura (solo taralli), lievitazione (bruschette), cottura, tostatura (bruschette), aromatizzazione o condimento, raffreddamento a temperatura ambiente, confezionamento. I lavoratori a tempo pieno sono 16 su due turni. Nessuno stagionale. Resp. emergenze Francesco Garofalo +39 3356100724. Nessuna attività esternalizzata o commercializzata. Nessun caso di richiamo/ritiro durante lo scorso anno. Il logo GFSI è utilizzato secondo la regola contrattuale. Durante l'audit visti i processi di produzione e confezionamento di: Bruschette al rosmarino, marchio Vegè, lt. di produzione 21130, confezione da 100 gr, in buste di polipropilene e confezionamento in scatole di cartone da 8 pz; taralli grandi tradizionali, lt. 21130, Casa Milo 250 g lt. di produzione 21130, scadenza 28.05.2022, confezionamento in buste di polipropilene e confezionamento in scatola di cartone da 8 pezzi. Il tempo di audit è stato rispettato. L'azienda è certificata IFS, ISO 9001, ISO 14001, biologica, Vegan OK, Kosher e Halal.

**5. Product Characteristics**

Product categories	14 - Bakery
Finished product safety rationale	Moisture content <8% equivalent to Aw <0.50; cooking temperature 180°C – 200°C.

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5. Product Characteristics					
High care	No	High risk	No	Ambient high care	No
Justification for area		It is not present the HR or HR area as a function according to properties of products.			
Allergens handled on site		Cereals containing gluten Sesame Milk Sulphur dioxide and Sulphites Soya			
Product claims made e.g. IP, organic		Biologico, Vegan OK, olio d'oliva evo, semola di grano duro rimacinata 100% pugliese			
Product recalls in last 12 Months		No			
Products in production at the time of the audit		Bruschette al rosmarino, marchio Vegè, lotto di produzione 21130, confezione da 100 gr, in buste di polipropilene e confezionamento in scatole di cartone da 8 pz; taralli grandi tradizionali, lotto 21130, Casa Milo 250 g lotto di produzione 21130, scadenza 28.05.2022, confezionamento in buste di polipropilene e confezionamento in scatola di cartone da 8 pezzi			

6. Audit Duration Details			
On-site duration	16 man hours	Duration of production facility inspection	8 man hours
Reasons for deviation from typical or expected audit duration	Combi audit with IFS (total man/days = 2). company belongs to a multi-site organization with centralized HO, already audited. Overlapped requirements were seen the first audit day at HO.		
Next audit type selected	Unannounced		

**Audit Duration per day**

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*Claudio Innocenti*

Audit Day	Date	Start Time	Finish time
1	2021-05-10	0900	1700
2	2021-05-11	0900	1700

	Auditor number	Name	Role
Auditor Number	21509	Rossella Ghionda	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
Leonardo Mancini - QC	X	X	X	X
Saverio Milo Milo - Owner			X	X
Antonello Floriello - Packaging operator		X	X	
Luca Saldarelli - Production operator		X		
Eustachio Capolupo - Maintenance Dept.			X	
Marcello Belviso - Production Manager	X	X		X

**GFSI Audit History**

Date	Scheme/Standard	Announced/Unannounced

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## Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No	Clause	Detail	Critical or Major	Ant. re-audit date

Critical			
No.	Clause	Detail	Ant. Re-audit date

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Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	2.5.1	Il diagramma di flusso DDF Rev 3 del 24.2.2021 non riporta la fase di rilavorazione dell'impasto prelevato dalla formatrice ad avvio impianto; l'impasto è subito reimpresso all'interno della stessa vasca impasto a cura dell'operatore, pertanto non si rilevano problemi di sicurezza	Correzione del DDF Rev. 3 con inserimento della fase di rilavorazione dell'impasto scartato dopo la formatura, con annessa analisi dei pericoli associati alla fase e valutazione dei rischi. Correction of DDF Rev. 3 by adding a new step corresponding to re-work of dough discarded after molding, with hazard	Aggiornamento della Check List di Revisione annuale del Manuale HACCP (CHECK LIST HACCP Rev. 2) esplicitando una verifica su tutte le fasi e le sub-fasi dei diagramma di flusso. Updating Check List for HACCP annual	La Check List di Revisione annuale non risultava efficace e necessitava un aggiornamento. HACCP plan Check List Revision wasn't effective and needed to be updated.	2021-06-14	Lead Auditor Rossella Ghionda Positive

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		<p>alimentare né di rintracciabilità.</p> <p>The flow chart DDF Rev 3 of 24.2.2021 does not contain the reprocessing step of the dough taken from the moulding machine at the start of the plant; the dough is immediately put back into the same dough tank by the operator, so there are no food safety or traceability problems.</p>	<p>analysis and risk assessment associated with the new step.</p> <p>Data correzione: 17/05/2021</p> <p>Documents: Folder: BRC – 2.5.1 - Correzione</p>	<p>revision (CHECK LIST HACCP Rev. 2) adding an explicit control to all steps making up the flow charts.</p> <p>Data chiusura AC: 28/05/2021 Documents: Folder: BRC – 2.5.1 - AC</p>			
2	3.5.1.2	<p>Il fornitore di farine Amoruso, non è in possesso di Certificazioni GFSI, e, pur essendo considerato critico, non è ancora stato sottoposto audit di qualifica. Si sottolinea comunque, che tale audit risulta pianificato; il prodotto in accettazione, inoltre, viene sottoposto ai controlli definiti in procedura e non risultano mai rilevati problemi.</p> <p>The supplier of flours Amoruso does not have any GFSI certification and,</p>	<p>In data 24.05.2021 si è tenuto l'audit annunciato di qualifica presso il fornitore Molini Amoruso. L'audit ha dato esito positivo confermando la presenza di Amoruso nella lista dei fornitori approvati. On 24.05.2021 the qualification audit took place at Molini Amoruso plant. The audit result was positive and the supplier as confirmed in the list of approved supplier.</p>	<p>La procedura PRG 15 è stata aggiornata indicando esplicitamente che in casi di emergenza come le pandemie, laddove non fosse possibile eseguire degli audit fisici, bisogna procedere con gli audit documentali e da remoto. Il team qualità è stato formato in base ai nuovi requisiti introdotti.</p>	<p>Le verifiche ispettive presso i fornitori esterni erano state interrotte a causa della situazione di emergenza dovuta al Covid-19. Nella procedura delle verifiche ispettive non erano previsti eventi avversi di questo tipo e un conseguente piano di emergenza. Audit of suppliers were interrupted for emergency reasons</p>	2021-06-14	Lead Auditor Rossella Ghionda Positive

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Minor							
		although it is considered critical, it has not yet undergone a qualification audit. It should be noted, however, that this audit is planned; in addition, the accepted product undergoes the checks defined in the procedure and no problems have ever been identified.	Data correzione: 24/05/2021  Documents: Folder: BRC - 3.5.1.2 - Correzione	PRG 15 was updated: in case of emergency, for example audits cannot be performed because of a pandemic, it is requested to carry-out remote audits and documental audits. Quality team was trained about new requirements. Date: 04/06/2021	due to Covid-19. The procedure didn't prevent this kind of situations and an emergency action plan.		
3	3.9.2	Durante l'audit è stata rilevata la presenza di prodotto semilavorato Filoni CONAD, produzione del 10.5.2021 sprovvisto di identificazione; le schede di registrazione della produzione e della cottura hanno garantito, tuttavia, la identificazione del prodotto.  During the audit was detected the presence of a semi-finished product Filoni (Loaves) CONAD, production dated 10.5.2021	Il prodotto semilavorato sprovvisto di identificazione è stato segnalato al Responsabile di Produzione e prontamente etichettato con descrizione, lotto e data di produzione dei filoni. Unidentified semi-finished product was reported to the Production Manager and soon after disposed with a labelling including description, batch code and production date of baguettes.	Il Responsabile di produzione ha ricevuto specifico addestramento relativo alle GMP da adottare durante le attività produttive con particolare riguardo a garantire la tracciabilità del prodotto in tutte le fasi della produzione. Per un periodo di una settimana a partire dalla data di addestramento,	Il Programma annuale di addestramento del personale non ha previsto un addestramento specifico per la figura del Responsabile di produzione anche in riferimento alle sue mansioni specifiche. Annual training programm does not plan any specific activity for	2021-06-14	Lead Auditor Rossella Ghionda Positive

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		without identification; however, the production and baking registration sheets guaranteed the identification of the product.	Data correzione: 10/05/2021  Documents: Folder: BRC - 3.9.2 - Correzione	verifica giornaliera di efficacia dell'addestramento. Per un periodo di una settimana a partire dalla data di addestramento, verifica giornaliera di efficacia dell'addestramento. Production Manager received specific training on GMP to be adopted with regard to guaranteeing traceability throughout all production steps. Daily inspections for a period of one week starting from the training date to verify the effectiveness of the training. Daily inspections for a period of one week starting from the training date to verify the effectiveness of the training.	Production manager especially referred to all relevant tasks.		



*Claudio Innocenti*

Minor							
				Data chiusura AC: 28/05/2021			
				Documents: Folder: BRC - 3.9.2 - AC			
4	4.4.1	<p>Durante l'audit rilevata presenza di spugna incastrata fra la parete ed un tubo in sala produzione, area formatura; tale situazione non ha comportato rischi per la salubrità del prodotto.</p> <p>During the audit, the presence of a sponge used for cleaning and stuck between the wall and a pipe in the production room, forming area, was detected; this situation did not involve any risks for the health of the product.</p>	<p>La produzione in corso è stata bloccata e gli operatori hanno rimosso in sicurezza la spugna incastrata. Il Responsabile Qualità non ha rilevato problemi di sicurezza alimentare sul prodotto precedentemente confezionato. La produzione è stata dunque fatta ripartire in sicurezza. Production was promptly arrested to enable operators to remove the stuck sponge. Quality Assurance Office examined the finished product previously packed and didn't relieve any food safety issue. Production was then allowed to re-start in safe condition.</p>	<p>La Check-list mensile di ispezione stabilimento – HACCP e strutture è stata modificata per essere resa più efficace. Addestramento straordinario agli operatori di pulizia in relazione alla corretta esecuzione delle operazioni e verifiche di riconciliazione da effettuare alla fine delle operazioni. Check list - monthly inspection of the plant has been modified to get it more effective. Extraordinary training to all cleaning operators related to correct execution of al cleaning</p>	<p>Il controllo mediato dalla Check-list mensile di ispezione stabilimento – HACCP e strutture (MOD LG 6.1 Rev. 3) non ha consentito l'individuazione della spugna incastrata. The control executed following the Check list - monthly inspection of the plant - HACCP and structures (MOD LG 6.1 Rev. 3) failed to allow the identification of the stuck sponge.</p>	2021-06-14	Lead Auditor Rossella Ghionda Positive

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Minor							
			<p>Data correzione: 10/05/2021</p> <p>Documents: Folder: BRC - 4.4.1 - Correzione</p>	<p>procedures and to verification activities to be carried out at the end of the operations.</p> <p>Data chiusura AC: 28/05/21</p> <p>Documents: Folder: BRC - 4.4.1 - AC</p>			
5	4.4.2	<p>Il pavimento della sala produzione, in prossimità dell'area impasto, presenta una abrasione; tale abrasione non compromette la sicurezza alimentare del prodotto.</p> <p>The floor of the production room, near the kneading area, shows an abrasion; this abrasion does not compromise the food safety of the product.</p>	<p>L'abrasione al pavimento individuata in sede di audit è stata ripristinata. Floor abrasion observed during the audi has been restored.</p> <p>Data correzione: 28/05/21 Documents: Folder: BRC - 4.4.2 - Correzione</p>	<p>Il controllo mediato dalla Check-list mensile di ispezione stabilimento – HACCP e strutture (MOD LG 6.1 Rev. 3) ha fallito nel consentire l'individuazione dell'abrasione al pavimento. La Check- list mensile è stata modificata per essere resa più efficace. The control executed following the Check list - monthly inspection of the</p>	<p>Il controllo mediato dalla Check-list mensile di ispezione stabilimento – HACCP e strutture (MOD LG 6.1 Rev. 3) non ha consentito l'individuazione della spugna incastrata. The control executed following the Check list - monthly inspection of the plant - HACCP and structures (MOD LG 6.1 Rev. 3) failed to</p>	2021-06-14	Lead Auditor Rossella Ghionda Positive

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Minor							
				<p>establishment - HACCP and structures (MOD LG 6.1 Rev. 3) failed to allow the identification of the floor abrasion. Check list - monthly inspection of the manufacturing plant has been modified to get it more effective.</p> <p>Data chiusura AC: 21/05/21 Documents: Folder: BRC - 4.4.2 - AC</p>	allow the identification of the stuck sponge.		
6	4.6.2	Non disponibile la dichiarazione di conformità aggiornata alle disposizioni di legge vigenti relativamente ad una cisterna di stoccaggio olio da 1000 lt in polietilene, fornitore MAIDER IBC SRL; tale situazione tuttavia, non impatta la sicurezza alimentare del prodotto.	La dichiarazione di conformità visionata in sede di audit appartiene a un fornitore non più attivo. Il fornitore MAIDER IBC SRL non è più presente nella lista dei fornitori approvati. Si trasmette la dichiarazione di conformità dell'attuale fornitore Schutz GmbH.	Aggiornamento della procedura PRG 05 – Approvvigionamento, con inserimento di disposizioni specifiche al paragrafo 3.2 - VALUTAZIONE E QUALIFICA DEI FORNITORI. Conseguente addestramento al	La procedura PRG 05 – Approvvigionamento non presenta indicazioni sufficienti per una valutazione efficace dei fornitori di materiali plastici a contatto con gli alimenti. Procedure PRG 05 doesn't report	2021-06-14	Lead Auditor Rossella Ghionda Positive

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Minor							
		The declaration of conformity updated according to legal provisions in force for a 1000 litre polyethylene oil storage tank, supplier MAIDER IBC SRL is not available; however, this situation does not affect the food safety of the product.	Declaration of conformity examined during the inspection belongs to a supplier no longer active. The supplier MAIDER IBC SRL is not currently part of the approved supplier list. Declaration of conformity by the current supplier Schutz GmbH is transmitted.  Data correzione: 12/05/2021 Documents: Folder: BRC - 4.6.2 - Correzione	Controllo Qualità di stabilimento sulle modifiche adottate nella nuova revisione della procedura. Updating Procedure PRG 05 - with the inclusion of specific provisions in paragraph 3.2 - EVALUATION AND QUALIFICATION OF SUPPLIERS. Consequent training to the plant Quality Control on the changes adopted in the new revision of the procedure.  Data chiusura AC: 25/05/2021 Documents: Folder: BRC - 4.6.2 - AC	exhaustive information to lead an effective supplier validation with regard to plastic material I contact with food.		
7	4.9.1.1	Durante l'ispezione all'interno dello stabilimento, è stato trovato aperto il deposito stoccaggio sanificanti limitrofo all'area magazzino prodotti finiti;	Il Responsabile della manutenzione ha provveduto alla messa in sicurezza del deposito sanificanti ed alla segregazione del solvente	Il Responsabile Manutenzione ha ricevuto un addestramento relativo alla gestione ed allo stoccaggio dei	Il programma di addestramento annuale non ha previsto un rinnovo specifico relativo alle attività del	2021-06-14	Lead Auditor Rossella Ghionda Positive

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Minor							
		<p>inoltre, in sala confezionamento è stato trovato flacone solvente colla; tale situazione non ha comportato rischi di sicurezza alimentare del prodotto.</p> <p>During the audit inside the plant, the sanitizer storage warehouse next to the finished product warehouse was found open; in addition, a bottle of glue solvent was found in the packaging area; this situation did not involve any food safety risks for the product.</p>	<p>presente in area confezionamento. Maintenance manager was alerted and provided for locking sanitation products warehouse and segregating the solvent found in packaging area.</p> <p>Data correzione: 12/05/21 Documents: Folder: BRC - 4.9.1.1 - Correzione</p>	<p>prodotti chimici come previsto dal MOD BPL Buone Pratiche di Lavorazione, con una verifica dell'efficacia a distanza di una settimana. Maintenance Manager received training on correct managing and segregation of chemical products with effectiveness verification after one week from training.</p> <p>Data chiusura AC: 28/05/2021 Documents: Folder: BRC - 4.9.1.1 - AC</p>	<p>Responsabile Manutenzione. Annual training plan doesn't involve scheduled training activities with regard to responsibilities of Maintenance Manager.</p>		
8	6.1.1	<p>La Scheda rintracciabilità materie prime, registrazione del 10.5.2021, non riportava al momento dell'audit la registrazione dell'esito dei controlli preoperativi effettuati; l'ispezione</p>	<p>Addestramento agli operatori addetti alla produzione sulle corrette modalità di svolgimento e registrazione dei controlli pre-operativi secondo quanto previsto dalla PRG</p>	<p>Aggiornamento del MOD PRP 6.2 Scheda rintracciabilità materie prime per consentire l'immediata individuazione del</p>	<p>Il layout del MOD PRP 6.2 Scheda rintracciabilità materie prime non consente agli operatori di visualizzare</p>	2021-06-14	<p>Lead Auditor Rossella Ghionda Positive</p>

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		<p>condotta ha permesso di appurare che gli stessi erano stati effettuati con esito positivo.</p> <p>At the time of the audit, the Raw Material Traceability Sheet, registration dated 10.5.2021, did not report the outcome of the pre-operational checks carried out; the audit carried out confirmed that these had been carried out with a positive outcome.</p>	<p>8 Rev 5 – Procedura del processo produttivo. Training to production area's operator on proper execution and recording of pre-operative controls, based on PRG 08 Rev. 5 – Procedure related to Production Flow</p> <p>Data Correzione: 28/05/21</p> <p>Documents: Folder: BRC - 6.1.1 - Correzione</p>	<p>riquadro dei controlli pre-operativi. Addestramento agli operatori con verifica dell'efficacia. Updating the form MOD PRP 6.2 Scheda rintracciabilità materie to enable operators to immeidately visualize pre-operative check records box. Trainig to operators with effectiveness verification.</p> <p>Data chiusura AC: 28/05/21 Documents: Folder: BRC - 6.1.1 - AC</p>	<p>nell'immediatezza il riquadro di registrazione dei controlli pre-operativi. Layout of MOD PRP 6.2 didn't allow operators to immediately focus on pre-operative recordings.</p>		



*Claudio Innocenti*

Comments on non-conformities

Le NC rilevate durante l'audit precedente (3.6.4, 3.8.1, 3.9.1, 4.4.3, 4.7.5, 4.8.3, 4.9.2.1, 4.14.10, 4.15.2) sono state risolte; in corrispondenza dei singoli requisiti è inserita la relativa descrizione.

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## Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit due date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

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No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

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# Detailed Audit Report

## 1. Senior management commitment

### 1.1 Senior management commitment and continual improvement

È presente una politica integrata rev. 9 del 01.09.2020. È una politica integrata per quanto riguarda la sicurezza e l'ambiente. È firmato dal direttore generale; copia della politica è esposta in bacheca. La documentazione gestionale è trasversale per quanto riguarda il sito di Palo del Colle e gli altri due siti aziendali, il sito Palombaio per pasta e prodotti simili, e il sito di Palo del Colle paste secche. È stato formalizzato un Piano di sviluppo della cultura alimentare al 1.9.2020 che prevede un momento di sensibilizzazione rivolto a tutti gli operatori in merito alle disposizioni igieniche da seguire, oltre misure quali condivisione di reclami pertinenti; sono inoltre, stabiliti dei momenti di condivisione attività lavorative (affiancamento RQ ai diversi operatori) al fine approfondire le specifiche problematiche dell'attività, da effettuarsi entro il 2021. Il riesame della direzione è effettuato con cadenza annuale, visto Riesame del 15.09.2020 formalizzata sul mod PRG 1.1 Rev.1 effettuata per i tre siti con i loro rappresentanti: gli output sono opportunità di miglioramento: principale obiettivo è la sostituzione ed ampliamento silos di stoccaggio farine e integrazione software di gestione delle materie prime/ricette, da realizzarsi entro il 31.12.2021 per il sito di palo del colle. Ogni tre mesi sono previsti incontri per discutere gli obiettivi, l'ultimo il 30.03.2021. Vista la Tabella degli indicatori di qualità del processo, valutati trimestralmente (30.3.2021, 31.12.2020), che prevede: 1) una valutazione del livello di confidenza dei fornitori basata sulle NC registrate per i fornitori fondamentali; 2) valutazione dell'attuazione dei piani di miglioramento; 3) risultati dell'audit interno; 4) un indice di vendita che permette di visualizzare trimestralmente l'incremento/decremento della % di prodotti venduti. Ogni mese sono previsti incontri interni su qualità, legalità e sicurezza disponibili su formato excel, gli ultimi sono stati svolti in data 9.3.2021, 14.4.2021, con focus su anomalie emerse durante audit CONAD. Un sistema di whistleblowing è stato definito nel PRG 01 rev.06 del 16/07/2019: è stata installata una cassetta chiusa con l'istruzione che la descrive e la relativa modulistica - mod PRG 1.3.1 rev 0 del 16.07.2019. Non è stata ricevuta alcuna segnalazione. È disponibile una copia dello standard. Nessun uso del logo. Le NC emerse durante l'audit precedente risultano chiuse.

### 1.2 Organisational structure, responsibilities and management authority

Visto organigramma comune ai tre siti, rev. 12 del 1.9.2020, con Direzione Generale, Assistente Direzione Generale, Responsabile Qualità (RQ generale Francesco Garofalo, specifico per il sito Leonardo Mancini), Laboratorio, Gestione dei sistemi ambientali, Team HACCP, Responsabile di Produzione Palo del Colle. Sostituzione e supplenti sono definiti nello stesso documento che include anche le descrizioni delle mansioni; le competenze del personale sono definite nel MOD PRG16.1 Rev.1 del 12/07/2012, questo documento è stato illustrato al personale nel corso della formazione

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Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

## 2 The Food Safety Plan – HACCP

Piano HACCP PAA rev 3 del 28/01/2019. Il manuale è revisionato/validato a cadenza annuale. Il Team è multidisciplinare e composto da Peppino Milo Milo (AU) Francesco Garofalo RQ del gruppo e team leader - Saverio Milo (Direzione acquisti e personale), Dr. Marida Milo (Direzione commerciale), Giovanni Milo (Direzione logistica), Leonardo Mancini (RQ del sito specifico), Marcello Belviso (Produzione). I prodotti realizzati sono taralli e prodotti da forno. I prerequisiti operativi sono riportati alla sezione BPL, Rev 1 del 25.7.2018, e comprendono GMP, attrezzature, pulizia, manutenzione, controllo dell'acqua, rifiuti. I prodotti realizzati sono prodotti da forno di diverse forme /taralli, bruschette, ecc), principali ingredienti farine di frumento tenero, acqua potabile, olio vegetale e sale, cui possono essere aggiunti in quantità variabile lievito, malto di frumento, spezie, aromi, ecc.. Definiti i principali pericoli, sezione HA 2 rev.5 del 24.2.2021 dovuti a micotossine, acrilammide, metalli pesanti, E. coli, stafilococchi e contaminazione chimica (DON), MOSH e MOAH, pericolo radiologico e rischio biologico dovuto ai cereali parassiti. Gli allergeni presenti nel sito sono glutine, latte e derivati, sesamo e solfiti, soia. La valutazione del rischio si basa su PxG in HA1 rev 5 del 05/08/2019 utilizzando l'albero decisionale. Sono disponibili 3 diversi diagrammi di flusso DDF Rev. 3 24.02.2021 per i taralli, per i lievitati e per i prodotti tostati. I diagrammi sono verificati da RQ in data 19.3.2021 utilizzando una check list HACCP rev 2 del 4.8.2017 e approvati nell'ultima riunione dal Team HACCP del 14.4.2021. Le fasi del flusso produttivo sono le seguenti: produzione prodotti da forno bolliti: ricevimento e stoccaggio materie prime (stoccaggio spezie a base di formaggio avviene a temperatura controllata), setacciatura sfarinati, miscelazione e impasto, estrusione/formatura/taglio, bollitura (95 ° C x 1 min), cottura (circa 200 ° C x 30min variabile a seconda del tipo di articolo), raffreddamento, confezionamento ed imballaggio; produzione prodotti lievitati: ricevimento e stoccaggio materie prime (stoccaggio spezie a base di formaggio e lieviti avviene a temperatura controllata), setacciatura sfarinati, miscelazione e impasto, estrusione/formatura/taglio, lievitazione, cottura (circa 200 ° C x 30min variabile a seconda del tipo di articolo), raffreddamento, aggiunta di ingredienti in superficie, confezionamento ed imballaggio; produzione di prodotti da forno lievitati e tostati: ricevimento e stoccaggio materie prime (stoccaggio spezie a base di formaggio avviene a temperatura controllata), setacciatura sfarinati, miscelazione e impasto, estrusione/formatura/taglio, lievitazione, cottura (circa 200 ° C x 30min variabile a seconda del tipo di articolo), tostatura, raffreddamento, aggiunta di ingredienti in superficie, confezionamento ed imballaggio. E' stato individuato 1 CCP, in fase di confezionamento, relativo alla presenza di corpi estranei: CCP1 metal check tester 2.5 mm Fe- 2.5 mm N Fe e 2.5 mm SS verificati all'inizio, dopo 2 ore e alla fine. Vengono definite correzioni e azioni correttive. Mensilmente, inoltre, è effettuata una ulteriore verifica funzionamento MD. verificate. Scheda Controlli di confezionamento del 23.03.2021, Bruschette olive verdi Conad, confezione da 150 gr, L 21082, controllo effettuato dal Responsabile Produzione e conservato per 2 anni, e verifica di funzionamento mensile del 22.04.2021, efficace. Validazione limiti CCP: per MD visto report emesso da Almatecno il 01.07.2020 per MD modello PRN 05 S / N 719503, test ok.

2.5.1 Il diagramma di flusso DDF Rev 3 del 24.2.2021 non riporta la fase di rilavorazione dell'impasto prelevato dalla formatrice ad avvio impianto; l'impasto è subito reimpresso all'interno della stessa vasca impasto a cura dell'operatore, pertanto non si rilevano problemi di sicurezza alimentare né di rintracciabilità

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Clause/Section Ref	Justification

### 3. Food safety and quality management system

#### 3.1 Food safety and quality manual

Manuale integrato della qualità rev. 11 del 15.9.2020, comune ai tre siti, aggiornato a seguito messa in funzione sito di Palo del Colle. L'organizzazione segue la PRG 4.4 Rev. 5 del 2.8.2019, monitoraggio di documenti e registrazioni, con Elenco generale dei documenti del SGQ, ultimo aggiornamento in data 24/2/2021. Diversi documenti sono disponibili sulle linee di produzione.

#### 3.2 Document Control

Il controllo dei documenti è affidato all'ufficio qualità. utilizzando un file excel con lo stato di revisione "Elenco generale dei documenti del SGQ", per tutti i documenti come procedure, istruzioni, fogli di registrazione, specifiche ecc. Ultimo aggiornamento il 24/2/2021. Tutta la documentazione elettronica è protetta da password, così come i plc di gestione degli impianti

#### 3.3 Record completion and maintenance

L'organizzazione segue la Rev. 5 del 2.8.2019, monitoraggio di documenti e registrazioni, con lista di documenti verificata e informativa ultimo aggiornamento al 24/2/2021. Nel Mod PRG 4.3 il tempo di conservazione è di minimo 2 anni (1 anno in più della shelf life), Mod PRG 4.2 per la lista di distribuzione. Procedura di backup: è responsabile una società di servizi esterna (Integry srl, che gestisce integralmente il sistema informatico) con l'operatore amministrativo Francesco Tedesco. Un server principale centrale è impostato in Lab Palombaio, e un altro nei due siti di Paolo del Colle. Ogni server è impostato con un NAS esterno (Synology) con 4 terabyte di memoria. Ogni notte alle 02.00 una copia ht viene lanciata e sottoposta a backup. I test di restore vengono eseguiti ogni mese. Server e NAS si trovavano in stanze separate.

#### 3.4 Internal audits

La procedura di audit interno è PRG15 Rev. 8 del 05/08/2019. Audit interni svolti come previsto nel MOD PRG 15.5 rev. 1 del 15.02.2020, pianificata l'effettuazione di 4 verifiche annuale per l'anno 2021. La frequenza è correlata ad un rischio calcolato sulla base dei seguenti criteri: n di NC a seguito audit precedenti, precedenti, criticità del processo per la sicurezza alimentare, casi di emergenza. Gli audit interni sono eseguiti da personale qualificato (Ufficio Qualità) come F. Garofalo (qualifica di revisore interno, visto certificato rilasciato in data 7/04/2003 da BSI). Durante l'audit viene utilizzata una lista di controllo BRC / IFS combinata (Check list rev. 0 del 3.1.2020) e sono verificati argomenti quali controllo dell'HACCP e food safety plan – PRP – food defence e frodi – procedure che garantiscano la conformità allo standard. Visti audit del 17.3.2021, 15.2.2021, 15.01.2021, 14.12.2020, non sono emerse anomalie.

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Ispezioni interne: settimanale, controllo preoperativo ad inizio settimana: verifica pulizia, integrità stabilimento, ordine, cartellonistica, visti report del 10.5.2021, 03.05.2021; mensile su strutture, servizi e spogliatoi, locali di lavorazione ed impianti, visti report del visti report del 10.5.2021, 16.4.2021. nessuna anomalia rilevata nel 2021

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

Procedura di fornitura controllata PRG 05 del 05/08/2019 rev.16, comune ai tre siti; verificato l'elenco dei fornitori qualificati mod. PRG 5.7 rev. 0 aggiornato il 20.04.2021 relativamente al sito in oggetto, con la tipologia di prodotto/servizio fornito. a qualifica si basa sulla valutazione delle informazioni tecniche e delle specifiche dell'azienda e sul questionario Mod PRG 5.2. La valutazione del rischio delle materie prime (ingredienti (farine, spezie, oli, vino, ecc e imballaggi primari) è nel Mod PRG 5.7 HASVP Rev.0 del 02/08/2018 aggiornamento settembre 2020, dove le materie prime sono state abbinate ai fornitori e valutate per tutti i pericoli: criteri di sicurezza alimentare ed analisi del rischio di frode alimentare si è basata su Gravità e Probabilità con un tasso da 1 a 5; la valutazione finale è classificata in 4 livelli: verde (1-4), giallo (5-9), arancione (10-12) e rosso (13-25). Le misure definite sono: giallo: certificazione e analisi delle materie prime, arancione: audit di seconda parte, rosso: audit annuale e analisi delle materie prime. E' considerata sensibile alla frode tutta la materia prima biologica, quella certificata Halal, l'olio extravergine, la semola di grano duro di origine pugliese. Per i fornitori critici (es. tutte le farine) è richiesto il possesso di certificazione secondo standard riconosciuti GSFI oppure l'effettuazione di una verifica da parte del gruppo qualità aziendale. Negli altri casi la predisposizione del questionario è sufficiente. Vista qualifica del 20.4.2021 (Elenco fornitori aggiornamento 20.04.2021) Vista qualifica fornitore Sinergie Molitorie, effettuata in data 7.5.2021, Certificato BRC del 26.4.2021. Visto Questionario fornitore Casa Olearia Italiana SPA del 6.5.2021, Vista Dichiarazione HALAL del 6.5.2021, test di rintracciabilità effettuato su Olio di oliva raffinato DDT 2021001647 del 29.4.2021, Vista Scheda tecnica olio raffinato ottobre 2020, R 4, Casa Olearia Italiana SPA, Dichiarazione di conformità con caratteristiche chimiche-fisiche, allergeni, OGM. Fornitore di imballo Bioplast, Vista qualifica effettuata in data 11.3.2021, Scheda tecnica bobina in polipropilene tarallini CONAD del 11.3.2021, certificato BRC IOP scadenza 2.12.2021, n AG/GDO/18/14. Visto il questionario compilato dal fornitore di spezie Sidea il 24.06.2020. visto il test di tracciabilità fornito dal fornitore il 24.06.2020, visto anche il certificato FSSC 22000 con scadenza il 04.10.2021. Qualifica fornitore Liodry Foods SRL, certificato BRC FOOD Site code 1253959, scadenza 31.5.2021. Tutti i fornitori di materie prime critiche sono certificati secondo standard riconosciuti GSFI. Non sono presenti broker o agenti. L'aggiornamento della qualifica è effettuato a cadenza annuale, in sede di riesame.

3.5.1.2 Il fornitore di farine Amoruso, non è in possesso di Certificazioni GFSI, e, pur essendo considerato critico, non è ancora stato sottoposto audit di qualifica. Si sottolinea comunque, che tale audit risulta pianificato; il prodotto in accettazione, inoltre, viene sottoposto ai controlli definiti in procedura e non risultano mai rilevati problemi.

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

Il monitoraggio in fase di accettazione è basato su Istruzione Operativa Ricevimento/accettazione materie prime PRP 2 Rev. 0 del 18.6.2014, con la definizione dei criteri di accettazione; le registrazioni sono su schede di ricevimento. Visti controlli al ricevimento: Ricevimento imballi primari, Mod. PRP-2.2 Rev. 0, Ricezione del 15.1.2020, lotto 76965, fornitore Bioplast, DDT n. 149 del 14.1.2022, controlli in accettazione corrispondenza merce con ordine, e DDT, condizioni igieniche mezzo di trasporto, condizioni prodotti (integrità confezioni, aspetto, ecc ). Viene prelevato un campione che è allegato alla scheda controllo. Al momento del primo utilizzo vengono, inoltre, effettuati i controlli testi, grafica e colori, resistenza meccanica, adesione materiali accoppiati, saldatura, registrati sulla stessa scheda. Ricevimento olio evo, scheda ricevimento merci, PRP 2-1, vista registrazione controlli del 23.2.2021, lotto 142000040, FT 26, 1900 kg di olio: controlli eseguiti: condizioni igieniche automezzo, fornitore approvato, prodotto inserito nella lista prodotti approvati, corrispondenza scheda tecnica e ingredienti, controlli etichettatura, eventuale certificazione Halal, biologica, ecc. Per prodotti refrigerati si effettua anche il controllo della temperatura e per la farina l'umidità, in aggiunta ai controlli sopra definiti. Vista Scheda Ricevimento farina del 9.3.2021, fornitore Amoruso, lotto 8, umidità pari a 15,1%, Vista Scheda Ricevimento lievito del 25.2.2021, rilevazione della temperatura di 4°C. Per le farine, gli oli e la semola di grano duro italiano e pugliese viene prelevato un campione e conservato per circa 3 mesi.

**3.5.3 Management of suppliers of services**

L'azienda si avvale di più servizi: Naturambiente, servizi di derattizzazione; laboratorio esterno Food Safety lab, rifiuti G.M. Service Import export. I fornitori sono qualificati a seguito di formalizzazione contrattuale delle condizioni del servizio. Verificato il contratto di fornitura dei servizi e lo svolgimento delle attività con Naturambiente, sottoscritto in data 1.9.2020, nel quale viene dettagliato il servizio di disinfestazione, con rinnovo annuale automatico.

**3.5.4 Management of Out sourced processing**

No outsourced activities falling within the application scope, including packaging.

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**3.6 Specifications**

L'azienda gestisce le specifiche di MP e PF, che sono riviste a cadenza annuale: verificate in audit Scheda tecnica estratto di rosmarino, del 20.1.2020, produttore VITIVA con indicazione delle caratteristiche chimiche, fisiche e microbiologiche, OGM, Shelf life; Scheda tecnica farina 00, rilasciata dal fornitore Amoruso. Vista Scheda tecnica olio raffinato ottobre 2020, R 4, Casa Olearia Italiana SPA, Dichiarazione di conformità con caratteristiche chimiche-fisiche, allergeni, OGM. Vista Scheda tecnica olio raffinato ottobre 2020, R 4, Casa Olearia Italiana SPA, Dichiarazione di conformità con caratteristiche chimiche-fisiche, allergeni, OGM. Tutte le specifiche dei prodotti finiti sono riepilogate nel modulo Scheda etichetta, nella quale è riportato l'elenco dei prodotti, le modalità di conservazione e confezionamento, le informazioni sulla composizione dei prodotti, le informazioni in etichetta; tale elenco è condiviso con tutti gli stabilimenti ed aggiornato ad aprile 2021. Viste Scheda tecnica del 21.4.2021, Tarallino finocchio marchio Prime nature, con indicazione di ingredienti, TMC, caratteristiche chimiche (perossidi, acidità) caratteristiche organolettiche, contaminanti chimici, allergeni, parametri microbiologici, etichetta nutrizionale, caratteristiche imballo e di logistica. Visto capitolato CONAD del 18.2.2020, prodotto a marchio, con dettagli in merito a tempo di vita (240 gg), composizione/ingredienti, modalità di conservazione, informazioni etichetta, specifiche tecniche, specifiche allergeni (sesamo, latte, soia e uova – uova non in uso nello stabilimento). Scheda tecnica bobina in polipropilene tarallini CONAD del 11.3.2021, fornitore Bioplast, bobina. Scheda tecnica secchiello fornitore RPC Superfos, del 7.4.2017, con dichiarazione di conformità alimentare.

**3.7 Corrective and preventive actions**

Visto PRG 15 reclami, azioni correttive di non conformità e azioni preventive di misurazione delle prestazioni del sistema, misurazione della soddisfazione del cliente in Rev.8 del 05/08/2019. Le CA sono gestite su file excel MOD PRG 15.1-15.3-15.4 (NC, CA e reclami). Nel corso dell'ultimo anno è stata registrata un'azione preventiva, in data 5.5.2021, in relazione al nuovo regolamento sesamo negli USA, in vigore dal gennaio 2023; l'azienda ha definito di aggiornare e stampare le nuove bobine con la dicitura richiesta, avendo cura di smaltire entro il 2023 le bobine attualmente in uso.

**3.8 Control of non-conforming product**

Visto PRG 15 reclami, azioni correttive di non conformità e azioni preventive di misurazione delle prestazioni del sistema, misurazione della soddisfazione del cliente in Rev.8 del 05/08/2019. Le CA sono gestite su file excel MOD PRG 15.1-15.3-15.4 (NC, CA e reclami). Nel corso del 2020 non sono stati rilevati prodotti non conformi. Rilevato 1 prodotto non conforme in data 8 maggio 2021, Tarallini olio di oliva, lotto 21119, 120 kg circa di prodotto – correttamente identificato in apposita area Prodotto non conforme, a seguito di problema impasto in partenza,

**3.9 Traceability**

Il sistema di rintracciabilità è di tipo misto, con registrazioni cartacee ed elettroniche, descritto nella PRP 6 Identificazione e rintracciabilità, Rev. 2 del 2.8.2019. Il prodotto finito è identificato – salvo richieste diverse da parte dei clienti -da un numero di 5 cifre, le prime 2 identificano l'anno, e le successive 3 il giorno di produzione e confezionamento secondo il calendario Giuliano, preceduto dalla lettera L. Il programma Wingest permette, dal numero di lotto, di rilevare tutti i clienti cui è destinato il lotto con i relativi DDT di consegna. Test effettuato in audit su Test effettuato in audit su Bruschettine alle olive con olio di oliva e olive verdi Conad, confezione da 150 gr, L 21082, da valle a monte: DDT 3073 del 26.3.2021, consegna a CONAD sede di Anagni di 4.410 cartoni da 14 buste, per un totale di 61.740 buste di bruschette da 150 gr. In base al numero di lotto, si rileva l'attività di confezionamento ed i relativi controlli eseguiti: Rif. Scheda Controlli di confezionamento del 23.03.2021, lotto 21802, nonché l'ora di inizio confezionamento: 9.25. A sistema informatico, inoltre, si verifica il numero di lotto della bobina CONAD, fornitore Bioplast, Lotto 76965. Sono stati confezionati in totale 4.662 pezzi (di cui 4.410 consegnati con DDT 3073 del 26.3.2021 e 252 con DDT 3494 del 9.4.2021), come evidenziato anche dal sistema Wingest. Sempre in base al numero di lotto, si rileva l'ordine di produzione 3504, che permette di consultare la relativa Scheda rintracciabilità materie prime; vista Scheda rintracciabilità materie prime del 22.03.2021, che riporta la quantità prodotta (695 Kg), le materie prime utilizzate con i relativi lotti: farina 00, kg 100 (fornitore

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Amoruso), lotto 8, olio di oliva sfuso 13 kg lotto 41/a21 (fornitore casa Olearia Italiana) e olio EVO lotto 142000040 (fornitore Azienda olearia Basile), sale fino 2 kg, lotto 140121 (fornitore Atisale), Farina di malto 0,4 kg, lotto 6074 (fornitore Mancinelli), lievito, 2 kg, lotto DO119L (fornitore Sinedi), olive verdi a rondelle Kg 10, lotto 20271AG (fornitore Euroolive), Lipoaroma oliva nera, 0,30 kg, L 2101000152 (fornitore DKS Aromatic), estratto di rosmarino, kg 0,013, L 301779-200018 (fornitore Vitiva). Sulla stessa scheda si riporta lo scarto di prodotto (9 kg). Test completato con successo in 2 ore. Bilancio congruo. Le uniche attività di rilavorazione riguardano parte dell'impasto proveniente dalla prima formatura, che viene rimosso e reimmesso contestualmente nell'impasto. Pianificata effettuazione di test annuale di rintracciabilità e predisposizione di Bilancio di massa a cadenza semestrale, visti test interno del 2.2.2021, su prodotto Bruschette CONAD Lotto 20256, da DDT n.9788 del 14.9.2020 e del 27.1.2021, prodotto Tarallini olio di oliva Lotto 20308, da materia prima, arrivo farina tipo 0 taralli, fornitore Casillo, del 23.10.2020

3.9.2 Durante l'audit è stata rilevata la presenza di prodotto semilavorato Filoni CONAD, produzione del 10.5.2021 sprovvisto di identificazione; le schede di registrazione della produzione e della cottura hanno garantito, tuttavia, la identificazione del prodotto

**3.10 Complaint-handling**

Vista PRG 15 reclami, azioni correttive di non conformità e azioni preventive di misurazione delle prestazioni del sistema, misurazione della soddisfazione del cliente in Rev.8 del 05/08/2019. Le CA sono gestite su file excel MOD PRG 15.1-15.3-15.4 (NC, CA e reclami). Nel corso del 2020 è stato ricevuto un reclamo, relativo ad apertura di una confezione da 100 grammi, rilevato da un consumatore. Nel corso del 2021 è stato ricevuto un solo reclamo, in data 1.3.2021, a seguito segnalazione di un consumatore, lotto prodotto 21007, Bruschette al rosmarino, rilevato prodotto molle; effettuata analisi causa, non è stato rilevato il problema, risposta al cliente del 1.3.2021

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

Linea Guida 2 Rev 7 del 06/05/2020, che definisce le misure da attuare anche in caso di attacchi digitali. L'azienda ha pianificato ed esegue 2 volte all'anno un test di richiamo completo del ritiro, ultimo effettuato in data 25.9.2020, prodotto Dolcetto Tuscan Crisps lotto 20139, cliente Fusion Gourmet, mail al cliente inviata il 25.9.2021, sollecitata risposta del cliente, ricevuta in data 28.9.2021. Visto elenco numeri di emergenza Lista contatti del personale chiave gestione crisi settembre 2020, inseriti riferimenti CSQA direttamente nel modulo "Standard format gestione incidenti". L'azienda non ha effettuato ritiro o richiamo di prodotto.

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

Clause/Section Ref	Justification
3.5.4	There isn't outsourced process
3.5.4.1	There isn't outsourced process
3.5.4.2	There isn't outsourced process

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3.5.4.3	There isn't outsourced process
3.5.4.4	There isn't outsourced process
3.9.4	No reworking

<b>4. Site standards</b>
<b>4.1 External standards</b>
Sito localizzato nella zona industriale di Palo del Colle, Strada Statale 96 Km113.2. Il sito attuale è stato realizzato su una struttura preesistente che è stata ricostruita e ristrutturata
<b>4.2 Site security and food defence</b>
E' stata effettuata un'analisi dei rischi per quanto riguarda i processi/prodotti derivanti da atti intenzionali riportata nella PR 0 Rev. 0, Sicurezza del sito produttivo con la descrizione dei rischi o delle misure di prevenzione e l'identificazione del team (R PROD e RQ). L'analisi ha portato ad un audit riguardante la funzionalità delle infrastrutture, degli impianti e delle procedure in essere. Le misure adottate sono le seguenti: recinzioni in tutto il sito e gestione controllata dei punti di accesso, chiusura dei punti di accesso; - sistema di sorveglianza di una guardia di sicurezza notturna e del fine settimana Istituto di vigilanza Metronotte Srl; Sistema di telecamere a circuito chiuso: diverse telecamere (31) registrano 24 ore su 24, 7 giorni su 7 ed è collegata al sistema di sorveglianza; le registrazioni sono conservate per 30 gg. Vista formazione effettuata in data 14.5.2020 in tema food defence. Pianificata un'ispezione ogni 4 mesi per verificare l'efficacia delle misure, l'ultima il 25.2.2021, non si registrano scostamenti. In data 23.2.2021 è stato eseguito un challenge test sulla difesa alimentare con l'ausilio di un autista della ditta Rotunno, che è stato fermato all'ingresso dello stabilimento dagli operatori aziendali. Visto Registro visitatori del 23.2.2021, Sig. P.C, operatore della derattizzazione. Numero di registrazione FDA 16111067886 10/01/2020.
<b>4.3 Layout, product flow and segregation</b>
Le aree di produzione sono distinguibili in zone a basso rischio dove il prodotto è esposto e zone dove il prodotto non è esposto. La contaminazione incrociata con allergeni è adeguatamente gestita da altre materie prime da derivati del latte, sesamo e solfiti - Esistono schemi dei flussi riguardanti le confezioni, la produzione del personale. Il flusso si sviluppa principalmente seguendo una forma a ferro di cavallo, opportunamente strutturata e pianificata. Una mappa emessa il 15.11.2020 definisce il flusso dei prodotti (taralli e altri prodotti da forno).
<b>4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas</b>
L'impianto è stato realizzato nel 2014 in cemento pre-fabbricato.  Le pareti sono in cemento e sono in condizioni di sicurezza, in generale. I pavimenti sono in cemento e rivestiti con resine industriali antiscivolo e impermeabili. Il drenaggio è adeguato. Viene utilizzata una quantità limitata di acqua per il tipo di prodotto. I soffitti sono in cemento, con finestre per l'aspirazione della luce in vetro e con anima in metallo. Le porte che conducono all'esterno sono tenute chiuse. Le

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lampade sono anti rottura. Le pareti sono in buone condizioni, così come le finestre, gli elementi sospesi sono in buone condizioni di pulizia. Ci sono aree a basso rischio in cui il prodotto è esposto.

4.4.1 Durante l'audit rilevata presenza di spugna utilizzata per la pulizia incastrata fra la parete ed un tubo in sala produzione, area formatura; tale situazione non ha comportato rischi per la salubrità del prodotto

4.4.2 Il pavimento della sala produzione, in prossimità dell'area impasto, presenta una abrasione; tale abrasione non compromette la sicurezza alimentare del prodotto.

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

Acqua da rete municipalizzata utilizzata per pulizie e come ingrediente, non sono presenti serbatoi di stoccaggio. Vista mappa del 15.11.2020, identificati 2 punti di prelievo a rotazione, punto di raccordo acquedotto/rete aziendale, rubinetto produzione. Frequenza analisi annuale sui 3 punti di prelievo. Visto RdP 43/06/20 del 15.06.2020, Laboratorio Console, Accredia 1151 L, punto di prelievo raccordo acquedotto/rete aziendale, valori analizzati Conta microbica a 22 e 36 °C, coliformi totali e fecali, Streptococchi, pH, parametri chimici, fisici, valori conformi. Valori conformi al decreto legislativo 31/01 e succ. modd. e intt. In merito al ghiaccio, Visto RdP 42/06/20 del 15.06.2020, Laboratorio Console, Accredia 1151. Non utilizzati gas sul prodotto. L'aria compressa non viene valutata in quanto non è mai in contatto con il prodotto o la linea; i filtri installati sulla macchina del compressore d'aria non sono definiti. Il vapore viene utilizzato per "cuocere" i taralli, ma non è vapore diretto, quindi nessun additivo viene aggiunto all'acqua di provenienza

#### 4.6 Equipment

Due impastatrici (taralli e multifunzione), 3 celle di lievitazione, 2 linee di produzione taralli (Tarpan) e una multifunzionale (MiniPan Line). Zona forni con 12 unità rotanti abbinata a forno multifunzionale + lineare su nastro linea Taralli. Tre multipack per il confezionamento in sacchetti di PP. Nuove installazioni in acciaio inossidabile. Nastri conformi al contatto con alimenti visti dichiarazione del 22/09/16 per Ropanyl. Vista Dichiarazione di conformità caraffe da parte del fornitore Intertek del 12.8.2016 idoneo al contatto con olio di oliva

4.6.2 Non disponibile la dichiarazione di conformità aggiornata alle disposizioni di legge vigenti relativamente ad una cisterna di stoccaggio olio da 1000 lt in polietilene, fornitore MAIDER IBC SRL; tale situazione tuttavia, non impatta la sicurezza alimentare del prodotto

#### 4.7 Maintenance

Vista procedura per la manutenzione IO Q 8.3 rev 5 del 17.4.2019. In azienda è presente un manutentore che gestisce l'officina interna, chiusa ai non addetti, sono effettuate manutenzioni a cadenza annuale e semestrali. L'elenco degli impianti e delle apparecchiature è riportato nell'Elenco Impianti ed attrezzature e relativo Programma di manutenzione, aggiornamento del 22.1.2020. La registrazione degli interventi è registrata su Richiesta intervento manutentivo, vista registrazione del 3.3.2021, intervento effettuato su bilancia matricola 1363. In uso grasso sintetico multiuso alimentare, Molikote G4500/G-450, come da registrazione NSF del 2.10.2002. Il servizio di manutenzione esterna viene utilizzato per alcune macchine, es Air Center per aria compressa.

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4.8 Staff facilities

Gli spogliatoi sono adeguati, provvisti di toilets, lavamani e docce, adeguatamente attrezzati. Non è consentito fumare, non viene fornito alcun servizio di ristorazione, né è presente un'area mensa. Numero sufficiente di armadietti. Nessuna area ad alto rischio né ad alto controllo

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

4.9.1 Chemical control

Tutti i prodotti chimici sono codificati e riportati nell'Elenco prodotti chimici aggiornato al 10.7.2020. Visto prodotto Sutter SF 110, disinfettate ad uso alimentare, Scheda tecnica e dichiarazione di conformità uso impianti alimentari maggio 2019. I prodotti sono immagazzinati in un'area definita e chiusa. Grasso sintetico ad uso alimentare Molikote G4500/G-450, registrazione NSF del 2.10.2002, Chlordet (visto ST giugno 2018) per settore alimentare e farmaceutico

4.9.1.1 Durante l'ispezione all'interno dello stabilimento, è stato trovato aperto il deposito stoccaggio sanificanti limitrofo all'area magazzino prodotti finiti; inoltre, in sala confezionamento è stato trovato flacone solvente colla; tale situazione non ha comportato rischi di sicurezza alimentare del prodotto

4.9.2 Metal control

Gli attrezzi metallici (forbici, raschietto, coltello) della produzione e del confezionamento sono riportati sull'Inventario degli attrezzi, MOD. LG 6.5.2 del 1.3.2019. Trimestralmente sono effettuate verifiche di presenza/integrità, vista registrazione Check List Ispezione materiali fragili del 12.4.2021. in merito ai metalli degli impianti, es. taglierine, giornalmente sono effettuati controlli preoperativi in merito alla relativa integrità, vista registrazione Scheda rintracciabilità materie prime del 22.03.2021, Bruschette olive verdi Conad, confezione da 150 gr, L 21082) con indicazione dei controlli preoperativi e Scheda Controlli di confezionamento del 23.03.2021, Bruschette olive verdi Conad, confezione da 150 gr, L 21082, controlli preoperativi: pulizie attrezzi ed impianti, integrità bandelle. Mensilmente, inoltre, vengono effettuate ispezioni su strutture, servizi e spogliatoi, locali di lavorazione ed impianti, visti report del 10.5.2021, 03.05.2021

4.9.3 Glass, brittle plastic, ceramics and similar materials

E' presente un elenco con indicazione di vetri e plastiche dure riportato in Check List Ispezione materiali fragili. Trimestralmente sono effettuate verifiche di presenza/integrità, vista registrazione Check List Ispezione materiali fragili del 12.4.2021. in merito a finestre, lampade e lucernari, gli stessi sono indicati nel report ispezione mensile, visti report 10.5.2021, 16.4.2021. In caso di rottura, in LG6 Rev. 6 del 16.7.2019 sono definite le procedure da seguire, prevista la registrazione delle NC. Non sono presenti imballaggi in vetro o plastica dura. Le lampade sono antirottura

4.9.4 Products packed into glass or other brittle containers

There are no packages made of fragile material.

4.9.5 Wood

Non presente legno in produzione, presenti pallet per il prodotto finito, controllati per verifica integrità all'arrivo secondo la procedura aziendale

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4.9.6 Other physical contaminants

In uso nelle linee di produzione e confezionamento penne rilevabili al MD. Le materie prime (farine, oli) sono consegnate sfuse. I prodotti confezionati sono disimballati mediante strappo o aperture con cordoncino

4.10 Foreign-body detection and removal equipment

4.10.1 Selection and operation of foreign-body detection and removal equipment

Il controllo dei corpi estranei è garantito da: un setaccio per la farina dei silos e filtri a rete da 0,5 cm, setaccio 2x2cm per il sale e gli altri ingredienti. Presente un filtro SS con maglia di 1 mm ai serbatoi di olio. Sulle linee di confezionamento sono installati 3 MD, dotati di tester di controllo da 2,5 mm Fe-2,5 mm N Fe e 2,5 mm SS. I sistemi di controllo si basano sulla verifica dell'integrità di macchine e infrastrutture ogni settimana (Ispezioni interne: settimanale, visti report del 10.5.2021, 03.05.2021). in relazione al MD, si effettuano controlli giornalieri e mensili. Nel caso di non funzionamento strumenti di rimozione corpi estranei si applicano le AC definite in IO HACCP 8 rev. .0 del 1.9.2020. Le confezioni espulse dal MD sono ispezionate dal responsabile Confezionamento. Niente magneti, niente selezionatrici ottiche

4.10.2 Filters and sieves

Presenti setaccio per la farina dei silos e filtri a rete da 0,5 cm, setaccio 2x2cm per il sale e gli altri ingredienti. Presente un filtro SS con maglia di 1 mm ai serbatoi di olio. I sistemi di controllo si basano sulla verifica dell'integrità di macchine e infrastrutture ogni settimana (Ispezioni interne: settimanale, visti report del 10.5.2021, 03.05.2021).

4.10.3 Metal detectors and X-ray equipment

Sulle linee di confezionamento sono installati 3 MD, dotati di tester di controllo da 2,5 mm Fe-2,5 mm N Fe e 2,5 mm SS (anche imballi in alluminio). I sistemi di controllo si basano sulla verifica giornaliera in fase di confezionamento, inizio e fine della produzione e ogni due ore (Rif. Scheda Controlli di confezionamento del 23.03.2021, Bruschette olive verdi Conad, confezione da 150 gr, L 21082) e verifica di funzionamento mensile (report verifica MD del 22.04.2021). il sistema va in blocco in caso di rilevazione metalli. Le confezioni scartate vengono analizzate da RQ e gli esiti registrati. Il personale è stato formato. Non ci sono raggi X né smistatori ottici.

4.10.4 Magnets

There are no magnets

4.10.5 Optical sorting equipment

There are no devices for optical sorting.

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

There are no rigid containers.

4.11 Housekeeping and hygiene

Le pulizie vengono effettuate secondo quanto definito nell'istruzione operativa MOD PRP 1.1 rev.6 del 15/08/20 cui sono allegate istruzioni specifiche per ogni tipo di impianto ed area: area stoccaggio materie prime, silos inclusi, area produzione, confezionamento, magazzino, impianti e macchine – anche in corrispondenza delle varie fasi del processo, ecc..) con indicazione di frequenza (settimanale per tutti gli impianti), metodi (ausiliari chimici, tempi di contatto, istruzioni per l'attività), responsabilità per la pulizia e

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per verifica. Le pulizie vengono effettuate da personale interno, che effettua quotidianamente pulizie generali meccaniche e abbattimento polveri nei bagni, rimozione sfridi dai locali di utilizzo della semola; altre pulizie fondamentali vengono effettuate nel fine settimana. Vista registrazione pulizie settimanale del 7.5.2021, con monitoraggio effettuato da RQ. A cadenza mensile è effettuato anche un monitoraggio interno mediante Igiestest basato sulla rilevazione di proteine, vista registrazione del 19.4.2021, effettuato sul tavolo area impasti. Verifica efficacia effettuata mediante tampone RdP 1199/L\_AMB/20 del 28.12.2020, FOOD SAFETY LAB, su attrezzature nastro Minipan, con rilevazione di microrganismi a 30°C, Bacillus cereus, Listeria, coliformi fecali, Stafilococcus spp, lieviti e muffe. Valori compatibili con i limiti definiti nel Piano di analisi del 14.1.2021

**4.11.7 Cleaning in place (CIP)**

There isn't a CIP.

**4.11.8 Environmental monitoring**

Il piano di monitoraggio ambientale è definito nel Piano dei controlli analitici HACCP 6.1 Rev. 0 del 10.9.2020. Effettuati 6 controlli semestrali su attrezzature di produzione dopo la pulizia finalizzati alla ricerca di: carica microbica totale, Bacillus cereus, Listeria, Stafilococcus spp, muffe per superfici di contatto. I limiti sono definiti nello stesso piano di campionamento. Visto RdP 1199/L\_AMB/20 del 28.12.2020, FOOD SAFETY LAB, su attrezzature nastro Minipan, con rilevazione di microrganismi a 30°C, Bacillus cereus, Listeria, coliformi fecali, Stafilococcus spp, lieviti e muffe. Risultati conformi ai limiti (TBA <100 UFC / cm2, Bacillus cereus <100 UFC / cm2, Coliformi 0, muffe e lieviti <10UFC / cm2 ecc.)

**4.12 Waste**

I rifiuti prodotti sono scarti di imballaggio conferiti all'azienda G.M. Service Import export, come da contratto del 2.5.2018, tacitamente rinnovato. I materiali di scarto sono raccolti in specifici contenitori. Non sono stati riscontrati accumuli di rifiuti. Relativamente ai prodotti a marchio non vi è surplus perché gli imballaggi sono forniti dal cliente e ad esso restituiti eventualmente, né è effettuata distribuzione interna dei prodotti a marchio del cliente agli operatori.

**4.13 Management of surplus food and products for animal feed**

Non è effettuata distribuzione interna agli operatori dei prodotti a marchio del cliente. Alcuni prodotti ancora idonei al consumo umano vengono dati in beneficenza, ovvero alla Parrocchia SS Immacolata Palombaio, oppure all'ASD Oroverde, ma solo prodotti a marchio proprio. Vista registrazione Reg CE 183/2005 del 29.07.16.

**4.14 Pest management**

Gestione infestanti Pest management, PRP 1 rev. 6 del 15.8.2020. Il Responsabile interno è il RQ. Verificato il contratto stipulato con Natura ambiente il 1.9.2020, previsti 12 interventi annui di: derattizzazione, deblatizzazione, monitoraggio insetti, manutenzione lampade. Previsti inoltre 3 interventi di fumigazione e 1 intervento di disinfestazione. Vista mappa aggiornata al 24.6.2020. Sono installate: all'esterno 21 trappole con esche derattizzanti esterne (Il prodotto utilizzato è Difenacoum, Rattofene pasta, visto TS Rev.01 / 2009.), all'interno: 13 trappole a cattura multipla (ratti e striscianti), 10 lampade UV, 5 trappole Anobodi,, 3 trappole Tribolium e 5 trappole lepidotteri. La valutazione dei limiti di tolleranza – cui corrispondono azioni specifiche da intraprendere - è effettuata direttamente durante il monitoraggio,

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e prevede la comparazione fra entità rilevazione (probabilità) e localizzazione del punto di monitoraggio (gravità). Vista registrazione del 29.4.2021, e doppia firma dei rapporti. Non si sono verificate infestazioni nell'ultimo anno. Il personale coinvolto è formato e competente (sono stati visionati CV e attestati del corso di formazione, es. entomologo Nicassio Francesco). Finora non è stato intrapreso alcun intervento di emergenza per i parassiti. Vista relazione annuale, del Dott. Nicassio del 5.2.2021, effettuate ispezioni interne: settimanali, visti report del 10.5.2021, 03.05.2021. La formazione del personale interno è svolta per quanto riguarda le osservazioni e la prevenzione; per es. le porte devono essere mantenute adeguatamente chiuse.

**4.15 Storage facilities**

L'organizzazione effettua lo stoccaggio interno degli imballaggi secondari e primari in aree delimitate. La gestione degli imballaggi segue il metodo FIFO, le bobine IP sono stoccate separatamente. Le farine sono stoccate in silos o sacchi, mentre gli oli vegetali nei serbatoi, a temperatura ambiente, le registrazioni in essere e il plc di gestione carichi permettono di gestire separatamente prodotti IP. Il prodotto finito è conservato a temperatura ambiente, le scorte sono limitate in quanto si lavora su ordini acquisiti. Lieviti e spezie a base di formaggio sono stoccati a temperatura controllata, 0-4°C. Questo sistema non è collegato ad un allarme, ma ogni giorno l'operatore verifica la temperatura interna utilizzando un altro termometro e registra i risultati su MOD PRP 5.2 Rev. 1 del 16.12.2015. Verificate le registrazioni della temperatura di conservazione della cella della materia prima (per lievito e formaggio) in data 11.5.2021. Non previsto controllo temperatura prodotto finito né atm. Il prodotto può essere stoccato presso la sede di Palombaio, non sono presenti altri depositi esterni

**4.16 Dispatch and transport**

Il trasporto dei prodotti finiti viene generalmente effettuato dal cliente. I trasporti dei prodotti finiti vengono effettuati a temperatura ambiente. Il carico dei prodotti viene effettuato mediante rampe di carico coperte e sistemi con chiusura verso l'esterno. Prima della partenza, il magazziniere effettua un controllo pulizia automezzi registrato, vista registrazione su Scheda carico prodotto da forno, Vista registrazione del 26.3.2021, prodotto Bruschettine alle olive con olio di oliva e olive verdi Conad. Il prodotto può essere trasferito al sito Palombaio se l'ordine riguarda anche altri prodotti.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.8.8	No catering services on site.
4.9.4.1	No brittle plastic containers
4.9.4.2	No brittle plastic containers
4.9.4.3	Non vi sono confezioni in materiale fragile.

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4.10.4.1	No magnets
4.10.5.1	No optical sorting
4.10.6.1	There are no rigid containers.
4.10.6.2	There are no rigid containers.
4.11.7.1	There isn't a CIP
4.11.7.2	There isn't a CIP
4.11.7.3	There isn't a CIP
4.14.3	
4.15.4	No MAP storage
4.15.5	No external storage
4.16.3	Contol temperature during delivery is not an issue.

## 5. Product control

### 5.1 Product design/development

Presente Procedura PRG 18 Rev. 5 del 31/05/2017 che descrive le attività di progettazione e sviluppo. I dati sono riportati su schede progetto, vista Scheda progetto del 14.1.2021, nuovi incarti prodotti da forno, destinazione USA bruschette tradizionali, prima produzione effettuata il 21.4.2021, lotto prodotto 21129. Approvazione incarto e dati etichettatura del 8.2.2021. Progetto Scrocchia lunga, modifica parametri fisici (spessore e lunghezza sfoglie), Scheda progetto del 6.4.2021, effettuato test di produzione in data 7.4.2021, lotto 21129, i dati di shelf life non sono modificati. TMC definito a12 mesi data fine mese, effettuata una verifica annuale shelf life visto RdP 198/LAB/21 del 21.1.2021, Taralli MPK CONAD, lotto 20092, fine vita 28.12.2020, rilevati perossidi, acidi grassi liberi e sensoriale, esito conforme, FOOD SAFETY LAB, Accredia n. 0975L.

### 5.2 Product labelling

Il processo di sviluppo di una nuova confezione o etichetta prevede che bozza sia approvata dall'ufficio qualità e dalla direzione, anche nel caso in cui la stessa sia progettata inizialmente dal cliente. La

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validazione legale delle etichette è effettuata e registrata sulla Scheda etichetta/Check list, nella quale, oltre le caratteristiche specifiche dei prodotti, sono rendicontate e validate le informazioni da riportare in etichetta anche in relazione ai requisiti lgs; tale elenco è condiviso con tutti gli stabilimenti ed aggiornato ad aprile 2021. Viste Visto capitolato CONAD del 18.2.2020, prodotto a marchio, con dettagli in merito a informazioni etichetta. Vista approvazione dell'etichetta del 5.3.2021, secchiello da 3 kg, prodotto tarallo tradizionale marchio Don Peppino. I valori nutrizionali sono definiti sulla base delle analisi effettuate a cadenza annuale, laboratorio Merieux, ACCREDIA 0051L, RdP del 6.8.2020, bruschette olive verdi CONAD L 20185. Conformità con etichetta. In uso marchio Vegan OK, agricoltura biologica, semola di Puglia, vista Scheda tecnica semola di grano duro Puglia, fornitore Casillo, del 1.2021

### 5.3 Management of allergens

Procedura HA Gestione degli allergeni Rev. 2 del 2.5.2019. Gli allergeni presenti nel sito sono glutine, latte (spezie al formaggio), sesamo e solfiti, soia (può essere presente nella farina e nella semola). Sulle confezioni vengono pertanto inserite le diciture glutine, latte (spezie al formaggio), sesamo, soia (può essere presente nella farina e nella semola), non è inserita la voce solfiti in quanto la valutazione del rischio e le analisi effettuate in passato (10/09/2019, taralli Conad Lotto 19235 con <10ppm) hanno evidenziato l'assenza. Il formaggio grattugiato è fornito da un'azienda che non utilizza Grana padano o altri formaggi con lisozima, pertanto non presente uovo.

### 5.4 Product authenticity, claims and chain of custody

Sono stati definiti alcuni siti Web in cui trovare informazioni sulle frodi alimentari. La valutazione del rischio delle materie prime è nel Mod PRG 5.7 HASVP Rev.0 aggiornato al 30.06.2020, le materie prime sono state abbinate ai fornitori e valutate per tutti i rischi: l'analisi del rischio di frode alimentare è stata basata su Gravità e Probabilità con un tasso da 1 a 5; la valutazione finale è classificata in 4 livelli: verde (1-4), giallo (5-9), arancione (10-12) e rosso (13-25). Le misure definite sono: giallo: certificazione e analisi delle materie prime, arancione: audit di seconda parte, rosso: audit annuale e analisi delle materie prime. Le materie prime sensibili sono rappresentate da prodotti biologici, la semola di grano duro da grani italiani. Il piano di mitigazione si compone di diverse misure: 1) audit fornitori, se non certificati, 2) analisi per materie prime biologiche (RdP 2897/LAB/20 del 25/6/2020, bruschette tradizionali marchio Alessi, Lotto 20149 biologico, tutti i valori <0,005 ppm), 3) ricontrolla nel database SIAN per cercare il certificato del fornitore. I materiali IP sono diversi come materie prime biologiche, semola di grano duro, vino, oliva evo. I prodotti a IP sono identificati e tracciati, in tutte le fasi del processo

### 5.5 Product packaging

I materiali di confezionamento primario sono costituiti da film di PP o cestelli in PP. Imballo secondario cartoni, dotati di dichiarazione di conformità all'uso. Sono utilizzati seguendo il metodo FIFO. Verificati in audit i seguenti imballaggi: bobina in polipropilene tarallini CONAD, fornitore Bioplast, Scheda tecnica del 11.3.2021, Dichiarazione di conformità del 18.1.2021, con indicazione di simulante D2; Dichiarazione di assenza ftalati, Bisfenolo A, Perfluorinati del 24.2.2021. Secchiello in polipropilene Superfos, Scheda tecnica del 7.4.2017, Dichiarazione di conformità del 27.4.2015

### 5.6 Product inspection and laboratory testing

#### 5.6.1 Product inspection and testing

Visto Piano di analisi del 14.1.2021, con piano di campionamento su MP, PF, acqua, imballaggi e tamponi ambientali. Previste le seguenti analisi: materia prima: farina microbiologiche, filth test, micotossine e fitofarmaci 3 volte all'anno; chimico fisico e metalli pesanti 2 volte all'anno, con piano di rotazione per fornitori. Olio EVO, acidità, perossidi e spettrofotometria 1 volta/anno, metalli pesanti e multiresiduali 1

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ogni 2 anni; Spezie, 3 volte all'anno microbiologia (CBT, coliformi, E. coli, Salmonella, muffe e lieviti) filth test, fitofarmaci e metalli pesanti); prodotti finiti: mensilmente si effettua un'analisi microbiologica-chimica-fisica, 4 volte/anno filth test, 2 volte/anno micotossine, metalli pesanti e fitofarmaci, 1 volta/anno allergeni (soia). Verificati in audit: RdP 1928/LAB/21 del 14.4.2021 FOOD SAFETY LAB, prodotto Taralli MPK CONAD, lotto 21097; RdP 200/LAB/21 del 20.1.2021 farina di grano tenero, fornitore Casillo, lotto 879005. RdP 5846/LAB/20 del 24.11.2020, prodotto rosmarino Lotto RBT20340, fornitore SIDEA. Tutti i risultati sono conformi. Sono effettuati test di shelf life, con frequenza annuale: visto RdP 198/LAB/21 del 21.1.2021, Taralli MPK CONAD, lotto 20092, fine vita 28.12.2020, rilevati perossidi, acidi grassi liberi e sensoriale, esito conforme. Tutte le analisi sono state effettuate da FOOD SAFETY LAB, Accredia n. 0975L. Effettuate analisi nutrizionali, laboratorio Merieux, ACCREDIA 0051L, del 6.8.2020, bruschette olive verdi CONAD L 20185. Conformità con etichetta.

### 5.6.2 Laboratory testing

L'analisi interna è l'umidità che è l'unico test effettuato in laboratorio. Vista validazione analisi mediante confronto valore con analisi effettuata presso laboratorio esterno. L'analisi di umidità effettuata ad ogni fine cottura permette di gestire il processo di cottura, come da registrazione su Scheda produzione del 25.1.2021, umidità pari a 2.40 UR%, Visto Rdp 197/LAB/21 del 22.1.2021 con 2,2% UR%. Ogni anno viene effettuata la taratura della termobilancia, visto rapporto di taratura n ° 2470619 del 28/06 /2020di Metrologica

### 5.7 Product release

Il Responsabile Qualità o il CQ sono autorizzati al rilascio del prodotto, secondo quanto stabilito nella PRP 07 Rev 0 del 2.8.2020, ad esito positivo ei controlli eseguiti in produzione e in confezionamento (idoneità delle registrazioni, assenza di anomalie, valori fisici e chimici riscontrati, conformità legale e conformità del prodotto finito alla specifica), Elenco prodotti finiti a magazzino, vosta registrazione del 10.5.2021 lotto 21130 bruschette al rosmarino Vegè. Lo sblocco è registrato anche sul gestionale Wingest, visto sblocco prodotto stesso lotto del 10.5.2021

### 5.8 Pet Food

No pet foods are in place.

### Details of non-applicable clauses with justification

Clause/Section Ref	Justification
5.2.5	No cooking instructions on label.
5.8	No pet foods are in place.
5.8.1	No pet foods are in place.
5.8.2	No pet foods are in place.

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5.8.3	No pet foods are in place.
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## 6. Process control

### 6.1 Control of operations

L'azienda ha definito i controlli da effettuare PRP 3, rev. 1 del 30.4.2019 – per la produzione e PRP 4 Rev. 4 del 1.5.2018, controlli al confezionamento, in cui sono definiti i controlli preoperativi e di processi: Vista Scheda rintracciabilità materie prime (Scheda rintracciabilità materie prime del 22.03.2021, Bruschette olive verdi Conad, confezione da 150 gr, L 21082) registrazione di controlli caratteristiche impasti (temperatura acqua, ambiente, impasto, Wh, Wh/kg), peso crudo, tempo di stagionatura, peso, lunghezza, larghezza e altezza cotto, umidità prodotto finito, peso pre e post speziatura, e specifiche di produzione: lievitazione, cottura, tostatura (temperatura, tempo, e controllo visivo andamento); in merito alla lievitazione si rileva anche l'umidità. Scheda Controlli di confezionamento del 23.03.2021, controlli preoperativi: pulizie attrezzi ed impianti, integrità bandelle; controlli di confezionamento ermeticità confezione, etichettatura, Valore nominale, Espulsione bilancia in linea, prova MD; questi controlli sono effettuati ad avvio e fine produzione e ripetuti ogni 2 ore. Sono presenti allarmi automatici per blocco forno, aspirazione aria per essiccatoi e per nebulizzazione olio. I parametri di processo sono definiti nello stesso pannello di controllo dei processi; questi valori sono protetti da password. L'analisi di umidità effettuata ad ogni fine cottura permette di gestire il processo di cottura, come da registrazione su Scheda produzione del 25.1.2021, umidità pari a 2.40 UR

6.1.1 La Scheda rintracciabilità materie prime, registrazione del 10.5.2021, non riportava al momento dell'audit la registrazione dell'esito dei controlli preoperativi effettuati; l'ispezione condotta ha permesso di appurare che gli stessi erano stati effettuati con esito positivo

### 6.2 Labelling and pack control

In prossimità della linea di confezionamento sono presenti solo le bobine in uso o quelle avanzate che vengono prontamente rimosse dalla zona. Il controllo della confezione (lotto, etichetta, leggibilità) viene effettuato dall'operatore ogni 2 ore, ora di inizio e fine e registrato sulle Schede di confezionamento, visti controlli di confezionamento del 23.03.2021, Bruschette olive verdi Conad, confezione da 150 gr, L 21082. Nessun lettore visivo o ottico è in linea

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

Il confezionamento del prodotto tramite confezionatrici ponderali collegate a pc e controllo peso a fine linea automatizzato, con impostazione valori T1 e T2 di L 690/78. A fine confezionamento è possibile scaricare la registrazione delle pesate/calcolo media (Vista registrazione del 10.5.2021, h 11.58). Ad avvio linea viene effettuato il settaggio delle confezionatrici mediante passaggio attraverso il controllo peso di un peso campione da 500 gr e si verifica ad avvio impianto ed ogni due ore l'espulsione sottopesi. L'effettuazione dei controlli funzionamento impianti viene riportata sulla Scheda confezionamento, vista registrazione del 23.03.2021 e del 10.5.2021. La registrazione del peso delle confezioni è visualizzabile sul display del pc durante lo svolgimento delle attività ed è stampabile.

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6.4 Calibration and control of measuring and monitoring devices

La procedura di calibrazione è in IO Q8.2 rev.3 del 21/03/2018. L'elenco dei dispositivi (selezionatrici ponderali, bilance, MD, Termometri, data logger) è in MOD IOQ8.21 nel file excel. Tutte le tarature sono affidate a società di servizi esterne. L'unico dispositivo calibrato internamente è un datalogger con foglio di registrazione MOD IOQ 8.22 Rev. 02 ultima calibrazione 25.03.2019 con un altro datalogger calibrato (quello del Palombaio), la frequenza di calibrazione (utilizzo discontinuo) è ogni 2 anni. Bilancia Laumas modello TLB PROF1, rapporto di calibrazione del 17.07.2020 da parte di Metrologica. Verificata taratura Selezionatrice ponderale, Visto Rapporto di ispezione selezionatrice ponderale effettuato da CVP Accredia 165E del 17.2.2021, frequenza annuale; Vista taratura metal detector a cura di Almatecno il 01.07.2020 per MD modello PRN 05 S/N 719503

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
6.2.4	There is no viewer such as an optical scanner for checking online labeling.
6.3.2	Only product sold with check of weight

7. Personnel

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

La procedura di formazione è PRG 16 rev.4, emessa il 18/08/2018. Argomenti e frequenza (annuale) della formazione: definiti nel Programma di addestramento del 28.12.2020, per anno 2021. I lavoratori hanno frequentato il corso per alimentaristi, visto attestato B.M., del 2.7.2018, valido fino a settembre 2022, tenuto da RQ ed organizzato dall'azienda. Visto il rapporto di formazione sugli allergeni, monitoraggio CCP, tracciabilità, ordine e igiene del personale, procedura di pulizia, difesa alimentare, etichettatura e controllo del confezionamento, allergeni del 28.9.2020, tenuto da RQ del gruppo e RQ del sito di Palo a tutti gli operatori, durata 6 ore, verifica dell'efficacia mediante test orali e colloqui, registrazione dell'esito sul Rapporto di addestramento. Vista formazione effettuata in data 14.5.2020 in tema food defence e formazione del 11.1.2021 agli operatori del confezionamento, argomenti Registre e controlli in confezionamento, inclusi PRP e CCP MD.

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

Le norme igieniche HACCP sono definite nel MOD BPL 1 rev.00 del 02/05/2019 ed Allegato 11 HACCP, con regole chiare al personale (obbligo di lavarsi le mani indossando tutti i DPI, comportamenti scorretti da evitare); questo dottore è impiccato negli spogliatoi. Il controllo delle regole viene effettuato mensilmente con prove evidenti. I controlli effettuati sono supportati da checklist di conformità igienica e ispezioni per indumenti, mani e rispetto delle norme igieniche adeguate, vista verifica comportamento igienico/ispezione del 19.1.2021. I cerotti blu sono disponibili per i lavoratori e vengono testati su MD ogni mese nella scheda Verifica Metal detector, MOD PRP-4.2 rev. 4, ultimi monitoraggi effettuati in data 22.4.2021. Verificare le regole comportamentali per fronteggiare l'emergenza Covid-19 indicate nel documento emesso il

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16.03.2020 e affisso negli spogliatoi e negli uffici. Disponibile un modulo di autodichiarazione covid-19 che è compilato da tutti gli esterni e gli interni

**7.3 Medical screening**

Viene assegnata la dottoressa competente Ilaria Tatò che effettua analisi periodiche, previa sottoscrizione. I visitatori devono leggere e firmare il registro visitatori MOD PR 0.1 rev.4 con un rapido questionario. Vengono definite le istruzioni in caso di malattia o problemi di salute. Inoltre, è richiesta agli esterni di compilare un questionario incentrato sulla gestione emergenza covid-19. Visto Registro visitatori del 23.2.2021, Sig. P.C, operatore della derattizzazione.

**7.4 Protective clothing: employees or visitors to production areas**

L'abbigliamento da lavoro generale è composto da: pantaloni (2x), maglietta (5x), scarpe, felpa (2x); retina per capelli, guanti e maschere (usate come copri barba) sono a disposizione. Questi strumenti sono bianchi, ma gli addetti alla manutenzione e al magazzino sono blu. I visitatori hanno a disposizione camice usa e getta, cuffia per capelli e copriscarpe. Viene eseguita un'ispezione visiva dell'igiene degli indumenti da lavoro. Il test del tampone non viene eseguito. Nell'allegato al MOD BPL 1 rev.00 del 02/05/2019 MOD PRP 1.1 rev. 3 23/008/20 sono definite le regole per lavare in casa l'abbigliamento da lavoro, con indicazione di utilizzo di antibatterico con ciclo a 60°C

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

Clause/Section Ref	Justification

<b>Template control</b>	Food	<b>Version</b>	1.0
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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
No HR HC or AHC are set on site.
8.2 Building fabric in high-risk and high-care zones
No HR HC or AHC are set on site.
8.3 Maintenance in high-risk and high-care zones
No HR HC or AHC are set on site.
8.4 Staff facilities for high-risk and high-care zones
No HR HC or AHC are set on site.
8.5 Housekeeping and hygiene in the high-risk high-care zones
No HR HC or AHC are set on site.
8.6 Waste/Waste disposal in high risk, high care zones
No HR HC or AHC are set on site.
8.7 Protective clothing in the high-risk high-care zones
No HR HC or AHC are set on site.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

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*Claudio Innocenti*

8.1	No HR HC or AHC are set on site.
8.1.1	No HR HC or AHC are set on site.
8.1.2	No HR HC or AHC are set on site.
8.1.3	No HR HC or AHC are set on site.
8.1.4	No HR HC or AHC are set on site.
8.2.1	No HR HC or AHC are set on site.
8.2.2	No HR HC or AHC are set on site.
8.3.1	No HR HC or AHC are set on site.
8.3.2	No HR HC or AHC are set on site.
8.3.3	No HR HC or AHC are set on site.
8.4.1	No HR HC or AHC are set on site.
8.5.1	No HR HC or AHC are set on site.
8.5.2	No HR HC or AHC are set on site.
8.5.3	No HR HC or AHC are set on site.
8.6.1	No HR HC or AHC are set on site.
8.7.1	No HR HC or AHC are set on site.
8.7.2	No HR HC or AHC are set on site.
8.7.3	No HR HC or AHC are set on site.

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## 9 - Traded Products

### 9.1 Approval and performance monitoring of manufacturers/packers of traded food products

No traded goods are on the site.

### 9.2 Specifications

No traded goods are on the site.

### 9.3 Product inspection and laboratory testing

No traded goods are on the site.

### 9.4 Product legality

No traded goods are on the site.

### 9.5 Traceability

No traded goods are on the site.

## Module 11: Meat supply chain assurance

Scope

### 11.1 Traceability

Click or tap here to enter text.

### 11.2 Approval of meat supply chain

Click or tap here to enter text.

### 11.3 Raw material receipt and inspection

Click or tap here to enter text.

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**11.4 Management of cross-contamination between species**

Click or tap here to enter text.

**11.5 Product testing**

Click or tap here to enter text.

**11.6 Training**

Click or tap here to enter text.

**Module 12: AO ECS Gluten-free Foods**

**Scope** Click or tap here to enter text.

**12.1 Senior management**

Click or tap here to enter text.

**12.2 Management of suppliers of raw materials and packaging**

Click or tap here to enter text.

**12.3 Outsourced production**

Click or tap here to enter text.

**12.4 Specifications**

Click or tap here to enter text.

**12.5 Management of gluten cross-contamination**

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Click or tap here to enter text.

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

Click or tap here to enter text.

**12.7 Labelling**

Click or tap here to enter text.

**12.8 Product inspection and laboratory testing**

Click or tap here to enter text.

**Module 13 FSMA Preventive Controls Preparedness Module**

Version 2 July 2018

Clause	Module item	Conforms Y/N	Comments
13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant.		

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	Seams on food-contact surfaces must be 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.		
13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible.  Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: <ul style="list-style-type: none"> <li>• Economic adulterants which affect food safety</li> <li>• Environmental pathogens where ready-to-eat (RTE) food is</li> </ul>		

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	<p>exposed to the environment prior to packaging and the packaged food does not receive a kill step</p> <ul style="list-style-type: none"> <li>• Radiological hazards</li> <li>• Unintentional adulterants which affect food safety</li> </ul>		
13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine “hazards requiring a preventive control” (i.e., significant hazards).		
13.1.8	Establish one or more preventive control(s) for each identified “hazard requiring a preventive control” (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures		

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	<p>and responsibility for the following:</p> <ul style="list-style-type: none"> <li>• Notifying consignees of how to return or dispose of recalled product</li> <li>• Conducting effectiveness checks to verify recall is carried out</li> <li>• Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product</li> </ul>		
13.1.10	<p>Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.</p>		
13.1.11	<p>Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRC sections 2.11 and 3.7.</p> <p>Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).</p>		

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13.1.12	<p>Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production.</p> <p>Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.</p>		
13.1.13	<p>The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification.</p> <p>The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.</p>		
13.1.14	<p>Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following:</p> <ul style="list-style-type: none"> <li>• Sampling procedure to include method, quantity, frequency, and</li> </ul>		

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	<p>number of samples</p> <ul style="list-style-type: none"> <li>Analytical method</li> <li>Laboratory conducting analysis</li> <li>Corrective action procedure where pathogen is detected</li> </ul>		
13.1.15	<p>Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following:</p> <ul style="list-style-type: none"> <li>Adequate number and location of sample sites</li> <li>Timing and frequency of sampling</li> <li>Analytical method</li> <li>Laboratory conducting analysis</li> <li>Corrective action procedure where pathogen is detected</li> </ul>		
13.1.16	<p>Devices used to verify preventive controls must be calibrated.</p>		
13.1.17	<p>Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food</p>		

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	<p>safety plan, validating preventing controls, review of records, and reanalysis of the plan.</p> <p>Document the PCQI's training and qualification via job experience.</p>		
13.1.18	<p>All records required by 21 CFR § 117 must include:</p> <ul style="list-style-type: none"> <li>• Date and time of activity being documented</li> <li>• Signature/ initials of individual performing activity or conducting record review</li> <li>• Information to identify the facility (e.g., name and location)</li> <li>• Identity of the product and lot code where applicable</li> </ul>		
13.1.19	<p>The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.</p>		
13.1.20	<p>All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they</p>		

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	must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		
13.1.21	<p>Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities.</p> <p>Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.</p>		
13.1.22	<p>Supplier approval must be documented before receiving and using raw materials and ingredients.</p> <p>Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.</p>		
13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter		

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	at an adequate frequency.		
13.2.1	<p>Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:</p> <ul style="list-style-type: none"> <li>- During holding, human food by-products for use as animal food must be accurately identified.</li> <li>* Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.</li> <li>* Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.</li> </ul>		

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13.3.1	<p>A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart.</p> <p>One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.</p>		
13.3.2	<p>The site shall have a written food defense plan, which includes the following:</p> <ul style="list-style-type: none"> <li>• A vulnerability assessment identifying significant vulnerabilities and actionable process steps</li> <li>• Mitigation strategies appropriate to reduce the vulnerability</li> <li>• Procedures for food defense monitoring, corrective action and verification</li> </ul>		
13.3.3	<p>A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates</p>		

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	<p>the following key criteria (at a minimum):</p> <ul style="list-style-type: none"> <li>• Scale and severity of threat if a contaminant is added to product</li> <li>• Degree of physical access to the product</li> <li>• Ability of an attacker to successfully contaminate product— including consideration of an inside attacker</li> </ul> <p>A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.</p>		
13.3.4	<p>Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment.</p> <p>Justification shall be documented explaining how the strategy</p>		

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	significantly minimizes or prevents the vulnerability.		
13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies.  Procedures shall include recordkeeping requirements for all monitoring activities.		
13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: <ul style="list-style-type: none"> <li>• Method for identifying and correcting a lack of implementation</li> <li>• Method for reducing the likelihood of recurrence</li> <li>• Recordkeeping requirements for corrective actions</li> </ul>		
13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to		

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	<p>verify implementation of mitigation strategies.</p> <p>Verification procedures shall include:</p> <ul style="list-style-type: none"> <li>• A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days)</li> <li>• Other verification activities as appropriate (e.g., internal audit)</li> <li>• Method for verifying that reanalysis of the food defense plan was conducted</li> <li>• Frequency for verification activities</li> <li>• Recordkeeping requirements of all verification activities</li> </ul>		
13.3.8	<p>Reanalysis of the food defense plan shall be documented and performed every three years or whenever</p> <ul style="list-style-type: none"> <li>• A change in facility operations which creates a new significant vulnerability</li> <li>• Knowledge about a new threat applicable to the food or facility</li> </ul>		

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	<p>becomes known</p> <ul style="list-style-type: none"> <li>• Mitigation strategies are not implemented as intended</li> <li>• FDA requires reanalysis based on new threats or scientific evidence</li> </ul>		
13.3.9	<p>All records required by 21 CFR § 121 must include:</p> <ul style="list-style-type: none"> <li>• Date and time of activity being documented</li> <li>• Signature/ initials of individual performing activity or conducting record review</li> <li>• Information to identify the facility (e.g., name and location)</li> <li>• Identity of the product and lot code where applicable</li> </ul>		
13.3.10	<p>The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.</p>		
13.3.11	<p>All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be</p>		

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	retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.		
13.4.1	<p>Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used.</p> <p>A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.</p>		
13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as		

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	<p>the shipper or receiver, it shall ensure compliance with the rule.</p> <p>Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.</p>		
13.4.3	<p>Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier.</p> <p>Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.</p>		
13.4.4	<p>Contracts with loaders shall specify that the loader is responsible for following sanitary</p>		

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	specifications provided by shipper.		
13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.		
13.4.6	<p>Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper.</p> <ul style="list-style-type: none"> <li>• Sanitary condition of vehicles and transportation equipment</li> <li>• Following shipper's sanitary specifications (including pre-cooling requirements where applicable)</li> <li>• Recording compliance with operating temperature where critical to food safety</li> <li>• Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper</li> </ul>		
13.4.7	Contracts with carriers shall specify that the carrier implements a		

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	<p>training program for all personnel engaged in transportation activities, which covers</p> <ul style="list-style-type: none"> <li>• Awareness of potential food safety problems that may occur during food transportation</li> <li>• Basic sanitary transportation practices to address those potential problems</li> <li>• Responsibilities of the carrier</li> </ul>		
13.4.8	<p>The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.</p>	NA	
13.4.9	<p>The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.</p>	NA	
13.5.1	<p>Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following:</p>	NA	

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	<ul style="list-style-type: none"> <li>Principles of food hygiene and food safety</li> </ul> <p>Produce safety standards applicable to an individual's job</p>		
13.5.2	<p>Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following:</p> <ul style="list-style-type: none"> <li>Recognizing produce contaminated with known or reasonably foreseeable hazards</li> <li>Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards</li> <li>Correcting problems with harvest containers or equipment</li> </ul>	NA	
13.5.3	<p>One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.</p>	NA	
13.5.4	<p>A supervisor shall be identified with</p>	NA	

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	responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.		
13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.	NA	
13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce.  Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.	NA	

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13.5.7	Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.	NA	
13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.	NA	
13.5.9	Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria.  Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.	NA	
13.5.10	Agricultural water testing may be performed by the site	NA	

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	<p>(or site representative) or by a third party provided representative samples of the site's water source is secured.</p> <p>Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA-821-R-09-007," December, 2009 or equivalent method.</p>		
13.5.11	<p>During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water.</p> <p>Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris).</p> <p>Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize</p>	NA	

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	infiltration of pathogens into produce.		
13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.	NA	
13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.	NA	
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	NA	
13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.	NA	
13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created.  Where records are stored offsite, they must be retrievable within 24 hours.  Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific	NA	

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	studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
13.5.17	<p>Specific additional requirements for the harvesting, packing, and holding of sprouts.</p> <p>Establish and implement a written Environmental Monitoring plan for the testing of <i>Listeria</i> spp or <i>Listeria monocytogenes</i>.</p> <p>The environmental monitoring plan shall include the following criteria:</p> <ul style="list-style-type: none"> <li>• Target test (i.e., <i>Listeria</i> spp. or <i>L. mono</i>)</li> <li>• Sample frequency (no less monthly)</li> <li>• Sample timing (i.e., when in the process are samples collected)</li> <li>• Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces)</li> </ul> <p>The plan shall describe aseptic methods for</p>	NA	

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	<p>sample collection and testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent).</p>		
<p>13.5.18</p>	<p>Specific additional requirements for the harvesting, packing, and holding of sprouts.</p> <p>The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono.</p> <p>If Listeria spp. or L. mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process:</p> <ul style="list-style-type: none"> <li>• Resample positive surfaces and the surrounding area to determine the extent of contamination</li> <li>• Clean and sanitize the affected and surrounding areas</li> <li>• Resample and re-test to confirm the elimination of Listeria spp. or L. mono</li> <li>• Conduct finished</li> </ul>	<p>NA</p>	

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	<p>product testing as appropriate</p> <ul style="list-style-type: none"> <li>• Take additional action to prevent recurrence and to prevent adulterated food from entering commerce</li> </ul>		
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certifies that, having conducted an audit

For the scope of activities: Production (mixing, forming, boiling (possible), rising (possible), baking, toasting (possible) and packaging of dry and/or flavoured bakery products, enveloped in heat-sealed polypropylene bags or in polypropylene buckets and packaged in cardboard boxes or in polypropylene buckets. Produzione (miscelazione, formatura, bollitura (eventuale), lievitazione (eventuale), cottura, tostatura (eventuale) e confezionamento di prodotti da forno secchi, e/o aromatizzati, imbustati in sacchetti di polipropilene termosaldati o in secchielli di polipropilene e confezionati in scatole di cartone o in secchielli in polipropilene.

Including voluntary modules of: None

Exclusions from Scope: None

Product Categories: 14 - Bakery

at

**GR.A.M.M Gruppo Alimentare Mediterraneo Milo srl**

**BRC SITE CODE: 2077210**

SS 96 km 113,200 - 70027 Palo del Colle (BA), ITALY

Has Achieved Grade: A+

meets the requirements set out in the

**BRC Global Standard for Food Safety**

**Issue 8: February 2019**

Audit Programme:	Unannounced
Certificate No.:	BRC 2021-40677
Dates of Audit:	10/05/2021 & 11/05/2021
Certificate Issue date:	05/07/2021
Re-audit due date:	from 10/08/2021 to 17/07/2022
Certificate expiry date:	28/08/2022

Auditor n°:  
21509

For CSQA Certificazioni S.r.l.

The Chief Executive Officer  
Dr. Pietro Bonato



PRD N° 014B

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e IAL

Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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FSVPTAR010101



Customer: GR.AMMSrl  
 SS 96 km 113,200  
 70027 Palo del Colle (BA)

**TEST REPORT n °: 1925 / LAB / 22 of 30/03/2022**

Internal ID assigned by the laboratory: 1925/22      Sample receipt date 25/03/2022      Product: Baked goods  
 Condition and packaging upon arrival: Compliant      Temperature upon arrival: Temperature environment      Quantity: 150g

Laboratory Notes: REF. WITHDRAWAL REPORT N ° B180 / 22

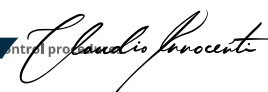
**DATA DECLARED BY THE CUSTOMER:**

Description: Skinny Rosemary  
 L 22080 EXP: 28/03/23  
 Sampling: Sampling carried out by the customer  
 Sampling date: 25/03/2022  
 Transport temperature: Ambient temperature

Test start date: 03/26/2022      End date of tests : 03/29/2022

**ANALYTICAL RESULTS**

Analytical proof	Value	Uncertainty	U.ty of measure	Start date - end of test
Count of microorganisms at 30 ° C Met: AFNOR 3M 01 / 1-09 / 89	<10	--	UFC / g	03/26/2022 - 03/29/2022
Count of Enterobacteriaceae Met: ISO 21528-2: 2017	<10	--	UFC / g	03/26/2022 - 03/27/2022
Enumeration of Escherichia coli beta-glucuronidase positive Met: ISO 16649-2: 2001	<10	--	UFC / g	03/26/2022 - 03/27/2022
Count of sulphite-reducing clostridia and spores * Met: ISO 15213: 2003	<10	--	UFC / g	03/26/2022 - 28/03/2022
Coagulase-positive staphylococci count Met: UNI EN ISO 6888-2: 2004	<10	--	UFC / g	03/26/2022 - 28/03/2022
Count of Bacillus cereus presumed Met: ISO 7932: 2004 / Amd 1: 2020 - excluding Annex C, D, E and F.	<10	--	UFC / g	03/26/2022 - 03/27/2022
Search for Salmonella spp. Met: AFNOR BIO 12 / 32-10 / 11	not detectable	--	not detectable / 25g	03/26/2022 - 28/03/2022
Yeasts Met: AFNOR 3M 01 / 13-07 / 14	Microorganisms present but less than 40	--	UFC / g	03/26/2022 - 03/29/2022

Client: GR.AMMSrl

**TEST REPORT n °: 1925 / LAB / 22 of 30/03/2022**

<b>Molds</b>	<10	--	UFC / g	03/26/2022 - 03/29/2022
Met: AFNOR 3M 01 / 13-07 / 14				

**NOTE**

The analytical results contained in this Test Report refer exclusively to the sample as received by the laboratory which the Customer, under his own responsibility, has declared to correspond to what is indicated in the description. In the case of sampling by the customer, the results refer to the sample as received and the information relating to the sample and sampling have been declared by the customer and the laboratory declines the responsibility.

The value obtained is understood to be already correct for any declared recovery value; the uncertainty, where reported, is to be understood as extended uncertainty calculated using a coverage factor of 2 and therefore with a confidence level of 95%; for microbiological tests the expanded measurement uncertainty is estimated according to ISO 19036 as standard uncertainty multiplied by a coverage factor k = 2 and an approximate confidence level of 95%. The combined standard uncertainty is assumed to be equal to the standard deviation of intra-laboratory reproducibility. Furthermore, according to the provisions of ISO 7218: 2013, if the result is between 4 and 10 cfu / ml or between 0.4 and 1 cfu / cm2 or between 40 and 100 cfu / g, the number of microorganisms indicated in the evidence should be considered "ESTIMATED".

This document may not be reproduced or partially disseminated in any of its parts without the written consent of the laboratory management or the recipient customer. This document relates only to the sample under test. The tested sample will be kept at this Laboratory for 15 days starting from the end of the tests.

Opinions and interpretations - not subject to ACCREDIA accreditation

Legend:  
 LOQ: limit of quantification. Met:  
 test method

(\*): Test not accredited by ACCREDIA

**Laboratory Manager**

*Dr. Viviana Ventura*

Firmato digitalmente da

VNTVVN81T60L109Y/7028000620412232.1Xfqs726MKD4jiWy7z4y  
 mr1t5g=

CN:  
 VNTVVN81T60L109Y/7028000620412232.1Xfqs726MKD4jiWy7z4y  
 mr1t5g=  
 O: INFOCERT SPA  
 OU: Ente Certificatore

END OF TEST REPORT



*Claudio Innocenti*

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**Translated text accurately reflects original message**

Agree  Disagree

Agree – with suggested edits

**Name** *Francesco Garofalo*

**Date** *6/29/22*



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

# CERTIFICATE OF TRAINING

is awarded to

## Francesco Garofalo

in recognition for having successfully completed  
the Food Safety Preventive Controls Alliance course:

### FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Monica Mauriello

completed on

06/23/2017

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



ILLINOIS INSTITUTE OF TECHNOLOGY



INTERNATIONAL  
FOOD PROTECTION  
TRAINING INSTITUTE



Certificate # 87010dd0

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

CONFIDENTIAL TREATMENT REQUESTED

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State of revision				
DATE	Rev	Nature of the modification	ISSUE	
			RGQ.	DG
02/05/2022	10	Integration of recall classes based on legislation USA-FDA		

1. PURPOSE AND SCOPE OF APPLICATION

This Guideline is intended to define the responsibilities and procedures to be adopted for the assessment and assessment of a potential or ascertained food risk and, after appropriate assessment, the possible activation of a Withdrawal / Recall.

This guideline was drawn up on the basis of the procedure issued by the Ministry of Health and on the basis of the criteria defined in the State - Regions Agreement of 11/13/2008 "Guidelines for the operational management of the alert system for food intended for human consumption".

This Guideline also applies to those situations that do not fall directly within the definition of food emergency situations but which in any case require the product to be withdrawn from the market (e.g. non-compliance on the product with regard to qualitative aspects, etc.).

2. DEFINITIONS

Recall: this term means the mandatory procedure to be carried out by the FBO, in accordance with the provisions of art. 19 paragraph 1 "If the product may have reached the consumer, the trader effectively and accurately informs consumers of the reason for the withdrawal and, if necessary, recalls the products already supplied to the consumer, when other measures are not sufficient to achieve a high level of protection of health."

Security Notice: form of communication, different from the reference of the FBO, used by the Ministry of Health containing information based on official sources, disclosed for precautionary purposes and for the protection of public health. The safety notice, in general terms, is issued in the form of a web page and / or a press release.

3. OPERATING MODES

3.1 Assessment of the potential or ascertained food risk

The food risk assessment team, as identified in MOD LG 2.3, carries out an assessment of the case that may arise from a complaint, notification by the authorities, internal feedback (for example following a suspected case of foreign bodies in the food), analytical confirmation (for example positivity to listeria), the "critical situations" as foreseen in the document KAT-Guide to Crisis Management for member establishments, other.

The assessment is performed following the flow chart / diagram defined in MOD LG 2.4A FOOD RISK ASSESSMENT.

The cases in which a serious risk to human health is identified have been divided on the basis of acute or chronic effects according to the following scheme:

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Immediate Effects:when the appearance of serious harmful effects on human health following the ingestion of a contaminated food occurs immediately or after a short period of time or on specific categories of the population, such as allergic subjects, immunosuppressed persons, the elderly, pregnant women ( e.g. food diseases, intoxications, allergies, etc.) as reported in Annex D of the guideline for the operational management of the alert system for food intended for human consumption, approved at the State-Regions Conference on November 13, 2008 letters a), b), f), j):

a) foods containing prohibited substances, in accordance with the provisions of Community provisions or, in their absence, national regulations;

b) foods containing residues of pesticides or metabolites deriving from their degradation for which the predicted short term intake exceeds the acute reference (ARfD) for the substance;

f) foods containing fungi or fungal toxins, bacteria or bacterial toxins, algal toxins, parasites and their metabolites, viruses or prions, which, on the basis of the analytical findings obtained, in the presence of limits set by national or Community standards, based on risk assessment, are capable of inducing the onset of disease in humans with high probability; j)

prepackaged foods containing allergens that are not among the ingredients listed on the label.

Long-term effects:when the intake of a food can lead to probable long-term effects, cumulative toxic effects on the health of the consumer or his descendants, as reported in Annex D of the guideline for the operational management of the alert system for food intended to human consumption, approved at the State-Regions Conference on 13 November 2008 letters c), d), e), g), h), i):

c) foods containing residues of pesticides or their metabolites or products of their degradation for which no acute reference dose has been established, but there is an acceptable daily intake (ADI) and the predicted short term intake dose clearly exceeds the ADI;

d) foods containing teratogenic, genotoxic or carcinogenic substances whose levels found exceed the limits set by Community legislation or, in its absence, by national legislation;

e) foods containing teratogenic, genotoxic or carcinogenic substances for which there are no established limits, but the predicted short term intake (PSTI) exceeds the tolerable daily intake (TDI);

g) foods with a level of Cs-134 and Cs-137 radioactive contamination higher than the limit established by EC regulation no. 737/90, of 22 March 1990 relating to the conditions for importing agricultural products from third countries, following the accident which occurred in the Chernobyl nuclear power plant, as amended by EC regulation no. 616/2000;

h) genetically modified organisms, as defined in art. 3 of EC regulation no. 1829/2003, of the European Parliament and of the Council of 22 September 2003, concerning genetically modified food and feed, with the exception of food referred to in art. 47 of the aforementioned provision;

the) new foods and new food ingredients, as defined in art. 1 of EC regulation no. 258/97 of European Parliament and of the Council, for which it appears that no marketing authorization has already been granted to an operator in the sector or to a company.

Classification of class recalls according to FDA - USA regulations

ENGLISH	ITALIAN
<p>Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.</p> <p>Class I recall:a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.</p> <p>Class II recall:a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.</p> <p>Class III recall:a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.</p> <p>Market withdrawal:occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.</p>	<p>Recalls are actions taken by a company to remove a product from the market. Recalls can be made on the company's initiative, at the request of the FDA, or on the order of the FDA under the law.</p> <p>Class I recall:a situation where there is a reasonable likelihood that use or exposure to a non-compliant product will cause serious adverse health consequences or death.</p> <p>Class II recall:a situation where use or exposure to a non-compliant product may cause temporary or medically reversible adverse health consequences or where the likelihood of serious adverse health consequences is remote.</p> <p>Class III recall:a situation where use or exposure to a violating product is unlikely to cause adverse health consequences.</p> <p>Withdrawal from the market:occurs when a product has a minor infringement that would not be subject to FDA legal action. The company withdraws the product from the market or corrects the infringement. For example, a product withdrawn from the market due to tampering, with no evidence of production or distribution problems, would be a withdrawal from the market.</p>

3.2 Activation and management of the Recall / Withdrawal

If the serious risk is ascertained, it will be necessary to proceed with the management of the withdrawal / recall following the scheme / flow chart defined in MOD LG 2.4B PRODUCT RECALL DIAGRAM.

Furthermore, in the case of acute toxicity risk, in order to ensure more effective information for the potentially interested consumer, the form of communication must also be used which provides for the publication of the recall in the press, ANSA dispatches, radio, TV taking into account the level of distribution reached (local, regional, national, international), and the following communication methods:

- Publication of the warning on your site
- Publication of the recall on social networks

In the case of risk of chronic toxicity, in addition to the recall message by affixing signs at the points of sale concerned, the following communication method must also be used:

- Publication of the warning on the site
- Publication of the recall on social networks

Just in case scientific evaluation is required to ascertain the existence of a serious risk, as listed in the following paragraph, it will be necessary to follow the criteria set out in the EFSA "Risk communication Guidelines" document to determine the level of risk ([http://www.efsa.europa.eu/it/corporate/doc/riskcommguidelines\\_it.pdf](http://www.efsa.europa.eu/it/corporate/doc/riskcommguidelines_it.pdf)).

In the event that, following the aforementioned assessment, the existence of a high risk, the product must then be withdrawn from the market and, as regards the recall, the consumer must be informed by affixing a sign at the points of sale, the publication of the recall on the website, and, depending on the level of distribution (local, regional, national), make press releases, radio, TV. In the event of an unknown risk, as a precaution, and in order to take measures to protect health if the product has gone to the final consumer, the product must be withdrawn from the market and, as regards the recall, proceed with the affixing of signs at the points of sale.

### 3.3 Cases in which a scientific evaluation is necessary to ascertain the presence of a serious risk

#### sanitary:

- 1) Foods containing substances other than those mentioned in letters a), b), c), d), e) above, which exceed the maximum limit set by Community legislation, or, in his absence, from the national one;
- 2) Foods containing substances whose use is not authorized or is contrary to the requirements established for official approval by Community or national legislation;
- 3) Foods that present a risk due to physical agents, such as foreign bodies;
- 4) Foods of animal origin from countries / establishments not included in the Community lists of officially recognized countries / establishments;
- 5) Foods for which the official tests required for the detection of a serious risk have not been well performed or performed incorrectly;
- 6) Dietary foods that do not contain authorized quantities of some ingredients;
- 7) Materials intended to come into contact with food, as defined by art. 1 of EC Reg. 1935/2004, which cannot be used with food or which cause adverse effects through contact;
- 8) Foods that can cause damage to human health, if used according to the indications given on the labeling, or whose presentation methods do not allow the consumer to have the information necessary to avoid specific harmful effects on health;
- 9) Foods not suitable for human consumption because they are deteriorated or contain unsuitable ingredients or for other reasons;

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10) Foods dangerous for a specific population group due to their composition;

11) Any other risk, including emerging risks, which requires an adequate assessment.

### 3.4 Identification of the raw materials / products / materials involved

GR.AMM Srl is responsible for ensuring that all products / materials / raw materials involved in the withdrawal / recall are identified and quantified. All the goods involved must be detailed, indicating, for each reference involved: product name, brand, weight of the sales unit, lot, expiry date.

A distribution list must be prepared that contains the following information:

- Information relating to the product / material / raw material involved: manufacturer / supplier; number and date of the sales document; code, description, lot and expiry date of the product / material / raw material; quantity shipped; quantity still under the control of GR.AMM
- Information relating to the product / material / raw material shipped: recipient name; address; contact information (phone number, email, 24/7 phone number); type of recipient (transformer, distributor, reseller, etc.).

### 3.5 Notification of Withdrawal / Recall

Notification must take place quickly and must concern:

- Competent Italian authorities;
- US authority (if the recalled products were shipped to the US);
- All recipients of the products.
- Consumers (if necessary): the authorities must be consulted before disseminating any warning to consumers in the form of a press message, communication on a website and / or social network.

### 3.6 Management of products / materials / raw materials withdrawn / recalled

All available measures must be taken to remove the recalled / recalled products from the market. All contacts identified in the distribution list must be given precise instructions on how to segregate and manage the products subject to collection / recall: indicate if and which carrier will pass through the collection, indicate the date and time of collection, other information necessary for the correct management of the withdrawal / recall.

The products that are still under the control of GR.AMM Srl must be suitably identified and segregated. There must be a continuous and documented quantification of the products (shipped, collected, segregated at the GR.AMM) in order to be able to make a timely check of any products still in circulation.

The segregation must be done in such a way as to prevent inadvertent use of the product / material / raw material object of the withdrawal / recall. In this regard, proceed as follows:

- From an accounting point of view, the materials / products / raw materials subject to withdrawal / recall must be transferred to a virtual deposit (deposit 28) so as not to make them visible to the management system and not to run the risk of inserting them in a picking list. of the warehouse;

GR.AMM	INCIDENT MANAGEMENT GUIDELINES E OF FOOD EMERGENCIES	LG2 Rev 10 of 02/05/22 Page 6 of 9
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- From a material point of view, the materials / products / raw materials object of the withdrawal / recall must be positioned in a single point with the presence of numerous identification signs bearing the writing in large and red font: NON-COMPLIANT PRODUCT SUBJECT TO WITHDRAWAL / RECALL FROM THE MARKET

The authorities will have to verify and approve the final disposition of the materials / products / raw materials subject to the recall / recall and will also have the final destination which may be, depending on the case: destruction (for example when the product is not suitable for human consumption) , reprocessing (for example when reworking eliminates the food risk), new labeling (for example if it is an undeclared allergen that can be indicated by affixing a new label), other.

### 3.7 Verification of the effectiveness of the withdrawal / recall

GR.AMM Srl is responsible for verifying the effectiveness of the recall. Verification consists of:

- Verify that all recipients have received notification and taken appropriate action;
- If the response of the recipients is not 100% then the withdrawal / recall will be considered ineffective and the withdrawal / recall strategy / procedure will need to be re-evaluated.

It will be necessary to keep track of all the verification activities carried out.

### 3.8 Closing the withdrawal / recall

A request for closure of the withdrawal / recall can be made only after:

- all the goods have returned;
- the products affected by the recall / recall have had a destination;
- the recognition was made between the quantity subject to withdrawal / recall and the quantity actually returned;
- the effectiveness of the withdrawal / recall has been verified.

The request to close the recall will be formal and written and will be forwarded to the supervisory authorities. The request must declare that the withdrawal was effective in the sense that:

- all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy;
- the recalled product has been removed and a correct disposition or correction has been commensurate with the degree of risk of the recalled product.

Written notification that a recall has ended will be issued by the same competent supervisory authority at the company that made the recall.

## 4. EMERGENCY SITUATIONS

This Guideline also has the purpose of defining the actions to be taken and the responsibilities that arise from emergency situations that may occur in the context of the activities directly and / or indirectly controlled by GR.AMM:

- disruption of key services such as water, energy, staff availability;
- malicious contamination or sabotage;
- food emergencies - accidents;

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- pandemic.

Any situations described above will be addressed as follows: Water supply interruption

The company is equipped with an emergency tank to allow the continuation of normal work activities.

Energy interruption

The company is equipped with a generator that ensures the supply of electricity in the event of a black-out.

The autonomy of the generator is about three hours. The Production Manager will have the task of ensuring the continuity of activities by continually replenishing the fuel.

Personal availability

Any need for additional personnel is satisfied by obtaining labor from a cooperative company. We try to find personnel who have already carried out work activities at our organization and therefore do not require further training. In the absence of trained personnel, preventive training and the support of specialized personnel are carried out.

Intentional contamination or sabotage

The risk of malicious contamination or sabotage is kept under control thanks to day and night surveillance by a specialized company. All internal and external areas are also covered by a video recording system.

Any malicious event would be immediately identified. Epidemic /

Pandemic

In the presence of an epidemic and / or pandemic event, the company implements a series of preventive actions aimed at preventing the spread of viruses and / or contagious diseases, such as: - periodic screening of personnel to identify and isolate any clusters; - adoption of containment measures, such as social distancing, staggered entrances, distribution and installation of protective devices (masks, screens) and homeworking where possible.

In the event of unavailability of personnel, caused by social isolation, the company recruits workers already trained by a cooperative company or trains new ones alongside internal staff.

## 5. PERIODIC CHECKS

On an annual basis, during the review, the entire withdrawal / recall procedure must be verified, reviewed and validated. In addition to the annual review, it will be necessary to carry out a review whenever significant changes occur such as regulatory updates, reorganization of key personnel, etc.

A mock recall must also be made at least once a year. The fake recall

will be done following the following rules:

- Select a product that has been placed on the market;
- Make a complete tracking from raw materials to the recipients of the finished product;
- Check the communication system: for example, send emails, faxes, make a phone call to the contacts identified and wait for an answer.

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- At least once every two years (or once a year if there are more than one mock recall per year) the mock recall must be carried out suddenly, without planning. For example, the quality manager, without notice, selects any batch of a product placed on the market and asks the quality colleagues to make a mock recall. The aim is to evaluate the ability to react and the effectiveness of the result in conditions of improvisation and stress.

If any obstacles are found in the verification of the communication, a review of the withdrawal / recall procedure must be carried out.

Records of fake recalls made must be kept.

## 6. REFERENCE DOCUMENTS

Reg. (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002, articles 14-18-19;

State - Regions Agreement of 11/13/2008 "Guidelines for the operational management of the alert system for food intended for human consumption";

Ministerial note 0047556 - 15/12/2016-DGISAN-MDS-PP Procedures for recalling non-products

compliant and start-up of the system for publishing the data relating to the recalled products

Title 21: Food and Drugs PART 7 — ENFORCEMENT POLICY

Guidelines for the exchange of information in food control emergency situations -CAC / GL 19 - 1995 Codex Alimentarius.

## 7. RECALLED DOCUMENTS

MOD. LG 2.1A SANDARD FORMAT INCIDENT MANAGEMENT MOD. LG

2.1B SANDARD FORMAT INCIDENT MANAGEMENT USA MOD. LG 2.2

COMMUNICATION WITHDRAWAL

RECALL MODEL MINISTRY OF HEALTH MOD LG 2.3 USA

RECALL NOTICE

MOD LG 2.4A FOOD RISK ASSESSMENT DIAGRAM MOD LG 2.4B PRODUCT RECALL

DIAGRAM

MOD LG 2.4C RECALL MANAGEMENT TEAM MOD

LG 2.4D NOW RECALL COORDINATORS MOD LG

2.4E EMERGENCY CONTACT LIST

## Allegato 1

## CRITERI PER IL RICHIAMO

**Intesa Stato - Regioni  
13 novembre 2008  
"Linee Guida Sistema d'Allerta"**

## GRAVE RISCHIO

- Probabili effetti immediati e/o a breve termine sulla salute umana
- Sensibilità di una specifica categoria di consumatori
- Probabili effetti a lungo termine sulla salute umana
- Probabili effetti a lungo termine sulla salute dei discendenti
- Probabili effetti tossici cumulativi

**IL PRODOTTO PUÒ ESSERE  
ANDATO AL CONSUMATORE FINALE?**

SI

NO

SI

NO

**RITIRO  
RICHIAMO**  
-media/tv/radio  
-cartellonistica  
-sito web o  
social network

**RITIRO  
RICHIAMO**  
-cartellonistica  
-sito web o  
social network

RITIRO

RITIRO

## GRAVE RISCHIO DA ACCERTARE

*Allegato D lettere a - k*

**È STATA EFFETTUATA UNA  
VALUTAZIONE SCIENTIFICA?**

COMPLETA

PRELIMINARE/  
PARZIALELIVELLO DI  
RISCHIO

**IL PRODOTTO PUÒ  
ESSERE ANDATO AL  
CONSUMATORE FINALE**

BASSO

MEDIO

RITIRO

ALTO

RITIRO  
RICHIAMO

*Prime  
valutazioni  
da effettuare  
ai fini del  
richiamo*

*Risk communication  
Guidelines EFSA,  
July 2012*

	LIVELLO DI RISCHIO	IMPATTO	ESPOSIZIONE
RITIRO	BASSO	Scarso impatto sulla salute pubblica/ scarso interesse del pubblico	Nessuna esposizione
	MEDIO	Scarso impatto sulla salute pubblica/ forte interesse del pubblico Medio impatto sulla salute pubblica/ medio interesse del pubblico	Esposizione limitata
RITIRO RICHIAMO	ALTO	Forte impatto sulla salute pubblica/ scarso interesse del pubblico Forte impatto sulla salute pubblica/ forte interesse del pubblico	Esposizione diffusa/gruppi particolari
	SCONOSCIUTO	Sconosciuto da valutare	Esposizione sconosciuta

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**REQUIRED** 21 CFR, §1.503 requires that all documents be written in a language understandable to the FSVP QI. The original document(s) were written in a language other than English but have since been translated in an effort to meet FDA requirements. An individual that is fluent in both English and the document's original language must confirm that the translation has been accurately performed.

**Translated text accurately reflects original message**

Agree  Disagree

Agree – with suggested edits

**Name** *Francesco Garofalo*

**Date** *6/29/22*

**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)
- 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: \_\_\_\_\_

GR.A.M.M.	Standard format gestione incidenti USA Information Templates for FDA Communication	MOD. LG 2.1B Rev. 6 del 18/09/20
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**RECALLING FIRM Contacts**

*Provide this information to FDA for clear communication:*

**Manufacturer name:** GR.A.M.M. Gruppo Alimentare Mediterraneo Milo Srl

Position	Name, Title	Contact Information
RECALL coordinator	Francesco Garofalo Quality Manager	Office: +390803735950 Fax: +390803738273 email: qualita@gruppomilo.it
Most responsible individual: Public contact:	Peppino Milo Milo CEO – General Manager	Office: +390803735950 Mobile: +393485211970 Fax: +390803738273 email: g.milo@gruppomilo.it

**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.	

**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	

**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

**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		

**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.



**GR.A.M.M. Gruppo alimentare Mediterraneo Milo Srl**

Fraz. Palombaio Via Teologo Valente N.C. 70032 Bitonto (BA) Italia

MOD LG 2.3

Partita IVA 04835950728 Tel. 080.3735950 – Fax: 080.3738273

Rev. 6 del 18/09/20

web: [www.casamilo.it](http://www.casamilo.it) e-mail: [info@gruppomilo.it](mailto:info@gruppomilo.it)

## USA Recall Notice

***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 [COMPANY NAME] 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 email us 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:

Head Quarter +390803735950 (Monday to Friday, 9:30 a.m. to 5 p.m. CEST) email: [qualita@gruppomilo.it](mailto:qualita@gruppomilo.it)

General Manager +393485211970 (active 24/7) email: [g.milo@gruppomilo.it](mailto:g.milo@gruppomilo.it)

Management +393485211972 (active 24/7) email: [s.milo@gruppomilo.it](mailto:s.milo@gruppomilo.it)



Date:10/01/2020 6:34:40

Created Date  
2017-03-27 10:18:03.0

Registration Expiration Date  
2022-12-31

Last Updated  
2020-10-01

Registration Status  
**VALID**

Is this facility engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States?  
 Yes  No

### Section 1: Type of Registration

Facility Location: **Foreign Registration**

UPDATE OF REGISTRATION INFORMATION:

Registration Number: **16111067886** Pin No **Cebec027**

Are you the new owner of a previously registered facility?

Yes  No

Previous Owner's Title:

Previous Owner's Name:

Previous Owner's Registration Number:

### Section 2: Facility Name/Address Information

Facility Name  
**GR.A.M.M. S.R.L.**

Facility Name Suffix  
**Manufacturing**

Facility Street Address, Line 1  
**SS 96 km 113,200**

Facility Street Address, Line 2

City  
**palo del colle**

State/Province/Territory  
**Bari**

Zip Code (Postal Code)  
**70027**

Country/Area  
**ITALY**

Telephone Number  
**039 080 625662**

Fax Number  
**039 080 629557**

E-Mail Address  
**export@gruppomilo.it**

Unique Facility Identifier (UFI)  
**439804945**



### Section 3: Preferred Mailing Address Information

Complete this section if different from Section 2 Facility Name/Address Information (OPTIONAL)

Is the preferred mailing address the same as the facility address (Section 2)? Yes

Name	Telephone Number
<b>GR.A.M.M. S.R.L.</b>	<b>039 080 625662</b>
Address, Line 1	Fax Number
<b>SS 96 km 113,200</b>	<b>039 080 629557</b>
Address, Line 2	E-Mail Address
	<b>export@gruppomilo.it</b>
City	
<b>palo del colle</b>	
State/Province/Territory	
<b>Bari</b>	
Zip Code (Postal Code)	
<b>70027</b>	
Country/Area	
<b>ITALY</b>	

### Section 4: Parent Company Name/Address Information

(If applicable and if different from Sections 2 and 3). If information is the same as another section, check which section:

- Same as Facility Address (Section 2)
- Same as Preferred Mailing Address (Section 3)
- None of the above

Company Name	Telephone Number
<b>GR.A.M.M. S.R.L.</b>	<b>039 080 3735950</b>
Company Name Suffix	Fax Number
<b>Manufacturing</b>	<b>039 080 3738273</b>
Address, Line 1	E-Mail Address
<b>Via teologo Valente,sn</b>	<b>export@gruppomilo.it</b>
Address, Line 2	
City	
<b>Palombaio-Bitonto</b>	
State/Province/Territory	
<b>Bari</b>	
Zip Code (Postal Code)	
<b>70032</b>	
Country/Area	
<b>ITALY</b>	

### Section 5: Facility Emergency Contact Information



If information is the same as another section, check which section:

- Same as Facility Address (Section 2)
- Same as U.S. Agent Information (Section 7)
- None of the above

Individual's Title (Optional)

**ms**

Individual's Name (Optional)

**JANIS**

Individual's Middle Name (Optional)

Individual's Last Name (Optional)

**GROVER**

Emergency Contact Phone

**001 908 7979847**

E-Mail Address

**j.grover@gruppomilo.it**

Job Title (Optional)

**Section 6: Trade Names**

(If this facility uses trade names other than that listed in Section 2 above, list them below (e.g., "Also doing business as," "Facility also known as"))

Are there alternate trade names used by your facility in addition to the name provided in **Section 2: Facility Name/Address Information?**

- Yes
- No

**Section 7: United States Agent**

(To be completed by facilities located outside any state or territory of the United States, District of Columbia, or The Commonwealth of Puerto Rico)

First Name

**JANIS**

Telephone Number

**908 7979847**

Middle Name (Optional)

Emergency Contact Phone

**908 7979847**

Last Name

**GROVER**

Fax Number

Title (Optional)

**ms**

E-Mail Address

**j.grover@gruppomilo.it**

Address, Line 1

**101 BOWNE STATION ROAD**

Address, Line 2

City

**Stockton**

State/Province/Territory

**New Jersey**

Zip Code (Postal Code)

**08559**

Country/Area

**UNITED STATES**

**Section 8: Seasonal Facility Dates of Operation (Optional)**



Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis (Optional).

Harvest 1

Start Month

End Month

Harvest 2

Start Month

End Month

**Section 9: General Product Categories - Human/Animal/Both**

Food for Human Consumption  Food for Animal Consumption

**Section 9a: General Product Categories - Food for Human Consumption; and Type of Activity Conducted at the Facility**

To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Refrigerated Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks)	Frozen Food Storage Warehouse / Holding Facility (e.g., storage facilities)	Acidified Food Process or	Low-Acid Food Process or	Interstate Conveyance Caterer / Catering Point	Contract Sterilizer	Labeler / Relabeler	Manufacturer / Processor	Packer / Repacker	Salvage Operator (Reconditioner)	Farm Mixed-Type Facility	Other Activity Conducted (Please Specify)
3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS <sup>(1), (9)</sup>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Section 10: Owner, Operator, or Agent-in-Charge Information**

Provide the following information, if different from all other sections on the form. If information is the same as another section of the form, check which section:

If information is the same as Section 2, check the box:

- Section 2 - Facility Address Information
- Section 3 - Preferred Mailing Address Information
- Section 4 - Parent Company Address Information
- Section 7 - US Agent Address Information
- None of the above

Name of Entity or Individual Who is the Owner, Operator, or Agent-in-Charge: PEPPINO MILO MILO

Address, Line 1

Via teologo Valente,sn

Address, Line 2

Telephone Number

039 080 3735950

Fax Number

039 080 3738273



City **Palombaio-Bitonto** E-Mail Address **export@gruppomilo.it**  
 State/Province/Territory **Bari**  
 Zip Code (Postal Code) **70032**  
 Country/Area **ITALY**

**Section 11: Inspection Statement**

FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

**Section 12: Certification Statement**

The owner, operator, or agent-in-charge of the facility, or an individual authorized by the owner, operator, or agent-in-charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent-in-charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator or agent-in-charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent-in-charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

**NAME OF PERSON SUBMITTING THIS REGISTRATION RENEWAL:** PEPPINO MILO MILO

**CHECK ONE BOX**

- A. INDIVIDUAL ASSOCIATED WITH THE INFORMATION IN SECTION 10 (STOP HERE, FORM IS COMPLETED)
- B. ANOTHER AUTHORIZED INDIVIDUAL

**Address Information for the Authorizing Individual:**

Individual's Name	Telephone Number
-N/A-	-N/A-
Address, Line 1	Fax Number
-N/A-	-N/A-
Address, Line 2	E-Mail Address
-N/A-	-N/A-
City	
-N/A-	
State/Province/Territory	
-N/A-	
Zip Code (Postal Code)	
-N/A-	
Country/Area	
-N/A-	

*Claudio Innocenti*

# Italian Cheese Blend

Savory thins made with an Italian Cheese Blend & Extra Virgin Olive Oil



# TUSCAN CRISPS

## Italian Cheese Blend

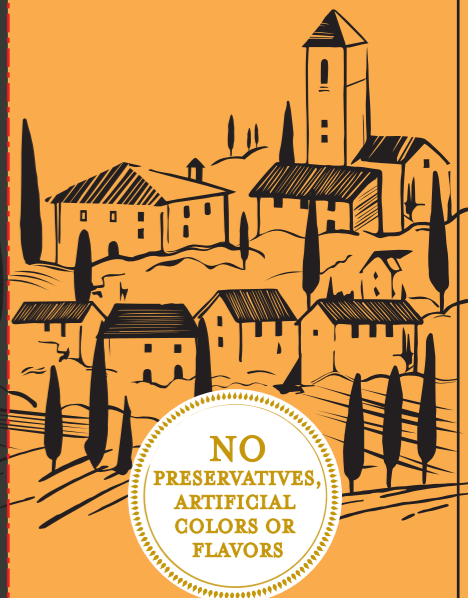
MADE IN ITALY



Savory thins made with an Italian Cheese Blend & Extra Virgin Olive Oil

Net Wt. 5.3oz (150g)

# OVEN BAKED Italian Cheese Blend



NO PRESERVATIVES, ARTIFICIAL COLORS OR FLAVORS

Enjoy the authentic flavors of Italy created with the finest, authentic Italian ingredients. Our thin and savory Tuscan Crisps are delicately baked by a family of artisans in Italy's Puglia region. Serve as an accompaniment to hors d'oeuvres, or enjoy them as a healthy, satisfying snack.

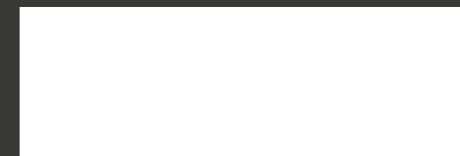
# OVEN BAKED Italian Cheese Blend



Made with the finest quality Italian Extra Virgin Olive Oil, Tuscan Crisps are crafted from a unique and healthy blend of rice and wheat flour. Try all 5 of our savory and sophisticated flavors including Olive Oil & Sea Salt, Rosemary & Olive Oil, Italian Cheese Blend, Sour Cream & Onion and Parmesan Garlic & Herb, for a world class snacking experience.

STAMPASUD  
Cod. Prod. 3000563  
L20059-21\_2259

Best if used by:



# TUSCAN CRISPS



Italian Cheese Blend  
Savory thins made with Extra Virgin Olive Oil

INGREDIENTS: Wheat Flour, Rice Flour, Olive Oil, Italian Extra Virgin Olive Oil, Salt, Natural Cheese Flavor, Dehydrated Onion, Brewer's Yeast, Cheese (Milk, Salt, Cultures, Enzymes), Malted Wheat Flour.

CONTAINS: Wheat & Milk.

Manufactured in a facility that may process products that contain wheat, milk, egg, soy, peanut and tree nut ingredients.

Store in a cool and dry place.

Distributed by Fusion Gourmet,  
Rancho Dominguez, CA 90220  
Visit us at [www.fusiongourmet.com](http://www.fusiongourmet.com)



PRODUCT OF ITALY



## Nutrition Facts

about 5 servings per container  
Serving size 10 pieces (30g)

Amount per serving  
**Calories 140**

% Daily Value\*

<b>Total Fat</b> 4g	<b>5%</b>
Saturated Fat 1g	<b>5%</b>
Trans Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 340mg	<b>15%</b>
<b>Total Carbohydrate</b> 22g	<b>8%</b>
Dietary Fiber less than 1g	<b>3%</b>
Total Sugars less than 1g	
Includes 0g Added Sugars	<b>0%</b>
<b>Protein</b> 3g	

Vit. D 0mcg 0% • Calcium 10mg 0%  
Iron 0.5mg 4% • Potas. 50mg 2%

\*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

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

Tuscan Crisps - Italian Cheese Blend



Matte varnish

Please make artwork repro ready for print.  
Check barcode quality at repro.

CONFIDENTIAL TREATMENT REQUESTED

*Claudio Innocenti*

# Olive Oil & Sea Salt

Savory thins made with  
Extra Virgin Olive Oil & Sea Salt

**DOLCETTO**

## TUSCAN CRISPS

Olive Oil & Sea Salt

MADE IN ITALY



Savory thins made with  
Extra Virgin Olive Oil & Sea Salt

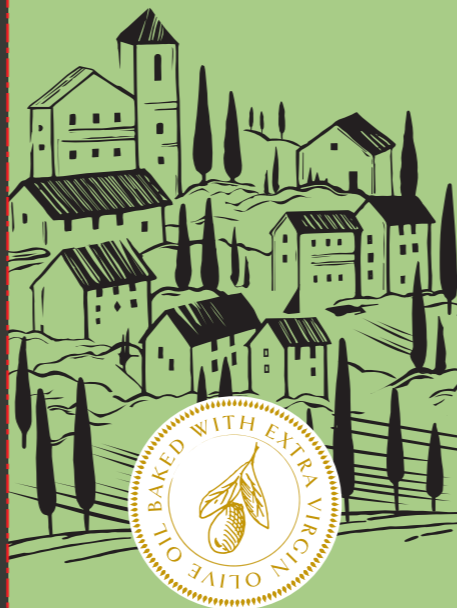
Net Wt. 5.3oz (150g)

OVEN BAKED  
Olive Oil &  
Sea Salt

**NO  
PRESERVATIVES,  
ARTIFICIAL  
COLORS OR  
FLAVORS**

Enjoy the authentic flavors of Italy created with the finest, authentic Italian ingredients. Our thin and savory Tuscan Crisps are delicately baked by a family of artisans in Italy's Puglia region. Serve as an accompaniment to hors d'oeuvres, or enjoy them as a healthy, satisfying snack.

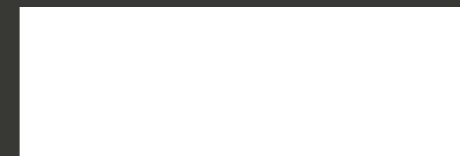
OVEN BAKED  
Olive Oil &  
Sea Salt



Made with the finest quality Italian Extra Virgin Olive Oil, Tuscan Crisps are crafted from a unique and healthy blend of rice and wheat flour. Try all 5 of our savory and sophisticated flavors including Olive Oil & Sea Salt, Rosemary & Olive Oil, Italian Cheese Blend, Sour Cream & Onion and Parmesan Garlic & Herb, for a world class snacking experience.

STAMPASUD  
Cod. Prod. 30001563  
L20059-21\_2257

Best if used by:



**DOLCETTO**

## TUSCAN CRISPS



Olive Oil & Sea Salt

Savory thins made with Extra Virgin Olive Oil

INGREDIENTS: Wheat Flour, Rice Flour, Olive Oil, Italian Extra Virgin Olive Oil, Salt, Brewer's Yeast, Malted Wheat Flour.

CONTAINS: Wheat.

Manufactured in a facility that may process products that contain wheat, milk, egg, soy, peanut and tree nut ingredients.

Store in a cool and dry place.

Distributed by Fusion Gourmet,  
Rancho Dominguez, CA 90220  
Visit us at [www.fusiongourmet.com](http://www.fusiongourmet.com)



PRODUCT OF ITALY



### Nutrition Facts

about 5 servings per container  
Serving size 10 pieces (30g)

Amount per serving  
**Calories 140**

	% Daily Value*
<b>Total Fat</b> 4g	<b>5%</b>
Saturated Fat 1g	<b>5%</b>
Trans Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 340mg	<b>15%</b>
<b>Total Carbohydrate</b> 22g	<b>8%</b>
Dietary Fiber less than 1g	<b>3%</b>
Total Sugars less than 1g	
Includes 0g Added Sugars	<b>0%</b>
<b>Protein</b> 3g	

Vit. D 0mcg 0% • Calcium 10mg 0%  
Iron 0.5mg 4% • Potas. 50mg 2%

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Tuscan Crisps - Parmesan, Garlic & Herb



Matte varnish

Please make artwork repro ready for print.  
Check barcode quality at repro.



## TUSCAN CRISPS

### Parmesan Garlic & Herb

Savory thins made with Extra Virgin Olive Oil

INGREDIENTS: Wheat Flour, Rice Flour, Olive Oil, Natural Cheese Flavor, Salt, Extra Virgin Olive Oil, Dehydrated Garlic, Parmesan Cheese (Milk, Salt, Cultures, Enzymes), Brewer's Yeast, Malted Wheat Flour, Dehydrated Basil, Dehydrated Parsley.

CONTAINS: Wheat & Milk.

Manufactured in a facility that may process products that contain wheat, milk, egg, soy, peanut and tree nut ingredients.

Store in a cool and dry place.

Distributed by Fusion Gourmet,  
Rancho Dominguez, CA 90220  
Visit us at [www.fusiongourmet.com](http://www.fusiongourmet.com)




/FusionGourmet

**PRODUCT OF ITALY**



8 19529 00285 9

OVEN BAKED  
Parmesan  
Garlic & Herb




Made with the finest quality Italian Extra Virgin Olive Oil, Tuscan Crisps are crafted from a unique and healthy blend of rice and wheat flour. Try all 5 of our savory and sophisticated flavors including Olive Oil & Sea Salt, Rosemary & Olive Oil, Italian Cheese Blend, Sour Cream & Onion and Parmesan Garlic & Herb, for a world class snacking experience.

## DOLCETTO

# TUSCAN CRISPS

## Parmesan Garlic & Herb

MADE IN ITALY



Savory thins made with Parmesan  
Garlic, Herbs & Extra Virgin Olive Oil

Net Wt. 5.3oz (150g)

Best if used by:

OVEN BAKED  
Parmesan  
Garlic & Herb



NO  
PRESERVATIVES  
ARTIFICIAL  
COLORS OR  
FLAVORS

Enjoy the authentic flavors of Italy created with the finest, authentic Italian ingredients. Our thin and savory Tuscan Crisps are delicately baked by a family of artisans in Italy's Puglia region. Serve as an accompaniment to hors d'oeuvres, or enjoy them as a healthy, satisfying snack.

# Rosemary & Olive Oil

Savory thins made with  
Rosemary & Extra Virgin Olive Oil

**DOLCETTO**

# TUSCAN CRISPS

Rosemary & Olive Oil

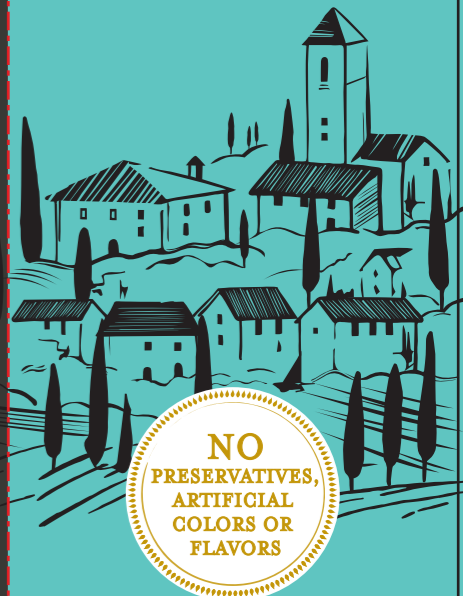
MADE IN ITALY



Savory thins made with  
Rosemary & Extra Virgin Olive Oil

Net Wt. 5.3oz (150g)

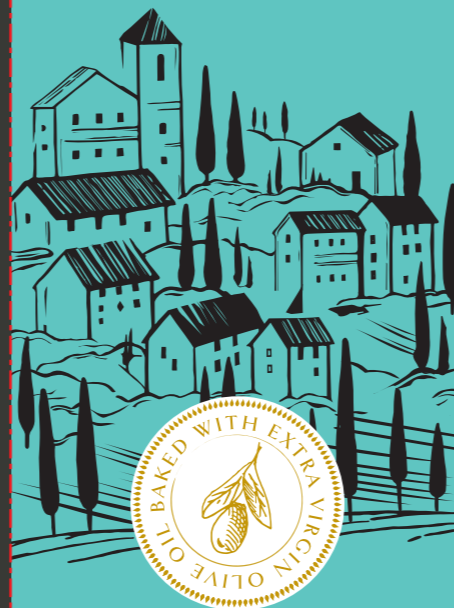
OVEN BAKED  
Rosemary &  
Olive Oil



**NO  
PRESERVATIVES,  
ARTIFICIAL  
COLORS OR  
FLAVORS**

Enjoy the authentic flavors of Italy created with the finest, authentic Italian ingredients. Our thin and savory Tuscan Crisps are delicately baked by a family of artisans in Italy's Puglia region. Serve as an accompaniment to hors d'oeuvres, or enjoy them as a healthy, satisfying snack.

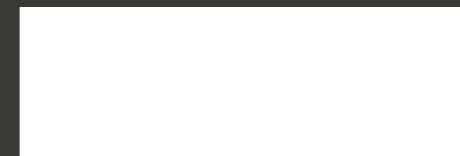
OVEN BAKED  
Rosemary &  
Olive Oil



Made with the finest quality Italian Extra Virgin Olive Oil, Tuscan Crisps are crafted from a unique and healthy blend of rice and wheat flour. Try all 5 of our savory and sophisticated flavors including Olive Oil & Sea Salt, Rosemary & Olive Oil, Italian Cheese Blend, Sour Cream & Onion and Parmesan Garlic & Herb, for a world class snacking experience.

STAMPASUD  
Cod. Prod. 30001563  
L20059-21\_2257

Best if used by:



**DOLCETTO**

# TUSCAN CRISPS



Rosemary & Olive Oil

Savory thins made with Extra Virgin Olive Oil

INGREDIENTS: Wheat Flour, Rice Flour, Olive Oil, Italian Extra Virgin Olive Oil, Salt, Brewer's Yeast, Dehydrated Rosemary, Malted Wheat Flour.

CONTAINS: Wheat.

Manufactured in a facility that may process products that contain wheat, milk, egg, soy, peanut and tree nut ingredients.

Store in a cool and dry place.

Distributed by Fusion Gourmet,  
Rancho Dominguez, CA 90220  
Visit us at [www.fusiongourmet.com](http://www.fusiongourmet.com)

/FusionGourmet

PRODUCT OF ITALY



## Nutrition Facts

about 5 servings per container  
Serving size 10 pieces (30g)

Amount per serving	% Daily Value*
<b>Calories</b> 140	
<b>Total Fat</b> 4g	5%
Saturated Fat 1g	5%
Trans Fat 0g	
<b>Cholesterol</b> 0mg	0%
<b>Sodium</b> 340mg	15%
<b>Total Carbohydrate</b> 22g	8%
Dietary Fiber less than 1g	3%
Total Sugars less than 1g	
Includes 0g Added Sugars	0%
<b>Protein</b> 3g	
Vit. D 0mcg 0%	Calcium 10mg 0%
Iron 0.5mg 4%	Potas. 50mg 2%

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Tuscan Crisps - Sour Cream & Onion



Matte varnish

Please make artwork repro ready for print.  
Check barcode quality at repro.



# TUSCAN CRISPS

## Sour Cream & Onion

Savory thins made with Extra Virgin Olive Oil

INGREDIENTS: Wheat Flour, Rice Flour, Olive Oil, Sour Cream & Onion Flavoring, Extra Virgin Olive Oil, Salt, Dehydrated Onion, Cheese (Milk, Salt, Cultures, Enzymes), Brewer's Yeast, Malted Wheat Flour.

CONTAINS: Wheat & Milk.

Manufactured in a facility that may process products that contain wheat, milk, egg, soy, peanut and tree nut ingredients.

Store in a cool and dry place.

Distributed by Fusion Gourmet,  
Rancho Dominguez, CA 90220  
Visit us at [www.fusiongourmet.com](http://www.fusiongourmet.com)




/FusionGourmet

PRODUCT OF ITALY



OVEN BAKED  
Sour Cream  
& Onion




Made with the finest quality Italian Extra Virgin Olive Oil, Tuscan Crisps are crafted from a unique and healthy blend of rice and wheat flour. Try all 5 of our savory and sophisticated flavors including Olive Oil & Sea Salt, Rosemary & Olive Oil, Italian Cheese Blend, Sour Cream & Onion and Parmesan Garlic & Herb, for a world class snacking experience.

# Sour Cream & Onion

---

Savory thins made with Sour Cream,  
Onion & Extra Virgin Olive Oil



# TUSCAN CRISPS

## Sour Cream & Onion

MADE IN ITALY



Serving suggestion

Savory thins made with Sour Cream,  
Onion & Extra Virgin Olive Oil

Net Wt. 5.3oz (150g)

Best if used by:

## OVEN BAKED Sour Cream & Onion




Enjoy the authentic flavors of Italy created with the finest, authentic Italian ingredients. Our thin and savory Tuscan Crisps are delicately baked by a family of artisans in Italy's Puglia region. Serve as an accompaniment to hors d'oeuvres, or enjoy them as a healthy, satisfying snack.

# FORMAGGIO

TRADITIONAL BLEND OF ITALIAN CHEESES

## Toscarelli

# TOSCANA

ITALIAN CRACKER THINS  
**FORMAGGIO**



THIN ITALIAN CRACKERS MADE WITH A TRADITIONAL BLEND OF ITALIAN CHEESES. AN IDEAL, LIGHT SNACK STRAIGHT FROM THE BOX OR PAIRED WITH YOUR FAVORITE CHEESE, DIPS, AND WINE.

**INGREDIENTS:** Wheat Flour, Rice Flour, Olive Oil, Italian Extra Virgin Olive Oil, Salt, Natural Cheese Flavor, Dehydrated Onion, Brewer's Yeast, Cheese (Milk, Salt, Cultures, Enzymes), Malted Wheat Flour.

**CONTAINS:** Wheat & Milk.

Manufactured in a facility that may process products that contain wheat, milk, egg, soy, peanut and tree nut ingredients.

Store in a cool and dry place.

Distributed by ASA Foods,  
Rancho Dominguez, CA 90220  
Visit us at [www.asafoods.com](http://www.asafoods.com)

PRODUCT OF ITALY



8 19529 00521 8

### Nutrition Facts

about 5 servings per container  
**Serving size 10 pieces (30g)**

Amount per serving	Calories	140	% Daily Value*
<b>Total Fat</b> 4g			<b>5%</b>
Saturated Fat 1g			<b>5%</b>
Trans Fat 0g			
<b>Cholesterol</b> 0mg			<b>0%</b>
<b>Sodium</b> 340mg			<b>15%</b>
<b>Total Carbohydrate</b> 22g			<b>8%</b>
Dietary Fiber less than 1g			<b>3%</b>
Total Sugars less than 1g			
Includes 0g Added Sugars			<b>0%</b>
<b>Protein</b> 3g			

Vit. D 0mcg 0% • Calcium 10mg 0%  
Iron 0.5mg 4% • Potas. 50mg 2%

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.



## FORMAGGIO

*Crafted in Italy by artisanal bakers, Toscana Italian Cracker Thins are the perfect blend of classic Italian flavors. Made with Extra Virgin Olive Oil and premium ingredients from a time-honored recipe, these light, golden thins provide a unique snacking experience.*

*Savor our three classic flavors including*

TRADIZIONALE  
FORMAGGIO  
ROSMARINO

## Toscarelli

MADE IN ITALY

# TOSCANA

ITALIAN CRACKER THINS



## FORMAGGIO

TRADITIONAL BLEND OF ITALIAN CHEESES

NET WT. 5.3 oz (150g)

Best if used by:



## FORMAGGIO

*Crafted in Italy by artisanal bakers, Toscana Italian Cracker Thins are the perfect blend of classic Italian flavors. Made with Extra Virgin Olive Oil and premium ingredients from a time-honored recipe, these light, golden thins provide a unique snacking experience.*

*Savor our three classic flavors including*

TRADIZIONALE  
FORMAGGIO  
ROSMARINO

# ROSMARINO

ROSEMARY & EXTRA VIRGIN OLIVE OIL



# TOSCANA

ITALIAN CRACKER THINS

## ROSMARINO



THIN ITALIAN CRACKERS MADE WITH ROSEMARY AND EXTRA VIRGIN OLIVE OIL. AN IDEAL, LIGHT SNACK STRAIGHT FROM THE BOX OR PAIRED WITH YOUR FAVORITE CHEESE, DIPS, AND WINE.

**INGREDIENTS:** Wheat Flour, Rice Flour, Olive Oil, Italian Extra Virgin Oil, Salt, Brewer's Yeast, Dehydrated Rosemary, Malted Wheat Flour.

**CONTAINS:** Wheat.

Manufactured in a facility that may process products that contain wheat, milk, egg, soy, peanut and tree nut ingredients.

Store in a cool and dry place.

Distributed by ASA Foods, Rancho Dominguez, CA 90220 Visit us at [www.asafoods.com](http://www.asafoods.com)

PRODUCT OF ITALY



8 19529 00522 5

### Nutrition Facts

about 5 servings per container  
Serving size 10 pieces (30g)

Amount per serving		% Daily Value*	
<b>Calories 140</b>			
<b>Total Fat</b> 4g		<b>5%</b>	
Saturated Fat 1g		<b>5%</b>	
Trans Fat 0g			
<b>Cholesterol</b> 0mg		<b>0%</b>	
<b>Sodium</b> 340mg		<b>15%</b>	
<b>Total Carbohydrate</b> 22g		<b>8%</b>	
Dietary Fiber less than 1g		<b>3%</b>	
Total Sugars less than 1g			
Includes 0g Added Sugars		<b>0%</b>	
<b>Protein</b> 3g			

Vit. D 0mcg 0% • Calcium 10mg 0%  
Iron 0.5mg 4% • Potas. 50mg 2%

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.



## ROSMARINO

*Crafted in Italy by artisanal bakers, Toscana Italian Cracker Thins are the perfect blend of classic Italian flavors. Made with Extra Virgin Olive Oil and premium ingredients from a time-honored recipe, these light, golden thins provide a unique snacking experience.*

*Savor our three classic flavors including*

TRADIZIONALE  
FORMAGGIO  
ROSMARINO



MADE IN ITALY

# TOSCANA

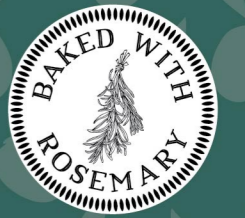
ITALIAN CRACKER THINS



## ROSMARINO

ROSEMARY & EXTRA VIRGIN OLIVE OIL

NET WT. 5.3 oz (150g)



## ROSMARINO

*Crafted in Italy by artisanal bakers, Toscana Italian Cracker Thins are the perfect blend of classic Italian flavors. Made with Extra Virgin Olive Oil and premium ingredients from a time-honored recipe, these light, golden thins provide a unique snacking experience.*

*Savor our three classic flavors including*

TRADIZIONALE  
FORMAGGIO  
ROSMARINO

Best if used by:



TRADIZIONALE

SEA SALT & EXTRA VIRGIN OLIVE OIL

Toscarelli

TOSCANA  
ITALIAN CRACKER THINS  
TRADIZIONALE



THIN ITALIAN CRACKERS MADE WITH SEA SALT AND EXTRA VIRGIN OLIVE OIL. AN IDEAL, LIGHT SNACK STRAIGHT FROM THE BOX OR PAIRED WITH YOUR FAVORITE CHEESE, DIPS, AND WINE.

INGREDIENTS: Wheat Flour, Rice Flour, Olive Oil, Italian Extra Virgin Olive Oil, Salt, Brewer's Yeast, Malted Wheat Flour.

CONTAINS: Wheat.

Manufactured in a facility that may process products that contain wheat, milk, egg, soy, peanut and tree nut ingredients.

Store in a cool and dry place.

Distributed by ASA Foods, Rancho Dominguez, CA 90220 Visit us at www.asafoods.com

PRODUCT OF ITALY



Nutrition Facts

about 5 servings per container  
Serving size 10 pieces (30g)

Amount per serving	Calories	140
% Daily Value*		
Total Fat 4g		5%
Saturated Fat 1g		5%
Trans Fat 0g		
Cholesterol 0mg		0%
Sodium 340mg		15%
Total Carbohydrate 22g		8%
Dietary Fiber less than 1g		3%
Total Sugars less than 1g		
Includes 0g Added Sugars		0%
Protein 3g		
Vit. D 0mcg 0%	Calcium 10mg 0%	
Iron 0.5mg 4%	Potas. 50mg 2%	

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

TRADIZIONALE

Crafted in Italy by artisanal bakers, Toscana Italian Cracker Thins are the perfect blend of classic Italian flavors. Made with Extra Virgin Olive Oil and premium ingredients from a time-honored recipe, these light, golden thins provide a unique snacking experience.

Savor our three classic flavors including

TRADIZIONALE  
FORMAGGIO  
ROSMARINO



Toscarelli

MADE IN ITALY  
TOSCANA  
ITALIAN CRACKER THINS



TRADIZIONALE

Crafted in Italy by artisanal bakers, Toscana Italian Cracker Thins are the perfect blend of classic Italian flavors. Made with Extra Virgin Olive Oil and premium ingredients from a time-honored recipe, these light, golden thins provide a unique snacking experience.

Savor our three classic flavors including

TRADIZIONALE  
FORMAGGIO  
ROSMARINO



TRADIZIONALE

SEA SALT & EXTRA VIRGIN OLIVE OIL

NET WT. 5.3 oz (150g)

Best if used by:

Empty box for best if used by date.

# SOUR CREAM & ONION

LIGHT & CRISP ITALIAN CRACKERS

## Toscarelli

# TOSCANA

ITALIAN CRACKER THINS

## SOUR CREAM & ONION



THIN ITALIAN CRACKERS MADE WITH EXTRA VIRGIN OLIVE OIL. AN IDEAL, LIGHT SNACK STRAIGHT FROM THE BOX OR PAIRED WITH YOUR FAVORITE CHEESE, DIPS, AND WINE.

**INGREDIENTS:** Wheat Flour, Rice Flour, Olive Oil, Sour Cream & Onion Flavoring, Extra Virgin Olive Oil, Salt, Dehydrated Onion, Cheese (Milk, Salt, Cultures, Enzymes), Brewer's Yeast, Malted Wheat Flour.

**CONTAINS:** Wheat & Milk.

Manufactured in a facility that may process products that contain wheat, milk, egg, soy, peanut and tree nut ingredients.

Store in a cool and dry place.

Distributed by ASA Foods, Rancho Dominguez, CA 90220 Visit us at [www.asafoods.com](http://www.asafoods.com)

PRODUCT OF ITALY



### Nutrition Facts

about 5 servings per container  
**Serving size 10 pieces (30g)**

Amount per serving	Calories	% Daily Value*
	<b>140</b>	
<b>Total Fat</b> 4.5g		<b>6%</b>
Saturated Fat 1g		<b>5%</b>
Trans Fat 0g		
<b>Cholesterol</b> 0mg		<b>0%</b>
<b>Sodium</b> 290mg		<b>13%</b>
<b>Total Carbohydrate</b> 22g		<b>8%</b>
Dietary Fiber less than 1g		<b>3%</b>
Total Sugars less than 1g		
Includes 0g Added Sugars		<b>0%</b>
<b>Protein</b> 3g		

Vit. D 0mcg 0%      Calcium 30mg 2%  
Iron 0.4mg 2%      Potas. 40mg 0%

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.



## SOUR CREAM & ONION

*Crafted in Italy by artisanal bakers, Toscana Italian Cracker Thins are the perfect blend of classic Italian flavors. Made with Extra Virgin Olive Oil and premium ingredients from a time-honored recipe, these light, golden thins provide a unique snacking experience.*

*Savor our four classic flavors including*

- TRADIZIONALE
- FORMAGGIO
- ROSMARINO
- SOUR CREAM & ONION

STAMPASUD  
Cod. Prod. 10001502  
L20019-21-\*\*\*\*

## Toscarelli

MADE IN ITALY

# TOSCANA

ITALIAN CRACKER THINS



## SOUR CREAM & ONION

LIGHT & CRISP ITALIAN CRACKERS

NET WT. 5.3 oz (150g)



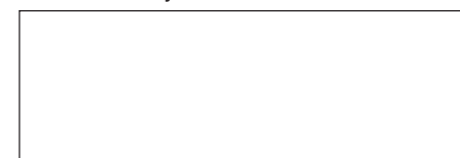
## SOUR CREAM & ONION

*Crafted in Italy by artisanal bakers, Toscana Italian Cracker Thins are the perfect blend of classic Italian flavors. Made with Extra Virgin Olive Oil and premium ingredients from a time-honored recipe, these light, golden thins provide a unique snacking experience.*

*Savor our four classic flavors including*

- TRADIZIONALE
- FORMAGGIO
- ROSMARINO
- SOUR CREAM & ONION

Best if used by:



## Search Results

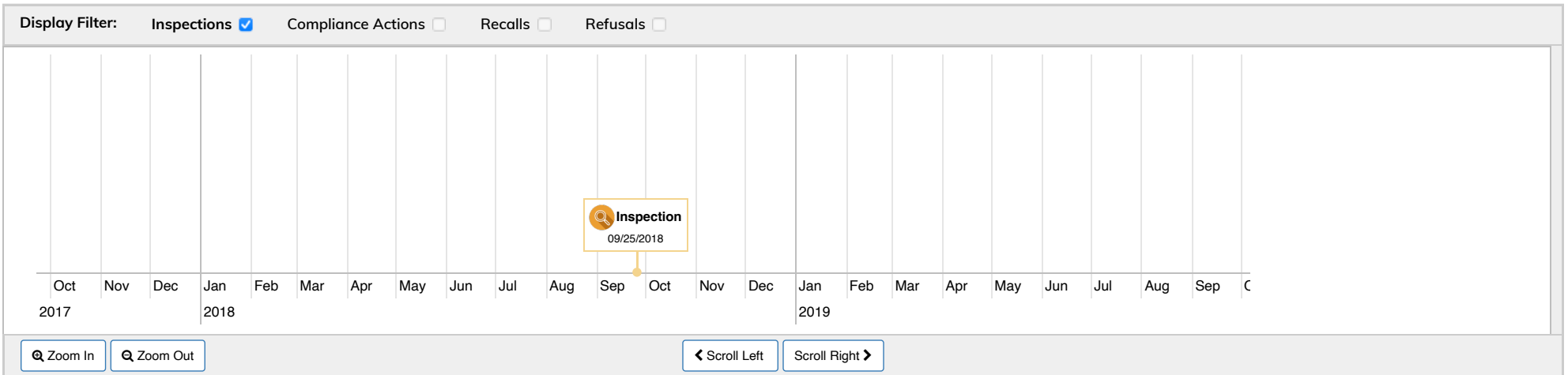
<b>FEI Number</b>	<b>Firm Name</b>	<b>Physical Address</b>	<b>Mailing Address</b>
3013416475	GR.A.M.M. S.R.L.	Strada Statale 96 km 113,200, Palo del Colle, Bari, 70027, IT	Strada Statale 96 km 113,200, Palo del Colle, Bari, 70027, IT

FEI Number  
**3013416475**

Firm Name  
**GR.A.M.M. S.R.L.**

Firm Address  
Strada Statale 96 km 113,200  
Palo del Colle, Bari 70027  
Italy

### FDA Actions Timeline



**3013416475 - GR.A.M.M. S.R.L.**

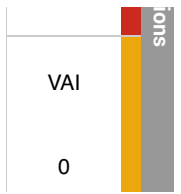
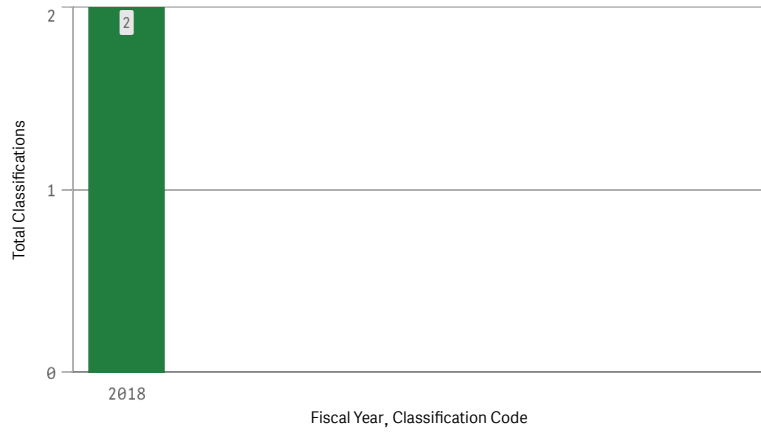
### Inspections

Inspections	Classifications
1	2

Inspection Classifications by Fiscal Year  
Fiscal Years: 2018 - 2018

Inspection Classifications by Type  
Fiscal Years: 2018 - 2018

NAI	Classification
2	
OAI	



**Inspections Details** [Help](#)

Inspection ID	Inspection End Date	Project Area	Product Type	Classification
1070412	09/25/2018	Food Composition, Standards, Labeling and Econ	Food/Cosmetics	NAI
1070412	09/25/2018	Foodborne Biological Hazards	Food/Cosmetics	NAI

**Inspections Citations Details**

No data found for the selected firm

\*Citations data include Form FDA 483 citations and may not necessarily represent citations on final classification letters.

**3013416475 – GR.A.M.M. S.R.L.**

### Compliance Actions

Warning Letters

0

Injunctions

0

Seizures

0

#### Actions by Percentage

No data found for the selected firm

#### Compliance Actions Details

No data found for the selected firm

**3013416475 – GR.A.M.M. S.R.L.**

## Recalls

### Recalled Products by Classification

No data found for the selected firm

### Recall Events by Status

No data found for the selected firm

### Recalls Details

No data found for the selected firm

## Import Refusals

### Refusals by Product Category

No data found for the selected firm


### Import Refusals Details

[Download Refusal Charges Reference](#)

No data found for the selected firm

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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 Alert and that the firm's products are allowed into the country.
- Only current/active Import Alerts are displayed. For more information see [Import Alerts](#).

No Import Alerts data found for the selected firm.

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## 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 present more recent or more complete data 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 rooms or inquire about other datasets that would 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. The compliance actions disclosed include 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](#).
- FDA has removed Medical Device Single Audit Program (MDSAP) audit reports, which are conducted by certified third-party auditors and may be considered in lieu of an FDA surveillance inspection, from the FDA Data Dashboard. FDA has determined that MDSAP audits do not meet the criteria for posting on the FDA Data Dashboard.