UNITED SAFETY AGENTS

FSVP

COMPLIANCE PLAN

AMORE SABINO LLC

Name of FSVP Importer

OLEIFICIO SANTA BARBARA - SOCIETÀ COOPERATIVA AGRICOLA

Name of Foreign Supplier

AMORE SABINO ORGANIC EXTRA VIRGIN OLIVE OIL | VARIOUS SIZES

Name of Product

AUGUST 07, 2021

Date of Initial Verification / Reverification

AUGUST 08, 2022

Date of FSVP Plan Expiration

VERIFICAITON COMPLETE | APPROVED FOR IMPORT

Status of Review

NUMBER 01

Version

– Confidential –

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OVERVIEW *of* FSVP PLAN

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

INSTRUCTIONS

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

TERMS & DEFINITIONS

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

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

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

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

RULES *of* USE

FOREIGN SUPPLIER VERIFICATION PROCEDURES

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

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

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

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

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

Continued onto next page.

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

Continued from previous page.

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

FREQUENCY *of* VERIFICATION PROCEDURES

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

USE *of* APPROVED SUPPLIERS ONLY

Food and/or food-related products should only be imported from foreign suppliers that have been verified to the standards of FSVP. Prior to importation, all steps necessary to successful 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: Oleificio Santa Barbara - Soc. Coop. Agricola

Product: Extra Virgin Olive Oil (Organic)

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

Review Start: July 14, 2021 Review End: Aug. 07, 2021

UNITED STATES CODE *of* FEDERAL REGULATIONS

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

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

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

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola

Product: Extra Virgin Olive Oil (Organic)

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

Review Start: July 14, 2021 Review End: Aug. 07, 2021

21 C.F.R. §1.500–§1.514

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

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

NOTES & COMMENTS

FSVP 21 CFR §1.500–§1.514

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

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

ATTESTATION *of* REVIEW & ASSESSMENT

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

I, _____ certify that I reviewed this FSVP plan on _____ and found
type name *today's date*

its contents to be acceptable.

Reviewer's Name: _____

Reviewer's Signature: _____

Reviewer's Title: _____

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

DESIGNATION *of* ROLES & SUMMARY *of* REVIEW

FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: Amore Sabino LLC FDA FEI: Not on file.

Physical Address: 4676 9th Street DUNS No.: 073503915

City: Carpinteria State: California, 93013 Country: United States

Mailing Address: 4676 9th Street

City: Carpinteria State: California, 93013 Country: United States

Phone Number: +1 (929) 250-6741 Email Address: info@amoresabino.com

Name *of* Representative*(s)*: Mr. Giacomo Title: Commercial Rep.

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

Company Name: Oleificio Santa Barbara - Soc. Coop. Agricola FDA FFR: 19420696668

Manufacturing Address: Via Provinciale 40 Per Roma Snc FDA FEI: 3019041366

City: Scandriglia Province/Territory: Rieti, 02038 Country: Italy

Office Address: Via Provinciale 40 Per Roma Snc

City: Scandriglia Province/Territory: Rieti, 02038 Country: Italy

Phone Number: +39 0765 878768 Email Address: info@oleificioscandriglia.it

Name *of* Representative*(s)*: Pierino De Andreis Title: Director

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

Agent/QI Name: Claudio Innocenti Signature: Claudio Innocenti

Title: Partner & Preventive Controls Qualified Individual. Date: Aug. 07, 2021

Agent/QI Name: William J. Barber Signature: W. J. Barber

Title: Preventive Controls Qualified Individual. Date: Aug. 07, 2021

SUMMARY *of* REVIEW

Details *of* Product(s)	*Is foreign supplier expected to implement controls for*			**Comments**
	Biological Hazards	**Chemical Hazards**	**Physical Hazards**	
Extra Virgin Olive Oil (Organic) 4 X Size formats.	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	Verified & Approved.
	☐ FSVP Importer	☐ FSVP Importer	☑ FSVP Importer	
	☐ Disclosure	☐ Disclosure	☐ Disclosure	
	☐ Customer	☐ Customer	☐ Customer	

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

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola

Product: Extra Virgin Olive Oil (Organic)

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

Review Start: July 14, 2021 Review End: Aug. 07, 2021

REGISTER *of* SUBSTANTIATING DOCUMENTS

HAZARD ANALYSIS

☑ *Requested* ☑ *Required* ☑ *Received* ☑ *Reviewed*

NOTES Oleificio Santa Barbara - Soc. Coop. Agricola's HACCP Plan received.
Dated: October 21, 2020. Plan Entitled: Self Control Manual for the Food Hygiene. Note: Translated
Contains information about: References Of Legislation And Good Practice; Self-Checking Plan Of Critical Points; Receipt And Storage Of Packaging; Incoming Raw Material Control Procedure; Packaging Control; Raw Material Storage; Packaging Storage; Procedure Of Processing Olives Of Organic Origin; Bottling Procedure; Maintenance; Cleaning And Sanitization; Procedure For Defense Against Pests; Training Of Staff In Food Hygiene; Corrective Actions; Non-Conformity Management; Recall; System Verification.

ON-SITE AUDIT

☑ *Requested* ☐ *Required* ☐ *Received* ☐ *Reviewed*

NOTES No substantiating information provided by the supplier.

Note: We respectfully request that a full copy of the supplier's annual on-site audit report be provided.
Note: On-site audit report was not relied upon to approve this foreign supplier.

SAMPLING OR TESTING RESULTS

☑ *Requested* ☑ *Required* ☑ *Received* ☑ *Reviewed*

NOTES Certificates of Analysis received from supplier.
Dated: October 12, 2020.
Tested for: Acidity.
Laboratory: Minifood.
Note: We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified chemical hazards (preferably by an ISO 17025-accredited laboratory).

OTHER FOOD SAFETY RECORDS

☑ *Requested* ☑ *Required* ☑ *Received* ☑ *Reviewed*

NOTES Completed Foreign Supplier FSVP Questionnaire received.
Dated: May 22, 2021
Completed by: Pierino De Andreis
Note: Hazard control sections left blank.
FDA Facility Registration Certificate received.
U.S. Agent: ExportUSA New York Corp.
Recall Plan received.

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 meant 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.

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola

Product: Extra Virgin Olive Oil (Organic)

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

Review Start: July 14, 2021 Review End: Aug. 07, 2021

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 recomended accord to their individually-marked time interval.

FACILITY FOOD SAFETY 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:*

ON-SITE AUDIT RESULTS

- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *other:* Not applicable.

LABORATORY TESTING RESULTS

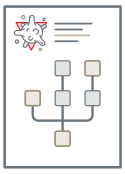
- ☑ if positive results are returned
- ☑ if recall or import refusal occurs
- ☑ if inspection occurs
- ☑ on an annual basis
- ☐ on a per-batch/shipment basis
- ☑ Chemical ☑ Biological
- ☐ *other:*

FDA REGISTRATION

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

FACILITY LICENSE

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



RECALL 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:*

QUALIFICATIONS

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

IMPLEMENTATION RECORDS

- ☑ if recall or import refusal occurs
- ☑ if inspection occurs
- ☐ on an annual basis
- ☐ on a per-batch/shipment basis
- ☐ *other:*

FSVP QUESTIONNAIRE

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

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

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

FDA COMPLIANCE ACTIONS & REGULATORY HISTORY

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

RESULTS *of* EVALUATION

Date *of* Action	Description *of* Action
Not Applicable.	FDA Data Dashboard search results indicate that supplier's compliance history does not include FDA Warning Letters, Import Alerts, or other applicable compliance actions.

Covers: Oleificio Santa Barbara - Soc. Coop. Agricola FEI: 3019041366 Date: Aug. 07, 2021

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

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola

Product: Extra Virgin Olive Oil (Organic)

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

Review Start: July 14, 2021 Review End: Aug. 07, 2021

REVISION LOG *for* FSVP PLAN

Version No.	Date *of* Change	Description *of* Revision
No. 01	August 07, 2021	Product and supplier underwent initial FSVP verification.

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

ANALYSIS & DETERMINATION *of* BIOLOGICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***Bacillus cereus*** ☐ ***Clostridium botulinum*** ☐ ***C. perfringens*** ☐ ***Brucella spp.*** ☐ ***Campylobacter spp.*** ☐ ***Pathogenic E. coli*** ☐ ***Salmonella spp.*** ☐ ***S. aureus*** ☐ ***L. monocytogenes*** ☐ ***Trichinella spiralis*** ☐ ***Giardia lamblia*** ☐ ***Shigella spp.*** ☐ ***Other***	NA	–	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. ——— SUPPLIER CONTROL MEASURES ——— 01. Hazard posed by recontamination with environmental pathogens is controlled through Current Good Manufacturing Practices. 02. Supplier has implemented a cleaning program and environmental monitoring for microbiological and biological hazards. 03. All product is positively released and hermetically sealed within plastic. 03. All staff undergoes formal food hygiene training. 04. All staff issued protective clothing. 05. All production operatives are required to cover head hair within the manufacturing area. 06. Adequate toilet and hand washing facilities provided. ——————NOTE—————— 01. The FDA does not recognize any biological hazards in reference to this product type. Appendix 1 (Hazards Tables) Category: Oil Products Subcategory: Cooking Oils	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. USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all biological hazards. ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Oil Products Category No.: 1 Subcategory: Cooking Oils ——————— ———————

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: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

ANALYSIS & DETERMINATION *of* CHEMICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***Drug residues*** ☐ ***Heavy metals*** ☐ ***Industrial chemicals*** ☐ ***Pesticides*** ☒ ***Mycotoxins/Toxins*** ☐ ***Radiological*** ☐ ***Unapproved colors & additives*** ☐ ***Chemical hazards due to mis-formulation*** ☐ ***Other***	1	2	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. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes raw material inspection and approval procedures to control for hazards posed by chemical agents prior to production. 02. Supplier utilizes laboratory testing to verify that product is free from chemical hazards prior to release. 03. Proper raw material storage and use procedures are in place. These procedures mandate that raw material is put into production within 48 hours of receipt in an effort to minimize any development of mold or toxins. Details: In case of contamination or toxin formation, removal of contaminated product, Repeat the formation of the employees that show incorrect hygienic procedure, possibly terminate them. ——————NOTE—————— USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards. Product is in Ready-to-Eat form upon arrival to FSVP Importer. Natural Toxins are not typically associated with olive oil. Risk level is low.	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. USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards. ——————————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Oil Products Category No.: 1 Subcategory: Cooking Oils ——————————— ———————————

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: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

ANALYSIS & DETERMINATION *of* ALLERGENIC HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☒ ***Undeclared allergens - Incorrect label*** ☒ ***Undeclared allergens - Cross-contact*** **ALLERGENS** ☐ ***Milk*** ☐ ***Eggs*** ☐ ***Fish*** ☐ ***Shellfish*** *(Crustacean)* ☐ ***Tree nuts*** ☐ ***Peanuts*** ☐ ***Wheat*** ☐ ***Soybeans*** ☐ ***Sesame****	3	3	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. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier certifies that: A) there are NO allergens handled on site. 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——————— ---------- Labeling Requirements ---------- - 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.	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. Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to meant that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&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. _____ ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Oil Products Category No.: 1 Subcategory: Cooking Oils _____ _____

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: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

ANALYSIS & DETERMINATION *of* ENVIRONMENTAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***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 poor formulation control.*** ☐ ***Bacterial growth and/or toxin formation due to reduced oxygen packaging.*** ☐ ***Other***	NA	–	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. ——— SUPPLIER CONTROL MEASURES ——— 01. Hazard posed by recontamination with environmental pathogens is controlled through Current Good Manufacturing Practices. 02. Supplier has implemented a cleaning program and environmental monitoring for microbiological and biological hazards. 03. All product is positively released and hermetically sealed within plastic. ———————NOTE——————— 01. The FDA does not recognize any environmental hazards in reference to this product type. Appendix 1 (Hazards Tables) Category: Oil Products Subcategory: Cooking Oils	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. Due to the long time-tables associated with international freight shipping, USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified environmental hazards. ——————————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Oil Products Category No.: 1 Subcategory: Cooking Oils ——————————— ———————————

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: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

ANALYSIS & DETERMINATION *of* PHYSICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***Metal*** ☒ ***Glass*** ☐ ***Extraneous Matter*** ☐ ***Plastics*** ☐ ***Stones*** ☐ ***Wood*** ☐ ***Natural Component of Food*** ☐ ***Other***	1	2	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. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes visual inspection procedures to confirm that finished product is free from glass fragments prior to release (during bottling step). 02. Glass and Breakable Plastic Program in use. 03. All product flows through a centrifuge and is separated from any remaining water/physical material. 04. Supplier utilizes Filtration procedures to confirm that finished product is free from glass fragments prior to release (during bottling step). Details: Filtration of the oil before packaging is an important phase of the process as it allows the removal of suspended particles, impurities still present and any unwanted foreign bodies. 05. All product is positively released by PCQI. ———————NOTE——————— We respectfully request Filter's specifications.	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. ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Oil Products Category No.: 1 Subcategory: Cooking Oils ——————— ———————

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: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

ASSESSMENT *of* FOREIGN SUPPLIER

1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: Oleificio Santa Barbara - Soc. Coop. Agricola

1.2. Supplier address: Via Provinciale 40 Per Roma Snc, Scandriglia, Rieti, 02038, IT

1.3. Products manufactured/supplied: Olive Oil, Ready-to-eat.

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

GFSI Standard:

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

1.6. Has the supplier provided specifications? ☒ Yes ☐ No

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

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

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

2.0 SUPPLIER PROCEDURES, PROCESSES & PRACTICES

2.1. Does supplier follow current GMPs? ☒ Yes ☐ No

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

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

3.0 SUPPLIER PERFORMANCE HISTORY

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

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

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

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

☐ Yes ☒ No ☐ N/A *Description:* *No, Import Alert & Warning Letter search-results, which were conducted on – or about – the Review End date, have been attached to this FSVP Plan.*

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

Description: *No, as of this FSVP Plan's Review End date, USA has no knowledge of any recall undertaken by supplier.*

Continued onto next page.

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

ASSESSMENT *of* FOREIGN SUPPLIER

3.0 SUPPLIER PERFORMANCE HISTORY *(Continued)*

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

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

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

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

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

☒Yes ☐No *Description:* *Yes, supplier (either directly, or through the FSVP Importer) has provided timely and adequate responses to our inquiries and requests.*

4.0 SUPPLIER APPROVAL

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

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

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

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

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

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

Additional Recommendations:

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

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

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola

Product: Extra Virgin Olive Oil (Organic)

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

Review Start: July 14, 2021 Review End: Aug. 07, 2021

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Claims Made Against Product

Organic. USA's review has not taken this claim into consideration as part of the FSVP verification process.

Overview *of* Foreign Supplier's Commercial Operation

Oleificio Santa Barbara - Soc. Coop. Agricola certifies that their facility is responsible for controlling all biological, chemical, and physical hazards (per Part 117) and serves as the manufacturer and exporter.

Testing Program & Accreditation

Certificates of Analysis received from supplier.
Dated: October 12, 2020.
Tested for: Acidity.
Laboratory: Minifood.
Note: We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified chemical hazards (preferably by an ISO 17025-accredited laboratory).

Supplier & Product Allergen Information

Supplier certifies that: A) there are NO allergens handled on site, 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 meant that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), tthe 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.

The oil can be packaged in bottles, with capacities ranging from 0,10 to 1 liter, and in tins from 2 to 5 liters. The bottling plant is semi-automatic. All dosing and bottling operations are carried out taking care to avoid oxygen contact with the product, because precisely in these phases the oil undergoes oxidative changes.

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola

Product: Extra Virgin Olive Oil (Organic)

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

Review Start: July 14, 2021 Review End: Aug. 07, 2021

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Supplier GFSI Status & Historical Performance

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

Close Supplier Monitoring

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.

NOTE

We respectfully request

- recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified chemical hazards (preferably by an ISO 17025-accredited laboratory).
- Filter specifications.

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

ADDENDUM

NOTE

Labeling Requirements

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

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

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

Food Allergen Labeling and Consumer Protection Act

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

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Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA
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

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Steve Mandernach, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti

AFDO

Certificate # 31d8ad94

FSPCA
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:

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

Gerald Wojtala, Executive Director
International Food Protection Training Institute

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

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AAFCO
Association of American Feed Control Officials

Certificate # 223faa17

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA

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

09/14/2018

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 | ILLINOIS INSTITUTE OF TECHNOLOGY

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AFDO

Certificate # d2e9c287

Produce Safety ALLIANCE

AFDO — ASSOCIATION OF FOOD & DRUG OFFICIALS SINCE 1896

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

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

Joseph Corby
Executive Director, AFDO

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

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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Foreign Supplier Verification Programs

delivered by Lead Instructor

Bob Bauer

completed on

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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Bob Bauer

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09/14/2017

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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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Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

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CLAUDIO INNOCENTI

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

FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD

delivered by Lead Instructor

Amanda Evans

completed on

07/25/2017

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

Gerald 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
ILLINOIS INSTITUTE OF TECHNOLOGY

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AFDO

Certificate # 2d697331

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

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FSPCA
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

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

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AFDO

FSPCA
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

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Certificate # 917b0241

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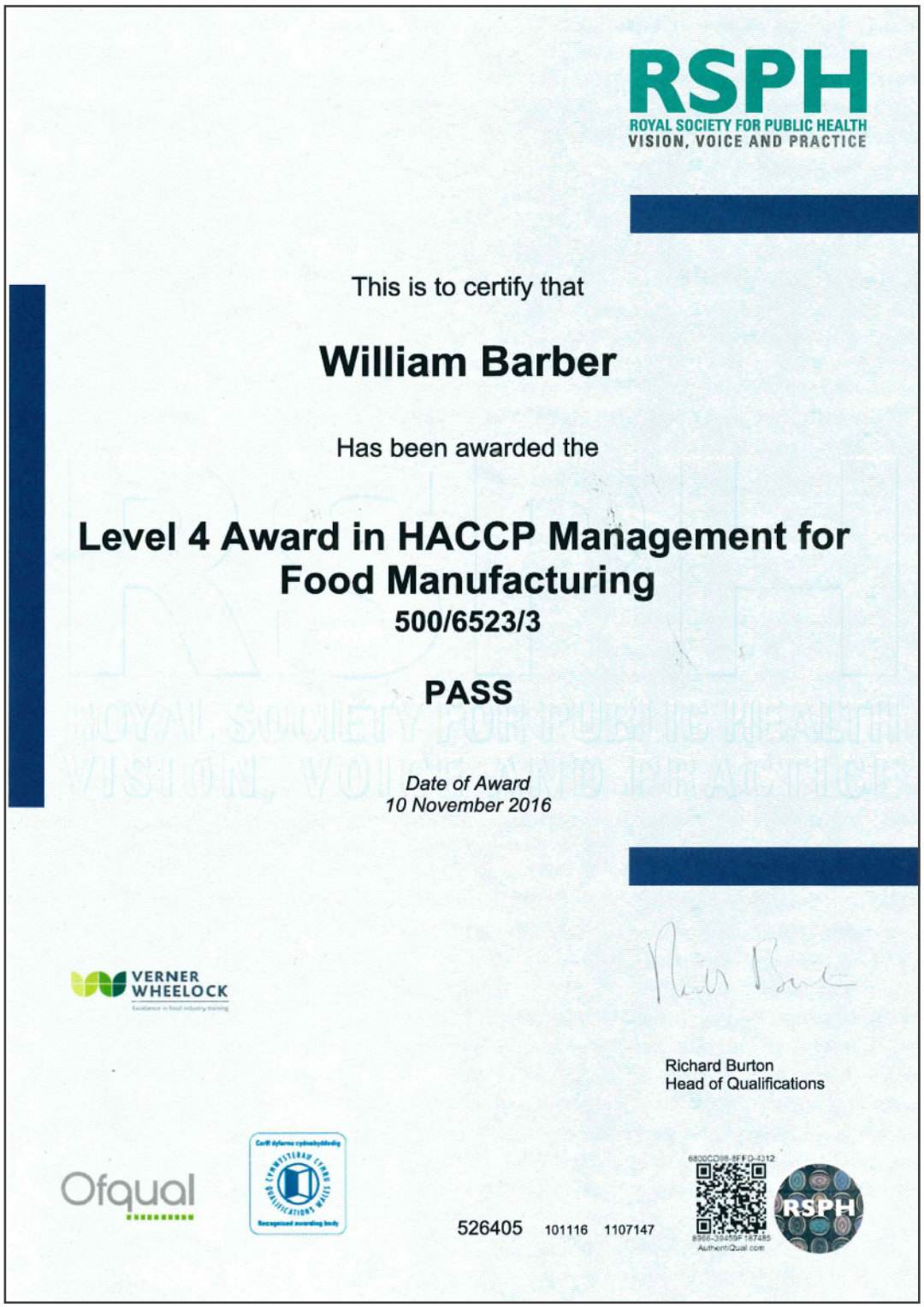

RSPH
ROYAL SOCIETY FOR PUBLIC HEALTH
VISION, VOICE AND PRACTICE

This is to certify that

William Barber

Has been awarded the

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

PASS

Date of Award
10 November 2016

VERNER WHEELOCK

Richard Burton
Head of Qualifications

Ofqual

526405 101116 1107147

RSPH

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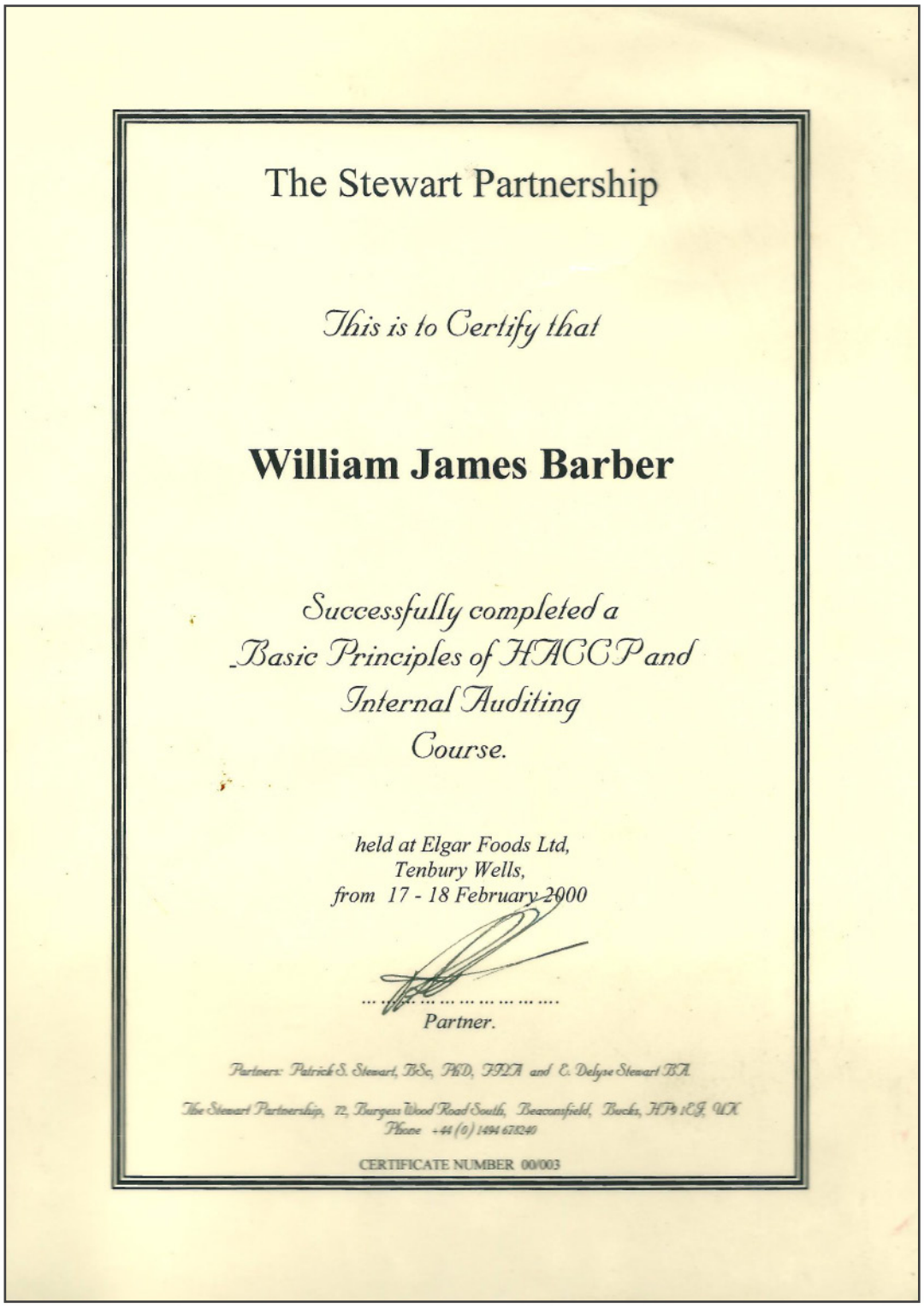


The Stewart Partnership

This is to Certify that

William James Barber

Successfully completed a Basic Principles of HACCP and Internal Auditing Course.

held at Elgar Foods Ltd, Tenbury Wells, from 17 - 18 February 2000

..... *Partner.*

Partners: Patrick S. Stewart, BSc, PhD, FIFST and E. Delyse Stewart BA

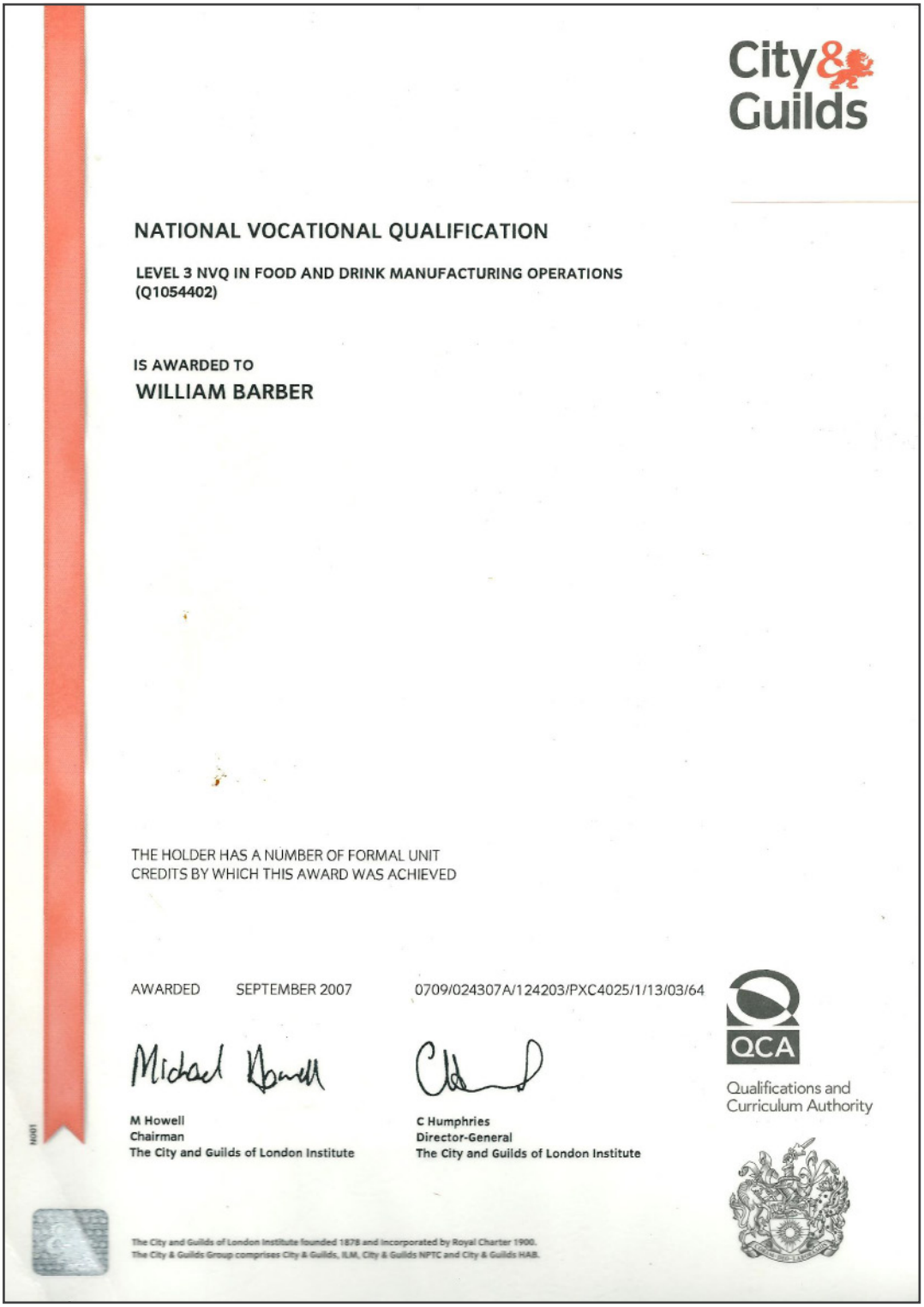
The Stewart Partnership, 72, Burgess Wood Road South, Beaconsfield, Bucks, HP9 1EJ, UK. Phone +44 (0) 1494 678240

CERTIFICATE NUMBER 00/003

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT



City & Guilds

NATIONAL VOCATIONAL QUALIFICATION

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

IS AWARDED TO

WILLIAM BARBER

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

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

M Howell
Chairman
The City and Guilds of London Institute

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

QCA
Qualifications and Curriculum Authority

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

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

City & Guilds

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

IS AWARDED TO
WILLIAM BARBER

WHO ATTENDED PERSHORE GROUP OF COLLEGES

AND WAS SUCCESSFUL IN THE
FOLLOWING TEN UNITS

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

CONTINUED

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

M Howell
Chairman
The City and Guilds of London Institute

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

R01

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

Supplier: Oleificio Santa Barbara - Soc. Coop. Agricola Product: Extra Virgin Olive Oil (Organic)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 14, 2021 Review End: Aug. 07, 2021

SUBSTANTIATING DOCUMENTS

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

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

SELF CONTROL MANUAL FOR THE FOOD HYGIENE
HACCP SYSTEM

PREPARED ACCORDING TO THE LAW CEE N 178/2002; 852/2004; 853/2004
Elaborated 21 ottobre 2020

RAGIONE SOCIALE	**COOP. COLTIVATORI DIRETTI DI SCANDRIGLIA**
LEGAL REPRESENTATIVE	**DE ANDREIS PIERINO**
PARTITA IVA	**00636130577**
REGISTERED OFFICE	**STRADA PROVINCIALE PER ROMA SNC. – SCANDRIGLIA (RI)**
WAREHOUSE	**STRADA PROVINCIALE PER ROMA SNC. – SCANDRIGLIA (RI)**
CITY	**SCANDRIGLIA**
TELEPHONE	**0765/878792**
HEALTH PERMIT	**N. PROT._____DEL____/____/_____**

R.I.A.	**PIERINO DE ANDREIS**

INSPECTORS:

SEE ORGANIZATION CHART

INDEX:

PREMESIS

This document has been elaborated by the team reported in the ***Procedure followed for the manual eleboration*** chapter based on data given by the Head of the food company, by meticoulus inspection on the field and on the seven principles of the HACCP system.

Legal rappresentative

DE ANDREIS PIERINO

Head of food company (signature)

PIERINO DE ANDREIS

GOALS

Based off of this manual the company has the following goals:

1. Respect the requirement of food hygiene as reported by the rule *CE n. 852-853/2004*
2. Constantly improve the quality of the products offered to the customers, especially from an hygiene point of view;
3. Improve the employees' formation, in particular the food hygiene concepts and the behaviours to adopt for a constant personal hygiene;
4. Minimize the waste of those products that can't be given to customers because not suficiently safe from a hygienic point of view;
5. Increase the loyalty of the customers and at the same time increase the business and the company's profit.

FIELD OF APPLICATION

This Manual describes the System of Self-Control and Correct Hygienic Practices adopted by the Organization and represents an internal organizational and operational reference to guarantee and demonstrate the commitment of the Management and of all the operators involved to ensure the conformity of its products and services to the safety, legality and quality requirements, as established by the laws in force.

In order to determine the risks for the healthiness and safety of food products (the suitability of food for human consumption from a hygienic point of view), the type of raw materials used, the type of finished product, the under which it has been treated and packaged and any other operation to which it is subjected, including administration to the consumer and the conditions in which it is displayed or in which it is stored, prior to sale or supply.

The design of the Self-Control System mainly made use of specialized bibliography, organizational models and international standards and the many years of experience of workers, consultants and above all company staff. This system is based on the H.A.C.C.P. (Hazard Analysis Critical Control Point) which allows to identify the risks relevant to food safety and the appropriate measures to keep them under control or to reduce them to an acceptable level. The HACCP method is based on seven application principles, as defined in the Codex Alimentarius:

- Analysis of the potential hazards associated with the various stages of the production process
- Identification of critical control points (CCP)
- Definition of critical limits to ensure control of critical points
- Establishment of a CCP monitoring system
- Definition of corrective actions
- Determination of the verification system
- Definition of the registration and planning documentation appropriate to these principles and to their application.

This Self-Control Manual applies to all activities related to:

- milling of olives
- storage of virgin olive oils.
- bottling of virgin olive oils.

The personnel currently operating must comply with the provisions of the Self-control Manual.

DEFINITIONS

The main words used in the manual**:**

RELIABILITY: aptitude of a person to perform the required function under the established conditions and for a specific period of time or the probability of success or the percentage of failures.

UPDATE: immediate and / or planned activity to ensure the application of the most recent information.

RISK ANALYSIS: process of collecting and interpreting information with the aim of identifying significant potential hazards, assessing their probability of occurrence (risk) and severity.

AUDIT: systematic, independent and documented process to obtain audit evidence and evaluate objectively, in order to establish to what extent the reference criteria have been met.

SELFCONTROL: all the operations that allow you to identify in your company every phase that could be critical for the safety of food products and that allow you to apply and keep up-to-date the appropriate safety procedures using the principles on which the HACCP system is based.

AGRICULTURAL COMPANY: any public or private entity, with or without profit, which carries out one or more of the following activities: production, preparation, transformation, manufacture, packaging, storage, transport, distribution, handling , the sale or supply, including administration, to the consumer.

CORRECTIVE ACTION: action aimed at eliminating the cause of a detected non-compliance or other undesirable situations detected.

PREVENTIVE ACTION: action to eliminate the cause of a potential non-compliance or other undesirable potential situation.

PACKAGING: the placement of a food product in a wrapper or container placed in direct contact with the food product in question, as well as said wrapper or container.

CONTAMINATION: introduction into food of microorganisms, chemical or physical agents that can alter their safety and integrity.

CONTROL: activity aimed at ensuring and maintaining compliance with the criteria established in the HACCP plan.

CONTROL AND TEST: measurement, examination, testing, verification activities for one or more characteristics of a product or service, against specified requirements, in order to ascertain its compliance with the specifications contained in a Specification.

CLEANING: operation aimed at removing, even with the aid of specific detergent substances, the patina of dirt (oil, pomace, other unwanted substance) adhering to the surfaces.

DEWEBBING: elimination of dust, debris and cobwebs from the processing rooms.

DISINFECTION: an operation that tends to eliminate pathogenic germs from the surfaces and to break down the microbial load, guaranteeing safe hygienic-sanitary conditions.

BEGINNING OF ACTIVITY AFFIDAVIT (DIA): document with which the food operator, the natural or legal person responsible for ensuring compliance with the legislation, declares and communicates to the territorially competent ASL that the food activity carried out complies with all the regulations in the food and non-food sector.

FLOWCHART: schematic and systematic presentation of the sequence and interactions between the phases.

LABELING: all the indications, trademarks or trade marks, images or symbols referring to the food product and appearing directly on the packaging or on a label affixed to it or on the closure device or on signs, rings or bands tied to the product itself.

PHASE: operation, procedure, equipment, activities along the production process, including raw materials, from procurement to final consumption.

PRODUCTION CHAIN: sequence of phases and operations involved in the production, processing, distribution, storage and management of a food and its ingredients, from primary production to consumption.

MATERIAL FLOWS: raw materials, additives, semi-finished products and packaging materials that, at any point in the supply chain, enter the production process.

DANGER ENTITY: extent of the damage to the health of the consumer.

IDENTIFICATION: method used to define the identity of a product.

FOOD PRODUCT HYGIENE: all the necessary measures to guarantee the safety and hygienic health of food products. These measures cover all stages from primary production to preparation, processing, manufacturing, packaging, storage, transport, distribution, handling, sale or supply, including administration, to the consumer.

CRITICAL LIMIT: value that separates acceptability from non-acceptability.

HACCP METHOD: (Hazard Analysis and Critical Control Point): scientific and systematic method to ensure the safety of food products, from primary production to final consumption, through the identification, assessment and control of significant hazards.

CONTROL MEASUREMENTS: action or activity (food safety) that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

MONITORING: performing a planned sequence of observations or measurements to assess whether the control measures are working as intended.

NON COMPLIANCE: failure to meet a requirement.

ORGANIZATION: set of people and means with defined responsibilities, authorities and interrelationships.

DANGER FOR FOOD SAFETY: biological, chemical or physical agent in the food, or condition of the food, which can potentially cause harm to the health of the consumer.

HACCP PLAN: the set of written documents that identifies in a formal and detailed manner all the procedures to be followed for the establishment and implementation of the HACCP system.

BASIC: basic condition and / or activity necessary to maintain a hygienically suitable environment for the production, processing and supply of food safe for human consumption.

CONTROL PROCEDURE: procedure to be established at each CCP to define how control is ensured.

PROCEDURE: the set of related or interacting activities that transform incoming elements into outgoing elements.

PRODOTTI NON TRASFORMATI: unprocessed food products.

RAW MATERIALS: products of primary production including products from the land, farming, hunting and fishing.

TRSFORMED PRODUCTS: food products obtained from the processing of unprocessed products.

END PRODUCT: product that is not subjected to further processing or processing by the organization.

CRITICAL CONTROL POINT (CCP): point, phase or procedure at which it is essential for the safety of the food to exercise a control action to prevent or eliminate or reduce to an acceptable level a danger to the safety of the food.

CONTROLLO POINT (CP): essential step to control the likelihood of introducing food safety hazards and / or the contamination or proliferation of food safety hazards in the product or in the working environment.

REQUIREMENT: need or expectation that can be expressed, generally implicit or binding.

SECOND LOOK: activity carried out to verify the suitability, adequacy, effectiveness of something to pursue the established objectives.

TRACEABILITY: ability to reconstruct the history and to follow the use of a product through documented identifications (relating to material flows and operators).

SANIFICATION: together with the cleansing and disinfection operations, destruction of the microbial forms still anchored on the surface.

FOOD SAFETY: concept aimed at excluding the possibility that food products may cause harm to the consumer if prepared and / or consumed in accordance with the intended use.

NON COMPLIANCE PROCEDURE: action to be taken with regard to a non-compliant entity (process, product, organization) in order to resolve the non-compliance.

REFERENCES OF LEGISLATION AND GOOD PRACTICE

The analyzes and considerations developed in this manual are based on a series of national regulations, both horizontal and vertical, as well as on the latest CE Regulations on food hygiene. The following table shows the standards to which reference was made to draw up the self-control manual:

TYPE MEASURE	N°/YEAR	TOPIC
Law	30 April 1962 n. 283	"Hygienic regulation of the production and sale of foodstuffs and beverages"
Decree of the President of the Repubblic	n.327 26 March 1980	"Implementation regulation of Law 30/04/62 n. 283 and subsequent amendments regarding the hygiene regulations of the production and sale of food and drink substances
D.P.R.	777 of 23/08/82	Materials and articles intended for contact with food.
Decree law	n. 109 of 27 January 1992	"Implementation of Dir. 89/395 / EEC and Dir. 89/396 / EEC concerning the labeling, presentation and advertising of food products"
Circolare	21/1995	Ministry of Health: Guidelines for Good Hygiene Practice Manuals
D.M.	09/08/95	Maximum limits of residues of active substances of plant protection products tolerated in products of plant and animal origin.
Direttiva	1/1997	Piedmont region: Guidelines for self-control
D.M.	27/01/97	Maximum quantities of residues of the active substances of health aids tolerated in products intended for food.
D.Lgs.	22 of 05/02/97	Implementation of EEC Directives 91/156 on waste, 91/689 on hazardous waste and 94/62 on packaging and packaging waste.
Circolare	1/1998	Ministry of Health: Guidelines for Good Hygiene Practice Manuals
D.Lgs.	31 of 02/02/01	Implementation of EEC Directive 98/83 relating to the quality of water intended for human consumption.
Regulation CE	n. 178/2002	Which establishes the general principles and requirements of food law, establishes the European Food Safety Authority and establishes procedures in the field of food safety;
Legislative Decree	n. 181 of 23 June 2003	"Relating to the labeling and presentation of food products, as well as related advertising"
Regulation CE	n. 852/2004	On the hygiene of food products;
Regulation CE	n. 853/2004	Specific rules for the hygiene of food of animal origin
Regulation CE	n. 854/2004	Specific rules for the organization of official controls on products of animal origin intended for human consumption
Regulation CE	n. 882/2004	Official controls aimed at verifying compliance with feed and food legislation and with animal health and welfare standards
Regulation CE	n. 1935/04	Materials and objects intended to come into contact with food products and which repeals Directives 80/590 / EEC and 89/109 / EEC.
Regulation CE	n. 2073/2005	Microbiological criteria applicable to food products

TYPE MEASURE	N°/ANNO	TOPIC
Regulation CE	n. 2074/2005	laying down implementation procedures relating to certain products referred to in regulation (ec) no. 853/2004 of the european parliament and council and the organization of official controls in accordance with the regulations of the european parliament and council (ec) no. 854/2004 and (ec) no. 882/2004, derogation from regulation (ec) no. 852/2004 of the european parliament and of the council and amendment of regulations (ec) no. 853/2004 and (ec) no. 854/2004
Legislative Decree	n.190 of 05 April 2006	"Sanctioning discipline for violations of EC Reg. 178/2002 which establishes the general principles and requirements of food law, establishes the European Food Safety Authority and establishes procedures in the food safety sector"
Regulation CE	n. 1881/2006	"which defines the maximum levels of some contaminants in food products"
Regulation CE	n.1883/2006	"establishing the sampling and analysis methods for the official control of the levels of dioxins and dioxin-like PCBs in some food products"
Regulation CE	n. 333/2007	"concerning the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo (a) pyrene in food"
Legislative Decree	n.193 del 06 novembre 2007	"Implementation of Directive 2004/41 / EC relating to controls on food safety and application of Community regulations in the same sector"

PROCEDURE FOLLOWED FOR THE ELABORATION OF THE MANUAL

In order to elaborate the manual of self control a work group for the HACCP system had to be created. Due to the size of the company, the group is formed by **DE ANDREIS PIERINO**, as holder of the company and as R.I.A.

The group has carried out an accurate analysis of the warehouse making sure the space meets the hygienic requirements requested by the current law and the rule of good practice, since the hygienic risks for the food can't neglect those coming from the working spaces.

After having provided the above analysis, the work group analized the working process of the company, in order to:

- identify and describe the products;
- determine the categories of homogeneous customers/consumers (chapter: company activity analysis) and the risks that they can run into while consuming the product.

The working process was then confronted with the laws commonly approved by good practice, in particular with the risk analysis system and the HACCP critical point control (Hazard Analysis and Critical Control Points), in order to achieve the self control system. Such system has been made following the phases listed below:

PHASE 1: ANALYSIS, IN EACH STEP OF THE PROCEDURE, OF THE RISKS FOR THE HEALTHINESS OF THE FOODS.

This consisted in identifying the present risks in each phase of the process and in the valuations of their risks. It's a delicate phase and of extreme importance because if the risk isn't identified the remedies to keep it under control can't be applied. This could lead to negative effects, in case the risk emrges. The risks can be classified in:

- chemical: contamination of unknown chemical substances, that aren't part of the original composition of the food, that can be achieved either on purpose or unintentionally.
  The contamination of the food due to these substances can implicate chronic diseases, meaning a prolonged exposure in time to minimal substances, that manifest during time after being exposed, with variable symptoms and difficult to identify. The chemical substances can derive from:

  - raw materials;
  - machineries or packaging that could brake and release chemical substances;
  - agronomic residues (pesticides, agrochemicals, ecc…), veterinary procedures (antibiotics and sulfonamides), zootechnics procedures (use of hormones and steroids), cleaning treatment and disinfection (detergents), industrial drain,

vehicles' pollution, industrial working, technological help, superficial treatments, di environmental contaminant, ecc…;

- toxic substances;
- environmental pollution

- Physical hazards: physical contaminants can derive from raw materials, especially of plant origin, or from the processing stages. In both cases, these are mainly accidental, not attributable to systematic errors in the process or in the conduct of certain operations, which in any case involve serious problems, the most important of which is possible damage to the health of the consumer, such as injuries to the mouth or gastrointestinal system and breakage of teeth. The presence of physical contaminants can also cause damage to machinery and equipment during the production process, as well as alterations in the organoleptic characteristics of a product. Even if the aforementioned problems do not occur, the discovery of foreign material in a food product still entails considerable damage to the image for the manufacturer.

  The food can be contaminated by various types of material, among which we mention:

  -**Glass fragments**, which can mainly cause cuts or lacerations to the mouth and gastrointestinal tract. They can mainly contaminate the raw materials of vegetable origin, as they can be taken together with the soil with the collection, or they can derive from glass containers for food due to technological problems (es: use of returnable bottles ot in perfect condition) or accidents during storage and transport;

  -**Metals**, which may also be already present in the raw materials of vegetable origin or contaminate the product during the processing stages due to the accidental detachment of metal components of the machinery or due to the fall of jewelry or other metal accessories of the operator, the latter reason why operators are prohibited from wearing watches, rings and any other jewelery during the work shift;

  -**Gravel and sand grains**, coming from raw materials;

  -**Wood chips**, coming from the ground or from pallets or packaging material;

  -**Plastic**, already present in raw materials or coming from containers;

  -**Machinery components**, whose presence depends on wear or poorly performed maintenance operations

  -**Hair and excretion of the personnel in charge of the manipulation** of the foods, which in addition to constituting physical contamination, as we shall see later, also involve biological contamination;

  -**Jewelery or jewelery parts of food handling personnel** degli alimenti, which is why it is forbidden to wear them during processing.

- microbial dangers: presence of saprophytic microorganisms and / or pathogenic microorganisms in the food. The presence of saprophytic microorganisms affects the shelf life of the food as it is

responsible for its alteration, for which the duration of a product is inversely proportional to the amount of saprophytes present on it, while the presence of pathogenic microorganisms can cause disease in humans by ingestion.

The dangers of a microbial nature are those that statistically create the greatest problems both from a sanitary and qualitative point of view. The identification, for each phase of the company's production process, of the dangers of biological contamination was therefore carried out with particular attention, in the awareness of the danger of the consequences for the health of the consumer, deriving from the occurrence of microbial contamination of the food.
Based on the scientific literature on the subject, the following aspects must be kept in mind:

a. the most common sources of contamination are constituted by:

- **ground**;
- **water**;
- **air**;
- **animals**;
- **Vehicles** such as plant, machinery, tools and work equipment, processing or washing water, ecc…;
- **Carriers** such as flies, cockroaches, rats, ecc…;
- **Personnel** in charge of the manipulation;

b. Microbial hazards can arise at any point in the production process. For this reason, many researchers divide microbial contamination according to when they tend to occur. This classification system, although not entirely accurate, as the same source of contamination often intervenes several times during the preparation of food, deserves, at least from the didactic point of view, to be followed. Microbial contamination can therefore be distinguished in:

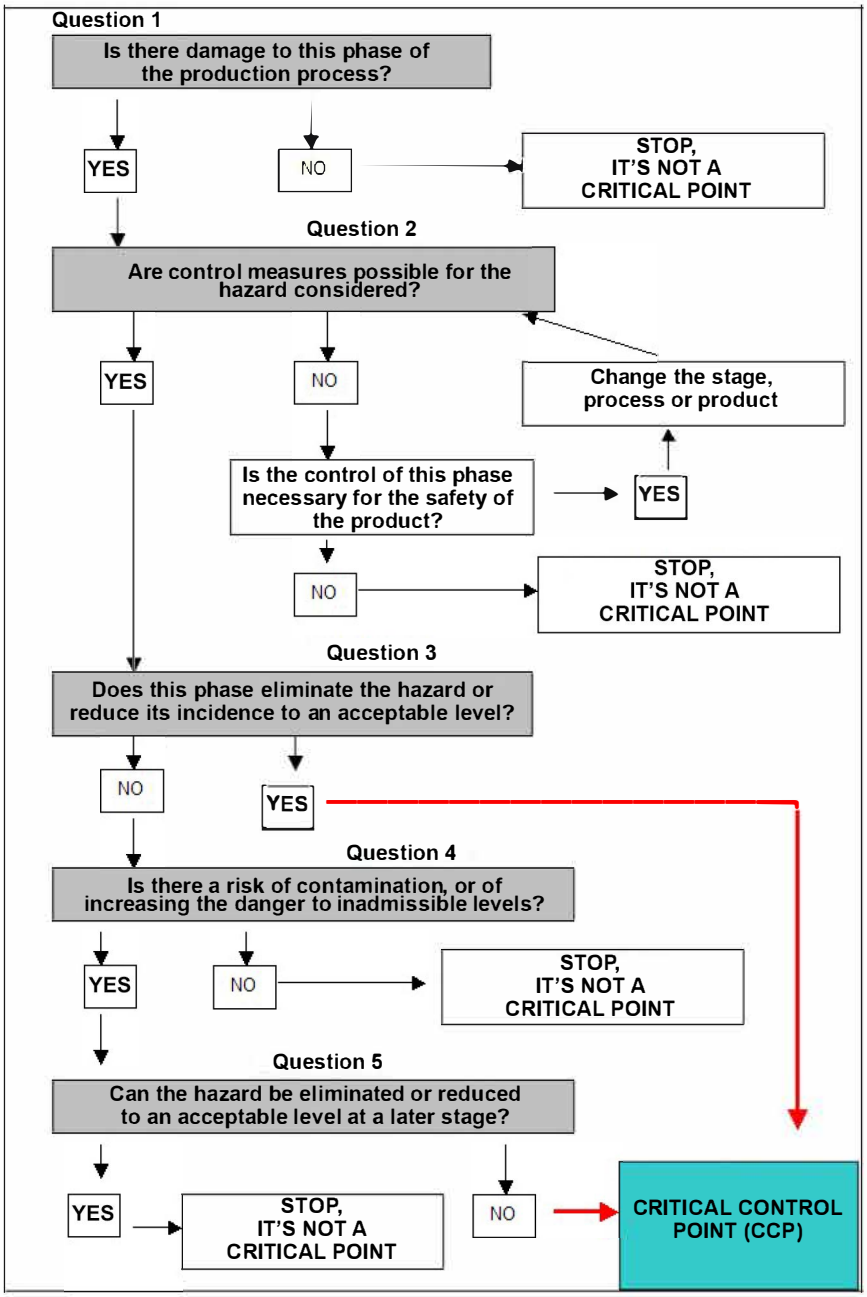
- primary contamination: biological contamination is already present at the origin, so the raw material is already contaminated by water, air, soil and microorganisms present in the animal itself. Hence the need to pay particular attention to the phase of receipt of raw materials, which is also a critical point for what concerns chemical and physical contamination;
- secondary contamination: biological contamination of food occurs during the processing phase. This phase can in fact involve a change in the chemical and physical structure of the raw materials making them more sensitive to the action of microorganisms and causing a selection of the microbial flora present on them. This type of contamination affects the epidemiology of food borne infections considerably more than the others, and is mainly due to the hygienic conditions

of the work environment and the hygienic conditions of the personnel involved in handling food;

- tertiary contamination: biological contamination occurs during the preservation and marketing of food by the same sources of contamination previously mentioned. This type of contamination is of particular importance in the sector of collective catering and pre-cooked dishes;
- quaternary contamination: occurs at the domestic level and in collective catering during the food preparation phase. Also in this case all the sources of contamination already mentioned for primary and secondary contamination are involved, but the most important role belongs to the operators in charge;
- cross-contamination: passage of microorganisms from one substance to another (usually from a raw to a cooked food product) by contact between them.

PHASE 2: IDENTIFICATION, FOR EVERY PHASE AND FOR EVERY DANGER, OF THE CONTROL POINTS (CP) AND CRITICAL CONTROL POINTS CCP.

This phase consisted in identifying for each phase of the production process the so-called "critical points" or all those activities critical to the health and hygiene of the product whose control is carried out through the GMP application, and the "critical control points" or those phases of the production process to which it is possible to apply prevention measures that allow to eliminate, prevent or minimize a danger, which in most cases has arisen in previous moments.
Any physical, chemical or other factor that can be used to control an identified health risk is a preventative measure.



PHASE 3: DEFINITION OF THE CRITICAL LIMITS, AND POSSIBLY OF THE OPERATIONAL LIMITS, TO BE RESPECTED TO KEEP THE IDENTIFIED CCPs UNDER CONTROL, AND OF THE GOOD PRACTICE RULES (GMP) FOR CPs, NECESSARY TO KEEP THE PRODUCT IN SAFE CONDITIONS.

Once the CCPs were identified, the working group proceeded to:

identify the parameters (biological, chemical or physical) to be used to control the CCPs in order to guarantee the hygienic and sanitary safety of the product (the most commonly used parameters are temperature, pH, the aw, time, humidity, total acidity, NaCl concentration, active chlorine, net weight, viscosity, preservatives, ecc…);

- establish, for each CCP, the critical limit, or a maximum and / or minimum value of the parameter which cannot be overcome as it determines the boundary between a compliant and non-compliant product.

PHASE 4: DEFINITION OF THE MONITORING PROCEDURES OF THE CRITICAL LIMITS, AND POSSIBLY OF THE OPERATIONAL LIMITS, FOR CCPs.

In order to ensure that the self-control is carried out in a functional and efficient way, the working group has identified procedures for monitoring the parameters capable of promptly highlighting the exceeding of critical limits and implementing the appropriate corrective actions;

PHASE 5: DEFINITION OF CORRECTIVE ACTIONS TO BE TAKEN IN THE EVENT OF NON-COMPLIANCE DETECTED IN A CCP.

This phase consisted in planning in advance the actions to be taken if the monitoring of the parameters shows a tendency to deviate or a real deviation from the established criteria, in order to avoid acting in an improvised manner. The corrective actions to be implemented if there is a tendency towards a deviation from the established criteria differ from those to be implemented in the event of deviation from the established criteria. In the first case we act on the monitored parameters in order to prevent the onset of damage and we therefore speak of preventive actions, while in the second case we act on a damage that has already occurred by managing a non-compliant situation and the action to be taken. implementing is defined as corrective;

PHASE 6: IDENTIFICATION AND APPLICATION OF CRITICAL POINTS CONTROL AND SURVEILLANCE PROCEDURES.

De-localized control procedures are general procedures, not connected to a specific phase of a production or distribution process but capable of exercising control over several phases of the same processes, as they allow the CPs to be controlled. In consideration of the particular nature of the Company, it seemed logical to refer to the following guidelines:

- Directive No. 1/1997 Piedmont Region: guidelines for self-control, developed by the Piedmont region;

The attention of the working group was therefore focused on those Generalized Critical Points which, if kept under strict control, offer considerable peace of mind on the hygiene of the finished product. The Generalized Control Procedures, applicable in every type of Company, therefore concern:

- selection and verification of suppliers;
- control of incoming goods;

- cleaning and disinfection;
- rodent control e disinfection;
- tool maintenance;
- water potability check;
- temperature check;
- waste removal;
- hygiene and personnel outfit;
- personnel formation.

PHASE 7: PERIODIC REVIEW, AND ON THE OCCASION OF VARIATIONS OF EACH PROCESS AND OF THE TYPE OF ACTIVITY, OF THE ANALYSIS OF RISKS, OF THE CRITICAL POINTS AND OF THE CONTROL AND SURVEILLANCE PROCEDURES.

The self-control system is an effective preventive tool that significantly increases the quality assurance of the production process and the finished product. However, it should not be forgotten that this system is not static but dynamic and through appropriate periodic checks, must aim at progressive improvement as, however well structured, it cannot absolutely prevent the occurrence of a non-conformity, but learning from one's mistakes prevents it from occurring a second time. For this reason the working group proposes to carry out control audits aimed at verifying:

- The correct application of the procedures by the staff;
- The correct document management of the system.

COMPANY ACTIVITY ANALYSIS

COMPANY ACTIVITY:

PRODUCTION AND SALE OF VIRGIN AND EXTRA VIRGIN OLIVE OIL
PRODUCTION AND SALE OF VIRGIN AND EXTRA VIRGIN OLIVE OIL OF ORGANIC ORIGIN

CHARACTERISTICS OF THE PRODUCT:

Olive oil is a fat that occurs in a liquid physical state at room temperature (20°C), and is constituted from a chemical point of view for 98-99% of a mixture of triglycerides called fraction "saponification" and for the remaining 1-2% from a set of compounds they represent the 'non saponification".

Rich in the right amount of unsaturated and polyunsaturated fatty acids, as required by modern dietology, it contains among the minor constituents, but no less important, in addition to beta-carotene (provitamin A) and Tocopherol (vitamin E), a whole range of antioxidants (phenolic compounds, ecc.) very important both for the conservation of the oil and from a nutritional and anti-aging point of view (free radical antagonists). Phytosterols are also important for their regulatory action on the absorption of cholesterol. Extra virgin olive oil, due to its peculiar qualities and its low acidity, is the best type of condiment to be used raw.

Virgin olive oils, free of water, nitrogenous substances and other growth factors, do not represent a substrate for the development of pathogenic or toxic microorganisms for humans. In addition, the production cycles of virgin oils, which are distinguished among other things by the total absence of additives or technological adjuvants, contribute to making the chemical risk associated with "process" contamination irrelevant.

The shelf life is indicated on the package with specification of the permitted life time (shelf life). The product must in any case be kept cool, possibly away from direct light and in containers full to the brim and tightly closed.

INTENDED USE:

The oils produced can be:

· withdrawn by the member and intended for his direct consumption

· packaged and sold directly to the final consumer

However, due to the type of individual references and the commercial and distribution chain, it is believed that no category of end user and consumption occasion can be excluded.

PROCESS DESCRIPTION:

1. RECEPTION OF OLIVES:

The partner delivers the olives he has collected to the company in slotted plastic boxes. The olives are weighed, identified and stored in the warehouse awaiting their pressing.

During the acceptance phase of the raw material, a series of quantitative and qualitative and identification checks are carried out which are fundamental for the correct management of the product, especially that of the supply chain. The supply chain product delivered is stored in an area previously identified with a sign (generally, the chain product is immediately sent for processing).

To prevent and minimize the possible development of molds and toxins, the drupes are stored in fenestrated plastic boxes raised from the ground, in a cool and airy environment, avoiding stasis of the olives for more than 48 hours.

2. DEFOLIATION AND WASHING:

In this phase the olives are deprived of leaves and twigs by means of a defoliator (which they reach via conveyor belts). It consists of an aspirator that removes leaves and twigs and a washing machine that removes the earthy residues and any water-soluble pesticides present on the peel with water. Defoliation aims to avoid the sour-astringent and bitter character of the leaf. Small quantities of fresh leaves can be tolerated in order to enhance the "fruity" character of some oils.

3. CRUSHING:

Once deprived of all impurities, the olives are ready to be pressed with mechanical crushers. The pressing of the olives has the purpose of releasing the oil from the vegetable tissues; a coarse paste is thus obtained composed of chopped pulp and stone fragments which, acting as draining, they favor the separation of the liquid part from the solid one. In the crushers, the drupes are processed in closed environments which reduce the risk of natural oxidation of the oil when it escapes from the oil cells to come into contact with atmospheric oxygen. In addition, the oil produced is spicier, richer in natural antioxidants, and therefore more preservable.

4. KNEADING

After pressing, the dough is sent to the kneading machine where it slowly undergoes continuous stirring in order to favor the meeting of the oil drops and increase the quantity of free oil: there is a need to reach 30 ° C with times ranging from 50 to 90 minutes and the heating is carried out with water circulation. The kneading times may undergo slight fluctuations depending on the progress of the production cycle.

The verification of the correctness of the processing times is carried out through a visual and tactile check by the mill manager who can delegate duly trained employees. The temperature of the paste coming out of the kneading machine must not exceed 37 °C.

5. EXTRACTION BY CENTRIFUGATION:

In the continuous system, the extraction takes place in a cylindrical / conical rotor by applying a centrifugal force; the aim is to separate, in a single step, the different parts of the kneaded paste (water, oil, pomace), taking advantage of the different density values.

6. SALE:

The quantities of oil that leave the mill must be identified and placed in containers (silos, tanks, drums) suitable for the transport of food.

If storage is carried out in containers provided by the buyer or by the partners, the mill Manager must ascertain the suitability and cleanliness of the container itself before using it.

7. STORAGE:

After the planned checks, the oil is stored in tanks in the warehouse area. The tanks, described in the plan, are marked with a label showing the number of the same.

The self-control manager guarantees the storage of the product in silos/containers correctly identified with signs indicating the number of the silos, the storage lot and the varieties.

8. FILTRATION:

Filtration of the oil before packaging is an important phase of the process as it allows the removal of suspended particles, impurities still present and any unwanted foreign bodies.

9. PACKAGING:

The oil can be packaged in bottles, with capacities ranging from 0,10 to 1 liter, and in tins from 2 to 5 liters. The bottling plant is semi-automatic. All dosing and bottling operations are carried out taking care to avoid oxygen contact with the product, because precisely in these phases the oil undergoes oxidative changes. Oxygen is the element responsible for the oxidative rancidity that occurs in the lipid matrix. The handling of the oil in the various phases is carried out using exclusively food-grade pipes.

The packaging operator also monitors the filling phase of the bottles in order to ensure that they remain intact and do not suffer shocks, collisions, breakages and chipping. Subsequently, the bottles are labeled by a machine that glues both the labels and the back labels.

Full and closed containers are cartoned and stored in a cool place before shipping.

The packaged product requires adequate storage conditions, away from light and heat, in order to avoid qualitative decay and subsequent downgrading of the oil. For this reason, it is necessary to periodically check the storage warehouse of the finished product in order to find any non-conformities that could compromise the quality of the product.

NB: The organic processing is carried out at different times compared to other processing (before or after the processing of non-organic olives).

In order to avoid contamination between the two different types of olives:

- **upon receipt of goods, the organic products are stored in a separate area from the rest of the olive oil**
- **before processing the organic, the machinery is cleaned and sanitized**
- **the organic oil is stored in containers (silos) distinct from the others and identified in order to allow their recognition.**

ANALYSIS OF THE COMPANY PREMISES

The business activity takes place in **VIA PROVINCIALE PER ROMA SNC. – SCANDRIGLIA (RI)**

The plant is located away from sources of contamination and the access road is well established and kept clean.

The plant, as reported in the company plan available in the company, is divided into different areas:

- Operative (where the manufacturing and bottling process takes place): processing room and bottling room;
- Warehouses: n. 3 warehouses.
- Offices: n. 2 offices.
- Locker room: n. 2 Locker room.
- Restrooms.
- display and sale of products.

The facilities have been designed, built and sized in order to allow effective cleaning and disinfection and to effectively comply with the mandatory regulatory requirements aimed at ensuring maximum respect for hygiene and wholesomeness of production. In a special area, the loading / unloading, reception and acceptance control of the raw material is carried out in order to limit and restrict the residence times of the drupes in flow areas. The raw material follows a preferential path to control and reduce possible cross-contamination with the subsequent stages of production.

FLOORING AND WALLS

Walls and flooring are made of durable materials that exclude the formation of cracks and the possibility of contamination of the environment and / or of the products being processed.

The floor of the processing areas is made of washable, disinfectable and non-slip material.

The walls, suitably tiled, are light in color and easily washable to simplify cleaning and disinfection operations.

CEILINGS, WINDOWS AND DOORS

The ceilings, which are also made of durable material and free of cracks, are designed, constructed and finished in order to avoid the accumulation of dirt and reduce condensation, the formation of mold and the scattering of particles.

The office windows have aluminum frames and are equipped with insect screens to prevent the entry of pests; the doors have smooth, non-absorbent surfaces that are easy to clean and disinfect.

LIGHTING AND VENTILATION

The electrical system is built according to CEE standards, equipped with grounding.

The premises are structured in such a way as to guarantee conditions of temperature, ventilation and brightness suitable for carrying out work and inspection activities. These conditions are sufficient to ensure an appropriate microclimate, regular air exchange and to avoid the proliferation of mold on ceilings and walls as well as the development of bad odors.

RESTROOMS

The restrooms have the connection to the water system, the toilet with delivery and drain of water, toilet paper holder, sinks with cold and hot water fittings, manual soap dispenser, paper towels, trash can with pedal openning.

Furthermore they have washable walls that can also be easily disinfected, they have a dressing room and are not in the production area.

WATER SUPPLY

The warehouse has a water system directly connected to the city's aqueduct, requirement that guarantees the potability.

ANALYSIS OF THE MACHINERY AND EQUIPMENT USED

All the machineries for the production are built with materials by law, compatible with the food, easily accessible for cleaning and disinfection and with anti-hardship protection according to the current law. The warehouse is suitable for the making of the foods according to the Regulation (CE) N. 852/2004 attached and the health permits.

The following machineries are used by the company:

DESCRIPTION	N° / NOTE
Defoliator	With CE label and manual book
Washer	With CE label and manual book
Crusher	With CE label and manual book
Kneading machine	With CE label and manual book
Centrifuge	With CE label and manual book
Extractor	With CE label and manual book
Silos	7
Filter	With CE label and manual book
Bottling machine	With CE label and manual book
Corking machine	With CE label and manual book
Labeller	With CE label and manual book

All machineries are easy to clean and disinfect, and are kept in perfect hygienic conditions.

PROCESSING METHOD

Represented below is the entire productive process, including the description of the whole sequence and different phases, the raw materials and the residues, the wastes and areas of possible rework.
In the representation of the productive process, symbols based off of the law UNI ISO 9004_4 have been adopted:

- for the raw material and the end product the eclipse: 
- for the operations/phases the rectangle: 
- for the by-products and wastes the triangle: 
- for the semi-finished products the square: 
- the arrows show the direction of the flow: 

Fig. 1 Olive oil productive process flow

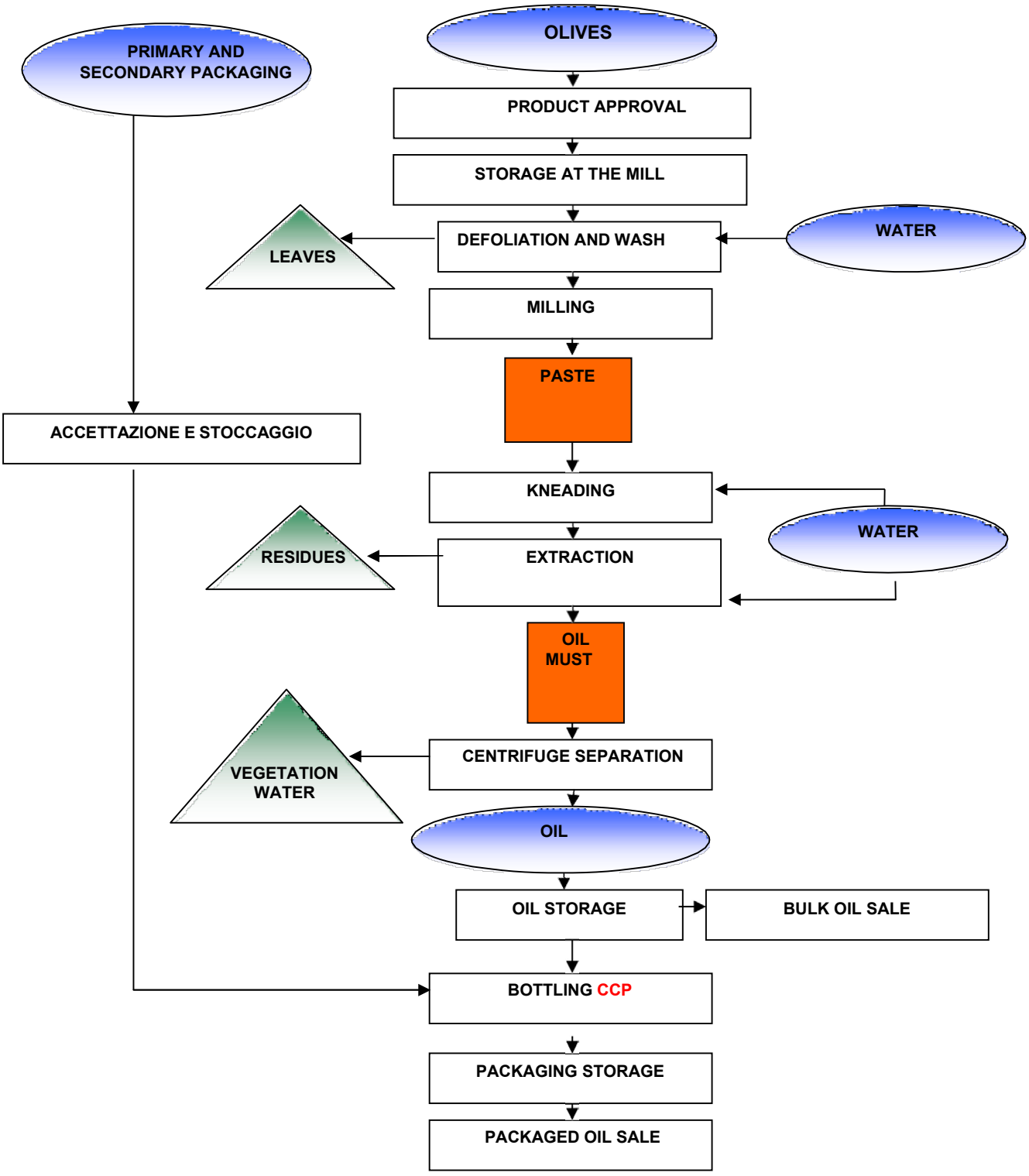
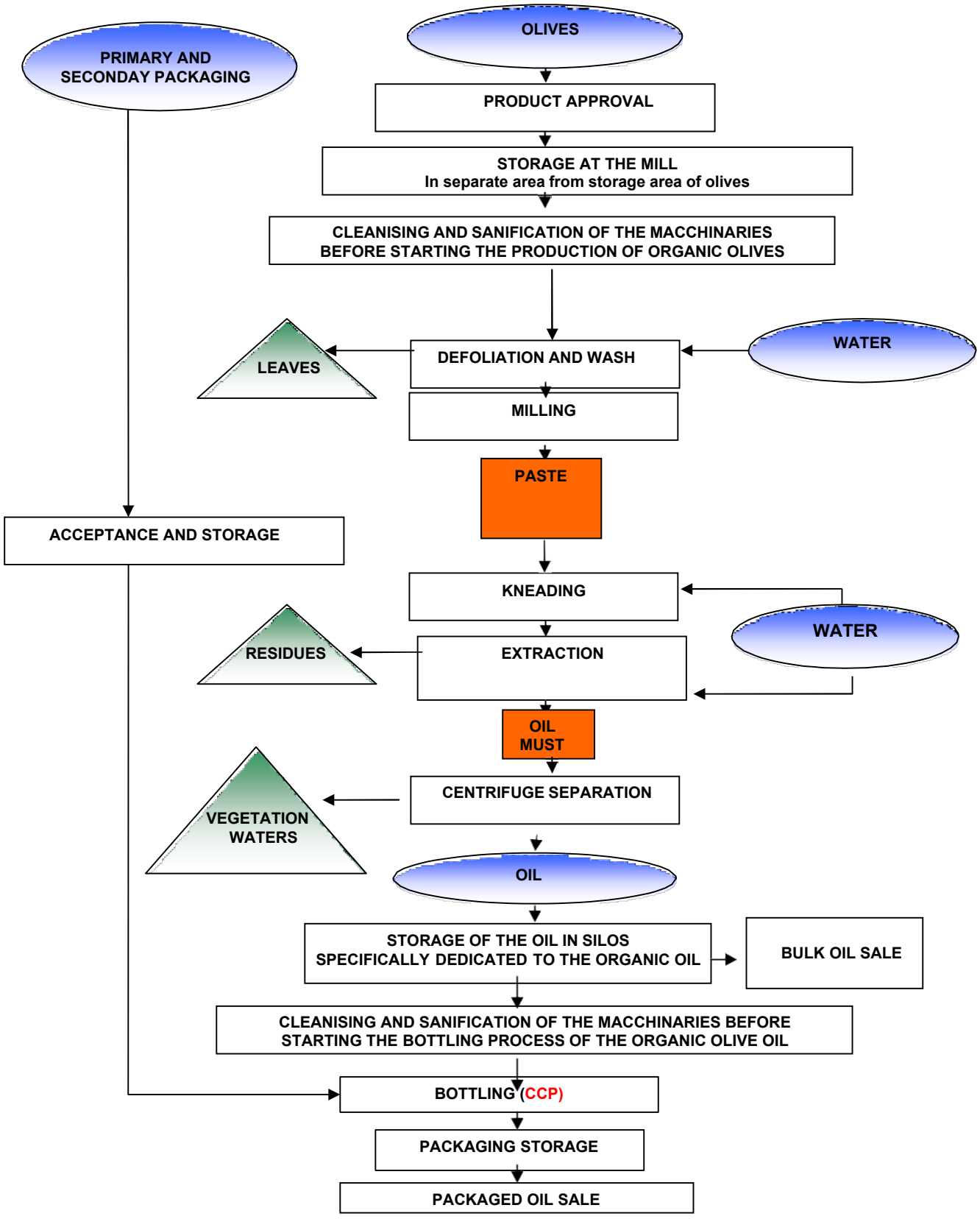


Fig. 2 Organic olive oil productive process flow



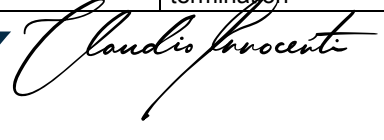
CRITICAL POINT OIL PRODUCTION AUTOCONTROL PLAN

LEGEND:
CCP = CRITICAL CONTROL POINT

CP = CRITICAL POINT
NC = NON COMPLAINT

CRITICAL POINT	PHASE	PRODUCT	IDENTIFIED RISK	CRITICAL LIMIT	CHECK DONE	KIND OF CONTROL	PREVENTIVE ACTION	CORRECTIVE ACTION
CP	**Storage**	olives	oxidative phenomena mold formation, due to lack of ventilation, excess of humidity or inadequate system of olive disposition.	Absence of oxidative phenomena and mold	presence of oxidative phenomena presence of mold	Visual	The areas for the storage of the olives have an adequate ventilation system to prevent humidity and condensaiton	waste goods nc
CP	**All**	olives	Infestation contamination	Absence of infestation	Presence of infestation or presence of traces of infe-station	Visual	Sanitation of the area and monitoring of the infestation: all employees periodically sanitize and monitor to reduce or eliminate the risk of contamination from insects. Formation of the employees	Disinfestation carried out by specialized company; nc opening; removal of contaminated goods; Repeat the formation of the employees that show incorrect hygienic procedure, possible termination
CP	**Defoliation** **Milling**	Olives Semi-finished (oil paste	All phases that involve the use of machinery may have a risk	Eligibility of the tools that are in contact with the goods	Eligibility in contact with the goods	Visual	Check of the presence of certificates of eligibility in contact with food,	waste goods; nc opening

CRITICAL POINT	PHASE	PRODUCT	IDENTIFIED RISK	CRITICAL LIMIT	CHECK DONE	KIND OF CONTROL	PREVENTIVE ACTION	CORRECTIVE ACTION
	Kneading **Extraction**	must) End product (oil)	Establish the onset risk given by the release of the metallic ions from the machineries; this could be due to machineries not being suitable for food treatment				Before purchasing the machineries and the materials intended to touch the foods	
CP	**Defoliation** **Milling** **Kneading** **Extraction**	Olives Semi-product (oil paste must) End product (oil)	All the phases that require the use of machineries may determine the risk of contamination from chemical product's residue use during the cleansing and disinfection of the machineries or during the maintenance of them	Absence of chemical residues	Visible presence of chemical residues	Visual, on the presence of visible chemical residue and on the cleaning/ disinfection modality	Correct cleaning and disinfection of the machineries as reported in the cleaning and disinfection plan Training of the employees	waste goods; nc opening Repeat the formation of the employees that show incorrect hygienic procedure, possible termination
CP	**Oil Storage**	oil	Contamination due to foreign substances released by the containers, due to the use of improper material/tools	Eligibility of the material in touch with the foods	Eligibility of the material in touch with the foods	Visual, on the documents accompanying the purchase of the material	Before purchasing the machineries and the materials intended to be in touch with the food, check the presence of the certificates of eligibility. Use containers classified as 'for food' possible in stainless steel	waste goods;; nc opening;
CP	**Oil Storage**	oil	Physical contamination and biological due to the containers	Absence of visible dirt and physical contaminants	Presence of dirt and physical contaminants	Visual	Correct cleaning and disinfection as reported on the cleaning and disinfection plan Training of the employees	waste goods; nc opening; Repeat the formation of the employees that show incorrect hygienic procedure, possible termination



CRITICAL POINT	PHASE	PRODUCT	IDENTIFIED RISK	CRITICAL LIMIT	CHECK DONE	KIND OF CHECK	PREVENTIVE ACTION	CORRECTIVE ACTION
CCP	**Bottling**	oil	Possible glass fragments contamination that could cause damage to the consumer	Absence external bodies	Presence external bodies	Visual	Training of the employees Check procedure of primary and secondary packaging Correct storage of packaging material	Removal of non compliant products Non compliant opening Repeat the formation of the employees that show incorrect hygienic procedure, possible termination
CP	**Bottling**	oil	Physical contamination and biological (bottles)	Absence of visible dirt and physical contaminants	Presence of dirt and physical contaminants	Visual	Correct cleaning and disinfection as reported on the cleaning and disinfection plan Training of the employees	Waste goods; nc opening; Repeat the formation of the employees that show incorrect hygienic procedure, possible termination

CRITICAL POINT FOR ACCEPTANCE AND STORAGE PACKAGING AUTOCONTROL PLAN

LEGEND:

CCP = CRITICAL CONTROL POINT

CP = CRITICAL POINT

CRITICAL PLAN	PHASE	PRODUCO	IDENIFIED RISK	CRITICAL LIMIT	CHECK DONE	KIND OF CHECK	PREVENTIVE ACTION	CORRECTIVE ACTION
CP	**ACCEPTANCE**	PACKAGING	Physical contamination	Absence of dirt Packaging integrity	Presence of dirt Packaging not intact	visual	Quality check of packaging entering applied Training of the personnel	Waste goods; nc opening Repeat the formation of the employees that show incorrect hygienic procedure, possible termination
CP	**ACCEPTANCE**	PACKAGING	Biological contamination	Absence of infestation	**Presence of infestation**	visual	Quality check of packaging entering applied Training of the personnel	Waste goods; nc opening Repeat the formation of the employees that show incorrect hygienic procedure, possible termination
CP	**ACCEPTANCE**	PACKAGING	Chemical contamination due to the promiscuity of the packaging to the chemical prodcuts	**Absence of chemical products stored in load compartment of carrier**	storage promiscuity	visual	Quality check of packaging entering applied Training of the personnel	waste goods nc opening Repeat the formation of the employees that show

CRITICAL POINT	PHASE	PRODUCT	IDENTIFIED RISK	CRITICAL LIMIT	CHECK DONE	KIND OF CHECK	PREVENTIVE ACTION	CORRECTIVE ACTION
								incorrect hygienic procedure, possible termination
CP	**STORAGE**	PACKAGING	Physical contamination	Absence of dirt Packaging integrity	Presence of dirt Packaging not intact	visual	Quality check of packaging entering applied Training of the personnel	waste goods nc opening Repeat the formation of the employees that show incorrect hygienic procedure, possible termination
CP	**STORAGE**	PACKAGING	Biological contamination	Absence of infestation	**Presence of infestation**	visual	Quality check of packaging entering applied Training of the personnel	waste goods nc opening Repeat the formation of the employees that show incorrect hygienic procedure, possible termination
CP	**STORAGE**	PACKAGING	Chemical contamination due to the promiscuity of the packaging to the chemical prodcuts	**Assenza prodotti chimici stoccati nell'aera di stoccaggio imballaggi**	storage promiscuity	visual	Quality check of packaging entering applied Training of the personnel	waste goods nc opening Repeat the formation of the employees that show incorrect hygienic procedure, possible termination

1. SUPPLIERS SELECTION

The olives are given by the members of the cooperative. The members can pick up the end product for personal use and get packed in order to sell to the consumer.

2. QUALITY CHECK OF THE RAW MATERIAL :

Goal: avoid compromised raw materials from the hygienic point of you from entering the facility.

The member delivers the olives that he has picked to the cooperative in plastic boxes.
As soon as the Coop approves the product, the olives will go through a hygienic check which is carried out by a professional elected by the cooperative. He will do a few sample checks, which will be of fundamental importance for the correct handling of the product, especially that of the production chain:

PRODUCT	color	odor	aspect	temperature of product or of packaging	Boxes	Expiration or validity
olives	♦	♦	♦		♦	

- Color: the color has to be traditional
- Odor: absence of abnormal odors
- Aspect: absence of mold and oxidative phenomena, absence of rotten parts
- Packaging:
    - **the crates in which the olives are carried have to be in plastic, intact, and with crevices**

What to do in case of non compliance:

- CORRECTIVE ACTION: Good refusal
- NON COMPLIANCE REPORT ACTIVATION

3. PACKAGING QUALITY CHECK:

Goal: forbid the entrance of damaged or contaminated packaging.

The packaging used is eligible according to the regulation in act related to materials intended for food contact.
As soon as the Coop approves the product, the packaging will go through a hygienic check which is carried out by a professional elected by the cooperative. He'll carry out the following tests:

Product	External Aspect	Packaging Integrity	Hygienic conditions of carrier	Attached documents
Packaging (bottles and cartons)	♦	♦	♦	♦

- External appereance: absence of dirt, infesting, physical contamination on packaging
- Packaging integrity: absence of veining or glitch on packaging
- Hygienic conditions of carrier: absence of dirt, infesting, various physical contamination and chemical products inside load compartment
- **Attached documentation: compliance certificate of the packaging (it has to be certified the eligibility for food contact)**

What to do in case of non compliance:

- CORRECTIVE ACTION: Good refusal
- NON COMPLIANCE REPORT ACTIVATION

4. RAW MATERIAL STORAGE PROCEDURE:

Goal: avoid contaminating the raw material while storing.

Generally the raw material given by the members is worked immediately.

In order to prevent and minimize the possible development of mold and toxins, the drupes are stored in plastic crates, with crevices, lifted from the ground, in a cool and ventilated space. Storage over 48 hours is avoided.

The raw materials are processed in the order of arrival.

Storage area: warehouse raw material storage.

What to do in case of non compliance:

- CORRECTIVE ACTION: removal of contaminated product, Repeat the formation of the employees that show incorrect hygienic procedure, possibly terminate them.
- NON COMPLIANCE REPORT ACTIVATION

5. PACKAGING STORAGE PROCEDURE:

Goal: avoid contamination and packaging damages during storage.

The packaging are stored in specific areas, lifted from the ground and positioned in a way to avoid damages.

The storage space is cleaned and disinfected following the procedure reported in this manual.

What to do in case of non compliance:

- CORRECTIVE ACTION: removal of contaminated product, Repeat the formation of the employees that show incorrect hygienic procedure, possibly terminate employees who do not adhere.

- NON COMPLIANCE REPORT ACTIVATION

6. OGANIC OLIVES PRODUCTION PROCESS

Goal: avoid cross contamination.

In order to avoid cross contamination between the organic products and the traditional products, the following precautions will be taken:

- Raw material reception: the organic raw materials are identified with signs
- Storage: during the storage, mixing the organic olives with those farmed traditionally will be avoided
- Production: before proceeding with the production of the organic olives, the personnel will clean the machineries and tools (that have been in touch with the olives farmed traditionally) according to what is indicated in the cleaning and disinfection plan (see cleaning and disinfection procedure).
- Conservation: organic oil is stored in dedicated silos.
- Bottling: the bottling of the organic olive oil is carried out at a different time compared to the bottling of the traditional oil; before proceeding with the bottling of the organic oil the personnel will clean the machineries according to what is indicated in the cleaning and disinfection plan.

What to do in case of non compliance:

- CORRECTIVE ACTION: removal of contaminated product, Repeat the formation of the employees that show incorrect hygienic procedure, possibly terminate them.
- NON COMPLIANCE REPORT ACTIVATION

7. BOTTLING

Goal: avoid contamination of the oil with glass fragments or dirt that has deposited on the bottles.

The bottles and the packaging are checked the first time when received, stored in a way to prevent inadvertent damages and the contamination and checked again when pulled out for use.

The person in charge of bottling gets the bottles for the storage, brings them to the bottling area where he carries out a visual check where he establishes its integrity and cleanliness.

What to do in case of non compliance:

The damaged bottles are discarded and treated as waste, whereas the dirty bottles are cleaned and sanitized.
In both situations a non compliant report is opened, a description of the corrective actions are documented.

8. DISPERSAL OF THE WASTES PROCEDURE

Goal: avoid stockpile of the wastes and contamination of the food matrices

The wastes produced by the company can be categorized into two groups:

- empty packaging

- manufacturing of by-products

The empty paper packaging, are stored inside closed containers provided with a pedal opening, and given to the public trash collection service with special containers.

Currently the oil extraction system divides the oil paste into:

oil;

olive pomace;

vegetation waters.

The vegetation waters are formed by a liquid separated by centrifugation from the oil must, diluted water of the paste which is possibly used to ease the extraction of the oil and water for washing the olives. These last ones are reported in the regulation, regarding the dispersal, of 11 November 1996 that bears "agronomic use of the vegetation waters and dumping of the olive mills".
The law 574/96 allows the agronomic use of the vegetation waters through a controlled spread on land designated for agricultural use, without the necessity of treating the waters.

The olive pomace is formed by the fibrous part of the fruit and by the fragments of the pit. It contains a variable quantity of vegetation water. Since the olive pomace still contains some oil, it's given to factories for the treatment of olive pomace.

What to do in case of non compliance:

- CORRECTIVE ACTION: removal of contaminated product, Repeat the formation of the employees that show incorrect hygienic procedure, possibly terminate them.
- NON COMPLIANCE REPORT ACTIVATION

9. MANTAINANCE

Goal: ensure that the installations, the machinaries, the tools and the company utensils are always efficient

The tools in the company undergo a regular check and a periodic maintenance expected by the manufacturer, in order to always guarantee their complete efficiency and to avoid any possibility of contamination.

All extraordinary mantainence is carried out by a specialized company and are documented by invoices.

If the person in charge of monitoring should notice any trace in the workflow or in the product to be non complaint as reported in the procedure,

he/she will immediately inform the R.I.A., whom will have to apply the NON COMPLIANT PROCEDURE, described in the manual.

10. CLEANLINESS AND SANITATION

Goal: provide the correct methods for the cleaning and sanitation of the building and the installation therefore the compliance with the laws of hygiene as reported by the law (CE) 852/2004, in order to eliminate or minimize the risk of contamination of the product.

ORDINARY CLEANING AND SANITATION:

The cleaning of the space, of the installations and the tools are carried by in-house personnel.
The personnel is in charge of cleaning the exterior areas, the working space and storage, the bathrooms, the installations and the tools following the schedule below:

Cleanliness and sanitation program

AREAS		*Frequency*				
		Daily	*Weekly*	*Monthly*	*Beginning and end Harvest*	*When empty*
Exterior areas	Floors	CLEANSING			CLEANSING	
Work spaces	Workflow	CLEANSING			SANIFICATION	
	Plastic cans and crates				SANIFICATION	CLEANSING
	Floors and lower parts of walls	CLEANSING			SANIFICATION	
	Glass and windows		CLEANSING		CLEANSING	
	high parts of walls + ceilings			DEWEBBING	DEWEBBING	
Storage areas and/or Packaging	Tanks					SANIFICATION
	Floors and lower parts of walls	CLEANSING			SANIFICATION	
	Glass and windows		CLEANSING		CLEANSING	
	high parts of walls + ceilings			DEWEBBING	DEWEBBING	
Packaging storage areas	Floors and lower parts of walls			CLEANSING	SANIFICATION	
	glasses and windows			CLEANSING	CLEANSING	
	high parts of walls + ceilings				DEWEBBING	
Offices	Floors and lower parts of walls	CLEANSING			SANIFICATION	

AREAS		Frequency				
		Daily	*Weekly*	*Monthly*	*Beginning and end Harvest*	*When empty*
	Nets					
	Glasses and windows		CLEANSING		CLEANSING	
	high parts of walls + ceilings				DEWEBBING	
Locker Rooms	Floors and lower parts of walls	CLEANSING			SANIFICATION	
	Glasses and windows		CLEANSING		CLEANSING	
	high parts of walls + ceilings				DEWEBBING	
Bathrooms	Floors	SANIFICATION			SANIFICATION	
	Bathroom fixtures	SANIFICATION			SANIFICATION	
	Tile floors		SANIFICATION		SANIFICATION	
	Glasses and windows		CLEANSING		CLEANSING	
	high parts of walls + ceilings			DEWEBBING	DEWEBBING	

For the cleaning and sanification of the areas, the company uses hot drinkable water (D. Lgs. n.31 of 2 Febraury 2001), specific detergents with a high degrease level (NaOH base) and specific disinfectants, all approved by the Ministry of Health (the technical forms are kept in the office).

The products and the tools necessary for the cleaning are stored in a specific closet accessible only by the staff.

The ordinary and extraordinary cleaning and sanification (the latter is carried out and the beginning and end of the harvest) procedures are described in the following chart:

Fig. 1 Daily cleanliness and disinfection

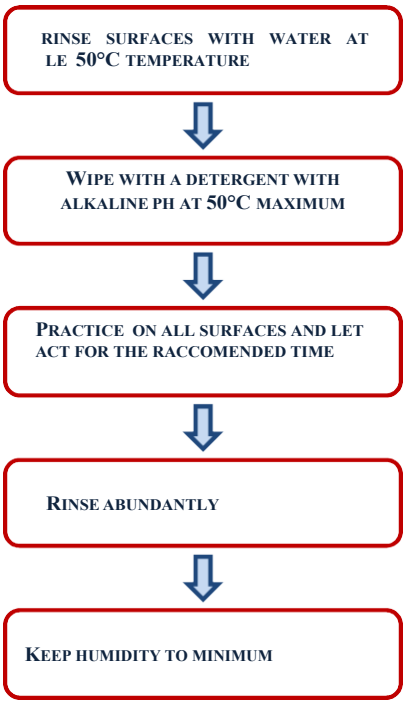
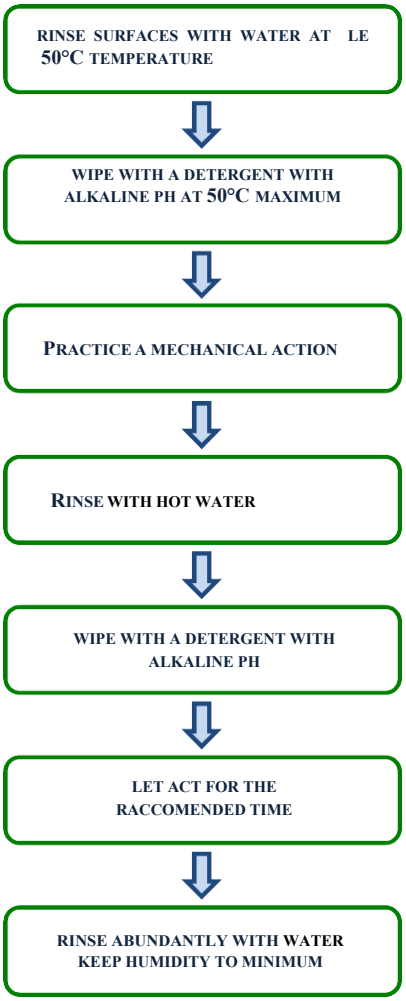


Fig. 2 Extraordianary cleanliness and disinfection (begining and end of harvest)



All cleaning procedures of the work space, the tools and the tanks are reported in the 'Cleanliness and disinfection registry'. A facsimile is reported in the 'Activity log cards self control' section.

As a reminder, the daily cleanliness and disinfection procedures are carried out at the end of the production nut also before starting the manufacturing of the organic olives.

What to do in case of non compliance:

- CORRECTIVE ACTION: apply extraordinary disinfection plan, repeat the formation of the employees that show incorrect hygienic procedure, possibly terminate them.
- NON COMPLIANCE REPORT ACTIVATION

11. FIGHTING THE INFESTANT AGENTS

Goal: to avoid the food from being contaminated by infestants.

Insects, acarus, rodents, birds and reptiles are all considered infestants.
It's of great importance to check for any infestant present in order to prevent any direct or indirect contamination of the food. It is also very important to handle correctly the chemical substances needed for disinfecting.
In order to obstruct the settlement of the infestants, certain actions are needed whereas to eliminate those already present in the warehouse the most appropriate measurements are required.
In order to obstruct the settlement of the infestants, the company has adopted the following rules:

- Periodic maintenance of the warehouse;
- Check for possible openings between doors and floors/walls;
- Isolation and obstruction of phone and electric panel;
- Installation of screens;
- Maintenance and cleanliness of internal and external areas (removal of weeds), so animals can't settle;
- Correct handling of wastes and by-products as well as removal of scraps for the perimeter of the warehouse;

Procedures for check:

The goal of the company is to monitor the possible presence of infestants. It buys appropriate tools from an external company all devices necessary to monitor possible presence of animals.
The company itself names in house staff in charge of monitoring the infestant agents.
The responsability in regards to the monitoring is reported in the MOD_1. The person in charge of monitoring, checks on a weekly basis, for any possible presence of infestants and records it in the Mod. 1.
In case of the presence of undesired animals, it's the manager's responsibility to open a non compliance ticket. It's also his responsibility to inform the pest control company who will be in charge of the following:

- Removal of contaminated food or food at risk of contamination;
- Personnel training;
- Identify procedures to decrease the possibility of infestation.

What to do in case of non compliance:

- CORRECTIVE ACTION: removal of contaminated food, reach out to pest control, repeat the formation of the employees that show incorrect hygienic procedure, possibly terminate them.
- NON COMPLIANCE REPORT ACTIVATION

12. POTABLE WATER

The building has a water installation that gets the water directly from the city's aqueduct, making the water automatically potable.

13. TRAINING OF THE EMPLOYEES ON THE SUBJECT OF FOOD HYGIENE

The person responsible of the food industry is in posses of the certificate of the 20 hours R.I.A. formation course, according to current rule. All of the employees are in possess of the personal nutritionist 8 hours formation course certificate, according to current rule.

All certificates are kept in the company's office.

14. PERSONAL HYGIENE

Goal: ensure an accurate personal hygiene of the worker.

The personal hygiene is fundamental to avoid contamination of the products, since the person can pass on bacteria from its hand to the food.

It's important the personnel carries out an accurate personal hygiene. It's known that a inadequate hygiene of the employees can create a danger for the safety of the products.

Below is a list of rules to follow in order for the worker not to be source of contamination.

BEFORE STARTING THE SHIFT:

- Remove necklaces, rings (only wedding band is allowed), watches, bracelets, earrings and personal items;
- Don't use perfumes or aftershave;
- Don't use cosmetics;
- Keep nails short and clean, no nail polish;
- Cosmetic or protective creams can be used only if completely absorbed before the beginning of the shift.
- Place any medicine for personal use, they have to be kept in the original packaging, in the locker at the disposal of supplied in order to avoid contamination of the work outfit. Pharmaceuticals (besides the life-saving) can't be brought inside the working areas and can be taken only outside of these spaces.
- Wear proper work outfit making sure it's clean and intact with no loose buttons:
  - Cap: must always be clean and protect all hair;
  - Shirts and pants: must be clean, intact and kept closed, pockets shouldn't contain any item that could fall during the shift;

- Gowns: must be of the right size, it's important that sleeves or loose limbs get in touch with the food; loose buttons should be repaired immediately; if the worker has to immerse its arm in the food, the sleeves have to be rolled up, to avoid any kind of contact;
- Gloves: they always have to kept intact, clean and they have to be changed or frequently washed;
- Footwear: they always have to kept intact and clean;
- Masks: if required by the job, they have to cover nose and mouth, they have to be replaced in frequently and disposed in the correct waste containers;
- Waterproof gowns: they always have to be intact and have to be washed in the designated emplacement.

- Wash hands;
- In case of cutaneous cut on hands and arms : protect with correct medication (es: band-aid);
- Don't introduce external objects and pens with lid into production areas;
- In case of problems with respiratory apparatus ask for a mask;

DURING THE SHIFT:

- Food, drinks, smoking and chewing gum is prohibited ;
- Wash your hands:
    - Before walking back in after the break;
    - Every time after eating, drinking or smoking in the court;
    - After having touched body part such as the nose, the eyes, the mouth, the ears, the hair;
    - Before and after going to the restroom;
    - After using the tissue;
    - After coughing or sneezing;
    - When moving from one position to another;
    - When starting a new task;
- Check the hygienic status of the working ares and the tools, if necessary go ahead and clean and disinfect;
- Never leave the utensils dirty between one task and the other;
- During production , never bring in brooms, rags and detergents;
- Limit the presence of packaging to minimal;
- Don't get fingers moist to grab paper or labels;
- Don't exit during the shift, in order to avoid contamination of clothes and shoes;
- Keep doors closed;
- Report to the manager any situation of non compliance (es.: unknown people, personnel with incorrect outfit, dirt, etc.);
- Immediately report to the manager any malfunctioning of the machinaries.

END SHIFT:

- Wash hands;
- Place work outfit in the disposal of supplied locker and proceed to the sanitation of the shoes and the DPI.

CONTAGIOUS SICKNESSES:

- Inform the manager of any contagious illness (tonsillitis, enteritis, skin disease, breathing apparatus and intestinal);
- In case of absence from work due do contagious sickness, it's necessary to ask the family doctor whether the illness can contaminate the food. If so, the person can go back to work only if the family doctor authorizes it with a written note stating healing took place. The note has to state the eligibility of the employee to touch the food. The note has to be handed in to the person in charge .

PERSONAL LOCKER:

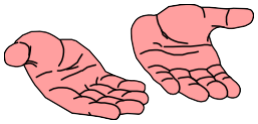
The lockers are divided into two compartments, one for the personal clothes and shoes and the other one for the working clothes and shoes.

- The employee is in charge of taking care of the locker and making sure to clean and disinfect it on a regular base.
- Preserve DPI, work clothes and shoes in one compartment, making sure they don't get in touch with personal clothes, shoes or items;
- It's forbidden to place chemical products in the locker: pharmaceuticals are allowed although they must be kept in original packaging and inside personal clothes.
- It's also forbidden to store food and drinks without packaging .

RACCOMENDED PROCEDURE WASHING HANDS:

1. Check for necessary tools: ensure liquid soap, nail brush, paper towel are available
2. Wet hand and arms with water around 45 °C
3. Apply soap on hands and brush, in order to have foam, scrub the nails, the fingers, back and front of hands
4. Rinse off hands and arms
5. Get more soap, wash again getting less accessible areas of the hand such as in between fingers
6. Rinse off again
7. Dry with paper towel which will then be thrown away.

THE HYGIENE OF OUR PRODUCT
COMES FROM THOSE OF OUR HANDS



What to do in case of non compliance:

- CORRECTIVE ACTION: removal of contaminated product, Repeat the formation of the employees that show incorrect hygienic procedure, possibly terminate them.
- NON COMPLIANCE REPORT ACTIVATION

15. CORRECTIVE ACTION

Implementation and maintenance manager: R.I.A.
Monitoring manager: RIA.
Goal: locate and eliminate the causes of non compliance

The company's self control plan foresees the planning and fulfillment of corrective actions with the purpose of pinpointing and eliminating the causes of non compliance found, in order to avoid future cases. The corrective actions to carry out in case of non compliance cases are reported in the 'Self control of critical point plan' section. For each manufacturing phase, potential hygiene risks for the foods are indicated and for each one of these phases there are the corrective actions to carry out. In case of non compliance, it's expected to open a non compliance report.

16. NON COMPLIANCE PROCEDURE MANAGEMENT

The goal of this process is to describe the way and responsibility for the Non Compliance (NC).

The procedure is applied in case of non compliance of the products provided, in the manufacturing process and in any other procedure.
The RIA is responsible of carrying out the procedure and verifying the correct fulfillment and efficiency of the corrective action: he has the task of analyzing and archiving the warning of the non compliance coming from the different functions/areas of the company and to decide relatively to operative solutions or possible corrective and/or preventive actions. Furthermore, he has to make sure the actions are carried out efficiently and within a set time.

DESCRIPTION OF THE PROCEDURE:

Each operator is responsible to identify and promptly report Non Compliance cases considering the company's self control system requirements that could appear during the fullfilment of the activities; all operators that find procedures or products non compliant to the regulations contained in the manual, **have to infrom the RIA, who will**:

1. **in case of product non comform** apply tag on the product identified;
2. will evaluate the Non Compliance (NC) and determine:
   - the corrective action (AC) to apply for the solution (Correction)
   - the person in charge of the NC resolution
   - the date set for the completion of the intervention.

3. will fill out the form "non compliant report", in which it'll be indicated:
    β) subject/activity referring to the NC stating:
        - supplier of the Non Compliant matter;
        - product/service in matter;
        - activity thanks to which the “Non Compliant”emerged;
    χ) Description of the Non compliance;
    δ) corrective action (AC) to carry out in order to solve (Correction) the NC
    ε) the person in charge of the NC resolution
    ϕ) the date set for the completion of the intervention..
    γ) progressive number of the Non compliance.
4. will verify the correct fulfillment and efficiency of the AC and:

    a) in case the AC has been applied correctly and had an efficient outcome, the non compliance is 'closed', and the date of closure will be shown.
    b) In case the resolution isn't carried out or doesn't have and efficient outcome, he will open a new 'non compliant' report and reactivate the same procedure described above.

A facsimile of the non compliant report to follow is reported in the 'Activity records of self-control sheet' section

17. TRACEABILITY AND RECALL OF THE PRODUCT PROCEDURE

SEE ATTACHMENT

18. SYSTEM CHECK

The revision is necessary to check the real validity and efficiency of the self control plan so that it can be determined whether or not the HACCP plan being used is still suitable.

Generally the audit is carried out when changes take place - for example, a market change, a pipeline change, a structural change, etc - and not more than a year from the last writing.

ACTIVITY REGISTRATION FOR THE SELF CONTROL SHEET

NON COMPLIANCE REPORT N. (assign a progressive number):
DATE ON WHICH THE NON-CONFORMITY WAS VERIFIED:

NON COMPLIANCE FOUND

- product/service referring to the NC: _____

- activity that revealed the NC: _____

- NC Description:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

CORRECTIVE ACTIONS USED:

_____

_____

_____

_____

_____

_____

_____

_____

MANAGER IN CHARGE FOR THE RESOLUTION OF THE NC:	_____
EXPECTED CLOSURE DATE OF THE NC:	____/____ /____
CORRECT TECHNICAL IMPLEMENTATIONS OF THE AC:	☐ YES ☐ NO
EFFICIENCYOF THE AC	☐ EFFECTIVE →**NC CLOSURE** ☐ NON EFFECTIVE→**NEED TO OPEN NEW NC REPORT**
NC CLOSURE DATE	____/____ /__
SIGNATURE OF THE MONITORING/TEST MANAGER (R.I.A.):	

CLEANING AND DISINFECTION REGISTRY: DAILY CLEANING ACTIVITY

Month _____Year _____From_____To _____

PRODUCTS USED FOR THE CLEANING:_____PRODUCTS USED FOR THE DISINFECTION: _____

DAY	EXTERNAL AREA: floors	PRODUCTION: processing line, floors and bottom part of walls	STORAGE AND/OR PACKAGING: floors and bottom part of walls	OFFICES: floors and bottom part of walls	LOCKER ROOMS: floors and bottom part of walls	RESTROOMS: floors, bathroom fixtures and bathroom fittings	OPERATOR IN CHARGE SIGNATURE
	INTERVENTION	INTERVENTION	INTERVENTION	INTERVENTION	INTERVENTION	INTERVENTION	
1	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
2	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
3	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
4	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
5	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
6	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
7	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
8	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
9	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
10	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
11	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
12	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
13	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
14	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
15	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
16	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
17	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
18	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
19	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
20	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
21	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
22	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
23	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
24	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
25	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
26	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
27	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
28	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
29	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
30	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	
31	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING	DISNFECTION	

CLEANING AND DISINFECTION REGISTRY: WEEKLY CLEANING ACTIVITY

Month_____Year _____

PRODUCTS USED FOR CLEANING: _____
PRODUCTS USED FOR DISINFECTING: _____

WEEK	PRODUCTION: glasses and windows	STORAGE AND/OR PACKAGING: glasses and windows	OFFICES: glasses and windows	LOCKER ROOMS: glasses and windov	RESTROOMS: tiled walls glasses and windows	OPERATOR IN CHARGE SIGNATURE
	INTERVENTION	INTERVENTION	INTERVENTION	INTERVENTION	INTERVENTION	
1	CLEANING	CLEANING	CLEANING	CLEANING	DISINFECTION tiled walls CLEANING glasses and windows	
2	CLEANING	CLEANING	CLEANING	CLEANING	DISINFECTION tiled walls	
3	CLEANING	CLEANING	CLEANING	CLEANING	CLEANING glasses and windows	
4	CLEANING	CLEANING	CLEANING	CLEANING	DISINFECTION tiled walls	

CLEANING AND DISINFECTION REGISTRY: MONTHLY CLEANING ACTIVITY

Month_____Year _____

DAY OF THE MONTH THAT HAS BEEN CLEANED	PRODUCTION: High walls and ceilings	STORAGE AND/OR PACKAGING High walls and ceilings	PACKAGING STORAGE Floors and bottom of walls Glasses and windows	RESTROOMS: High walls and ceilings	OPERATOR IN CHARGE SIGNATURE
	INTERVENTION	INTERVENTION	INTERVENTION	INTERVENTION	
	DEWEBBING	DEWEBBING	DEWEBBING	DEWEBBING	

CLEANING AND DISINFECTION REGISTRY: BEFORE AND AFTER HAVREST CLEANING ACTIVITY

PRODUCTS USED FOR THE CLEANING AND DISINFECTION:

ROOMS AND AREAS		ACTIVITY CARRIED OUT	HARVEST BEGINNING DATE	OPERATOR SIGNATURE	HARVEST END DATE	OPERATOR SIGNATURE
External areas	Floors	CLEANING				
Production areas	Production Lines	DISINFECTION				
	Plastic bins and crates	DISINFECTION				
	Floors and bottom part of walls	DISINFECTION				
	Glasses and windows	CLEANING				
	High walls and ceilings	DEWEBBING				
Storge area and/or Packaging	Floors and bottom part of walls	DISINFECTION				
	Glasses and windows	CLEANING				
	High walls and ceilings	DEWEBBING				
Packaging areas	Floors and bottom part of walls	DISINFECTION				
	Glasses and windows	CLEANING				
	High walls and ceilings	DEWEBBING				
Offices	Floors and bottom part of walls	DISINFECTION				
	Glasses and windows	CLEANING				
	High walls and ceilings	DEWEBBING				
Locker rooms	Floors and bottom part of walls	DISINFECTION				
	Glasses and windows	CLEANING				
	High walls and ceilings	DEWEBBING				
Restrooms	Floors	DISINFECTION				
	Fixtures and fittings	DISINFECTION				
	Tiled walls	DISINFECTION				
	Glasses and windows	CLEANING				
	High walls and ceilings	DEWEBBING				

Coop. Direct farmers of Scandriglia

FOOD TRACEABILITY PROCEDURE

REGULATION CEE N 178/2002

HACCP MANUAL 21/10/2020 ATTACHED

Processing 02/11/2020

COMPANY DETAILS

COMPANY	***Coop. Coltivatori Diretti di Scandriglia***
ACTIVITY	**Mill (olive milling)**
LEGAL and OPERATIVE OFFICE	**S.P. per Roma snc – Scandriglia (Ri)**
FOOD ACTIVITY MANAGER	**Pierino De Andreis**

Rev. 0	***02/11/2020***

Il R.I.A.

_____

1. Traceability procedures for food products

(Art. 17 Regulation Ce 178/ 2002 – Conference for relations between the state, the regions and the autonomous provinces of Trento and Bolzano - agreement 28 July 2005)
(Reg. CE 299/2013 – D.M. 8077/2009)

RESPONSIBLE FOR THE PROCEDURE

PIERINO DE ANDREIS

MONITORING MANAGER AND PROCEDURE MANAGER

PIERINO DE ANDREIS

The purpose of the following chapter is to ensure that the company is able to maintain the traceability of the food upstream, that is, to demonstrate what has entered its processing cycle and who has supplied it, so that, in a situation of emergency, it is possible to withdraw the lot or lots of a non-compliant product from the market . This objective is achieved through the adoption of systems and procedures that allow:

a) to make the relevant information available to the competent authorities upon request;

b) to collaborate in the withdrawal from the market of products that do not comply with food safety requirements and contribute to guaranteeing food safety by transmitting the information necessary for their traceability.

The traceability of olive oil is guaranteed through the SIAN electronic register, as well as by the packing slip of both the olives and the oil upon receipt and release. All this, even that stored in the company, is tracked through the electronic register.

1.1 Procedure for the withdrawal of food products from trade (art. 19 – 20 regulation CE 178/2002)

If the food business operator believes or has reason to believe, or becomes aware through the "Safety Notice" of the Ministry of Health, that a food does not comply with the health and hygiene safety requirements or that it presents a serious risk to health human, it must immediately:

A) SUSPEND THE SALE

B) INFORM THE CUSTOMERS

- the customers to whom he sold the product, according to the procedures set out in the circular letter from the ministry of health nr. 47556 of 15/12/2016, that is:
  1. disclosure of the recall notice by affixing signs at the point of sale;
  2. By disclosure on the company's website or social network profile, if in possession. In the event of a possible lack of a website or a page in the social media of the OSA, the recall notice published on the appropriate page of the portal of this Ministry will be sufficient and mandatory.

Below is attachement 1 for the recall criteria, with the model for the recall of the Ministry of Health, according to the indications given in the following link of the Ministry of Health (Recalls OSA: consumer information system)

http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=4633&area=sicurezzaAlimentare&menu=vuoto

RECALL CRITERIA

State - Regions agreement
13 november 2008
'Alert system guidelines'

SERIOUS RISK

- Likely immediate and / or short-term effects on human health
- sensitivity of a specific category of consumers
- Likely long-term effects on human health
- Likely long-term health effects of offspring
- Likely cumulative toxic effects

COULD THE PRODUCT HAVE GONE TO THE FINAL CONSUMER?

YES → WITHDRAWAL RECALL
- media/tv/radio
- signage
- website or social network

NO → WITHDRAWAL

YES → WITHDRAWAL RECALL
- signage
- website or social network

NO → WITHDRAWAL

SERIOUS RISK TO ACCEPT

Attachment D letters a - k

HAS A SCIENTIFIC EVALUATION BEEN CARRIED OUT?

COMPLETE → RISK LEVEL → THE PRODUCT MAY HAVE GONE TO THE FINAL CONSUMER

- BOTTOM
- MEDIUM → WITHDRAWAL
- HIGH → WITHDRAWAL / RECALL

PRELIMINARY / PARTIAL

First assessments to be carried out for the purpose of the recall

Risk communication Guidelines EFSA, July 2012

	RISK LEVEL	IMPACT	EXPOSED
WITHDRAWAL	LOW	Little impact on public health/ little interest of the public	No exposition
	MEDIUM	Little impact on public health/ strong public interest Medium impact on the public/ medium interest of the public	Limited exposure
WITHDRAWAL / RECALL	HIGH	Strong impact on public health/ little public interest Strong impact on the public/ strong interest of the public	Widesprade exposure/particular groups
	UNKNOWN	Unknown to evaluate	Unknown exposition

Allegato 2

Ministero della Salute
via G. Ribotta 5
Roma
Italia
00144
Tel.: +39123456789
Fax: +39123456789
www.salute.gov.it

Ministero della Salute

Modello di RICHIAMO

Data: | Marchio del prodotto:

Denominazione di vendita:

Nome o ragione sociale dell'OSA a nome del quale il prodotto è commercializzato:

Lotto di produzione:

Marchio di identificazione dello stabilimento/del produttore:

Nome del produttore:

Sede dello stabilimento:

Data di scadenza o termine minimo di conservazione:

Descrizione peso/volume unità di vendita:

Motivo del richiamo:

Avvertenze:

Inserire immagine uno:

Inserire immagine due:

Oleificio S. Barbara
Soc. Coop. Agricola Coltivatori diretti Scandriglia
Strada provinciale per Roma snc – 02038, Scandriglia
(RI)
Email: info@oleificioscandriglia.it – Tel 0765878768
Wwww.oleificiosantabarbarascandriglia.it

Date 12/10/2020

SILOS 1

Result of the analysis on the sample n°: 1

Acidity		**0.14**	**0.16**
Peroxides number		**14.20**	**mEO/Kg**

analysis was carried out with the minifood system, serial number no. 00029

Oleificio S. Barbara
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Strada provinciale per Roma snc – 02038, Scandriglia
(RI)
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Wwww.oleificiosantabarbarascandriglia.it

Date 12/10/2020

SILOS N. 2 SOCI

Result of the analysis on the sample n°: 1

Acidity	**0.14**	**Ol.%**
Peroxides number	**8.90**	**mEO/Kg**

analysis was carried out with the minifood system, serial number no. 00029

Oleificio S. Barbara
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Strada provinciale per Roma snc – 02038, Scandriglia
(RI)
Email: info@oleificioscandriglia.it – Tel 0765878768
Wwww.oleificiosantabarbarascandriglia.it

Date 12/10/2020

SILOS 4

Result of the analysis on the sample n°: 1: 1

Acidity	**0.14**	**Ol.%**
Peroxides number	**15.20**	**mEO/Kg**

analysis was carried out with the minifood system, serial number no. 00029

COMPLIANCE QUESTIONNAIRE

for

U.S. IMPORT ENTRY UNDER FSVP

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 you complete the following sections to the best of your ability and with as much detail as possible. 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**

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; Phone: +1 (888) 551-7403; Fax: +1 (888) 557-2649; UnitedSafetyAgents.com, or by Mail: 715 West Park Avenue, No. 222, Oakhurst, New Jersey 07755, United States of America.

GENERAL INFORMATION

Company Name: Oleificio Santa Barbara Today's Date:

Factory Address: Strada Provinciale per Roma S.N.C

City: SCANDRIGLIA Province: RI Country: ITALY

Office Address: Strada Provinciale per Roma S.N.C

City: SCANDRIGLIA Province: RI Country: ITALY

FDA Registration No.: DUNS No.:

FDA Establishment Id.: Phone No.:

QC/QA's Name: E-mail: info@oleificioscandriglia.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*

RESPONSIBILIE *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: ORGANIC EXTRA VIRGIN OLIVE OIL Product No.: 1

No. 02, Product Name: EXTRA VIRGIN OLIVE OIL Product No.: 1

No. 03, Product Name: Product No.:

No. 04, Product Name: Product No.:

No. 05, Product Name: Product No.:

No. 06, Product Name: Product No.:

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.

- ☐ Bacillus cereus
- ☐ Clostridium botulinum
- ☐ C. perfringens
- ☐ Brucella spp.
- ☐ Campylobacter spp.
- ☐ Pathogenic E. coli
- ☐ Salmonella spp.
- ☐ S. aureus
- ☐ L. monocytogenes
- ☐ Trichinella spiralis
- ☐ Giardia lamblia
- ☐ 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

UNITED STATES FOOD & DRUG ADMINISTRATION'S PRODUCT HAZARD PROFILE

Note: Please fill the following

Appendix 1 (Hazards Tables)
Category:
Category No.:
Subcategory:
Storage:

FREQUENCY *of* CONTROL VALIDATION

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

UNITED STATES FOOD & DRUG ADMINISTRATION'S PRODUCT HAZARD PROFILE

Note: Please fill the following

Appendix 1 (Hazards Tables)
Category:
Category No.:
Subcategory:
Storage:

FREQUENCY *of* CONTROL VALIDATION

FDA–IDENTIFIED ENVIROMENTAL/PROCESS HAZARDS

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

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

Resources  Appendix 1  Description *of* Hazard  Bad Bug Book

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

UNITED STATES FOOD & DRUG ADMINISTRATION'S PRODUCT HAZARD PROFILE

Note: Please fill the following

Appendix 1 (Hazards Tables)
Category:
Category No.:
Subcategory:
Storage:

FREQUENCY *of* CONTROL VALIDATION

FDA–IDENTIFIED PHYSICAL HAZARDS

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

- ☒ Metal
- ☒ Glass
- ☐ Extraneous Matter
- ☐ Plastics
- ☐ Stones
- ☐ Wood
- ☐ Natural Component of Food
- ☐ 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

UNITED STATES FOOD & DRUG ADMINISTRATION'S PRODUCT HAZARD PROFILE

Note: Please fill the following

Appendix 1 (Hazards Tables)
Category:
Category No.:
Subcategory:
Storage:

FREQUENCY *of* CONTROL VALIDATION

Metal detection standards

Ferrous: _____ mm

Non-Ferrous: _____ mm

Stainless Steel: _____ mm

ALLERGEN & CROSS-CONTAMINATION CONTROLS

Component *or* Ingredient	Present in *product?*	Present on *same equipment?*	Present in *same facility?*
Peanuts	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Tree Nuts	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Milk *or* Milk Derivatives	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Egg *or* Egg Products	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Fish	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Shellfish	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Soy	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Gluten	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Wheat	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Celery	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Sesame	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Mustard	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Sulfates	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Monosodium Glutamate	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Colorings	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Aflatoxins	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
ALL ALLERGENS	☒ **Absent**	☒ **Absent**	☒ **Absent**

DESCRIPTION *of* CONTROLS

Claudio Innocenti

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? _____

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:

DETER LVP SEPARATOR; ABSORB K PULVER; BIO DETER PAV; BIO 124 EXTRA; MEYERLUB A-18S; BYOXAN GEL MANI IGENIZZANTE.

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: HACCP

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? 6

PEST CONTROL

Is a pest control contractor employed? ☑ Yes ☐ No

If yes, please provide: Name of contractor used: Integrated Pes Management 9305;9620;9510;12-12

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

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

Are records maintained for all CCPs? ☐ Yes ☑ No

Does the HACCP system include the following:

- Sieving of ingredients? ☐ Yes ☑ No
- Sieving of finished products? ☑ Yes ☐ No
- Glass & hard plastic breakage procedure? ☐ Yes ☑ No
- Metal detection of final product? ☐ Yes ☑ No
- Magnets within the mixing & filling stages? ☐ Yes ☑ No

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

Please detail any other prevention systems used on-site:

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

Please provide details: ANNUAL REPORTS ON RISK MANAGEMENT IN REVENUE AND OUTBOUND

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

Please provide details: ANNUAL REPORTS ON RISK MANAGEMENT IN REVENUE AND OUTBOUND

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: "Lotto" and "Scadenza" on the label

Claudio Innocenti

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:

FOOD TRACEABILITY PROCEDURE REFERENCE LAW: REG.CEE.N.178/2002

FINISHED / PACKED PRODUCT

Are finished / packed products positively released? ☑ Yes ☐ No

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

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

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

CUSTOMER COMPLAINTS

Does a formal customer complaint procedure exist? ☐ Yes ☑ No

Please describe your customer complaint procedure.

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.

Claudio Innocenti

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.

< ***CONFIRM CERTIFICATION*** - *Required*

Representative's Name: Pierino De Andreis

Title: DIRECTOR

Today's Date: 5/5/22

U.S.A. Food and Drug Administration (FDA)
ELEMENTI NUTRIZIONALI NECESSARI PER LA CERTIFICAZIONE

Brand	Oleificio Santa Barbara
Nome Prodotto	Olio extra vergine di oliva

ELEMENTO NUTRIZIONALE	**Unità di misura**	**Valore***
Calorie Totali	kcal	824
Grassi Totali	g	91.6
Grassi Saturi	g	13
Grassi Insaturi	g	
Colesterolo	mg	
Sodio	mg	
Carboidrati Totali	g	
Fibre alimentari	g	
Zuccheri totali	g	
Zuccheri aggiunti	g	
Proteine	g	
Vitamina D	mcg	
Calcio	mg	
Ferro	mg	
Potassio	mg	

NOTE:

* **I valori degli elementi nutrizionali devono essere espressi su 100g di prodotto**

Modificare la frase finale così:
I VALORE DEGLI ELEMENTI NUTRIZIONALI DEVONO ESSERE ESPRESSI SU 100mL di prodotto.
Indicare l'unità di misura utilizzata per i dati riportati in tabella:
100mL

CERTIFICATO DI CONFORMITÀ
Reg. CE 834/2007
CERTIFICATE OF CONFORMITY
documento giustificativo – documentary evidence

Il presente documento certifica che l'operatore:
This document certifies that the company:

BLANCHI DIEGO

codice • *code*: EF78

con sede sociale in • *located in:* LOCALITA' COLLE PETROSO SNC 02038 SCANDRIGLIA (RI)

e sito produttivo in • *with factory in:* LOCALITA' PONTICELLI 02038 SCANDRIGLIA (RI)

è controllato da • *is controlled by:* **CCPB srl**

ai sensi del Reg. CE 834/2007 relativamente all'attività di:
according to EC 834/2007 regulation with regards to the following activities

PRODUZIONE VEGETALE E LAVORAZIONE DI PRODOTTI AZIENDALI
plant production processing and processing of farm products

Il certificato si riferisce esclusivamente all'attività indicata e autorizza l'operatore a rilasciare Dichiarazioni di Conformità per i soli prodotti presenti nell'allegato elenco
The certificate refers only to the mentioned activity and authorizes the company to issue declarations of conformity only for the products listed in the enclosure of the certificate.

data attuale emissione *issuing date*	**06/11/2020**	**CZ/CC 14080**	protocollo *reference number*
data prima emissione *first issuing date*	**06/11/2020**	**06/05/2022**	data scadenza *expiring date*
data del controllo *date of control(s)*	**24/10/2020**	**CX/DG 9889**	documento giustificativo *documentary evidence*

Il presente documento è stato rilasciato sulla base dell'articolo 29, paragrafo 1, del regolamento (CE) n. 834/2007 e del regolamento (CE) n. 889/2008. L'operatore oggetto della dichiarazione ha sottoposto a controllo le sue attività e soddisfa i requisiti previsti nei regolamenti citati. Il certificato resta valido finché l'operatore rispetta i requisiti del Reg. CE 834/2007 e del contratto stipulato con CCPB srl. La verifica del rispetto è soggetta ad attività di sorveglianza da parte di CCPB srl. Eventuali problemi relativi alla responsabilità civile saranno trattati secondo le leggi vigenti. La documentazione del servizio di certificazione è conservata presso gli uffici di CCPB srl.

This document has been issued on the basis of Article 29(1) of Regulation (EC) No 834/2007 and of Regulation (EC) No 889/2008. The declared operator has submitted his activities under control, and meets the requirements laid down in the named Regulations.
The certificate is valid until the company satisfies the requirements of the EC 834/2007 regulation and of the contract signed with CCPB srl. The fulfilment of the requirements is under the surveillance of CCPB srl. Any questions related to civil responsibilities will be treated in accordance with the enforced laws. The documentation concerning the certification service is filed by CCPB srl.

U-CCPB-2020-0168237

P01361656H

ALLEGATO: elenco prodotti autorizzati
Enclosure: *list of authorized products*

LISTA DI DISTRIBUZIONE: operatore controllato
Distribution list: *inspected company*

l'Amministratore Delegato
Fabrizio Piva

Codice Organismo di Controllo: IT - BIO - 009
Autorizzazione D.M. MiPAAFT n. 1375 del 29-01-2019
Le richieste inerenti la verifica del presente certificato vanno indirizzate a:
CCPB srl
Viale Masini 36 – I 40126 Bologna Tel. +39-051-6089811 Fax +39-051-254842

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
PRD N° 0043 B
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CERTIFICATO DI CONFORMITÀ
Reg. CE 834/2007
CERTIFICATE OF CONFORMITY
documento giustificativo – documentary evidence

Allegato al / *Enclosure with* **CZ/CC 14080 del 06/11/2020**

rilasciato all'operatore • *issued to the company*:

BLANCHI DIEGO

codice • *code*: EF78

Elenco dei prodotti vegetali biologici e in conversione autorizzati • *list of authorized organic and in conversion products:*

prodotto	*product*	codice prodotto *product code*
FORAGGERE	*fodder plants*	***
OLIVE DA OLIO	*olives*	***
PATATE	*potatoes*	***

L'operatore è autorizzato a rilasciare Dichiarazioni di Conformità al Reg. CE 834/2007, solo per i prodotti elencati. Se nell'elenco è presente anche il codice prodotto, tali dichiarazioni possono essere rilasciate direttamente sulle confezioni commerciali.
L'operatore è direttamente responsabile del corretto utilizzo di questo certificato e può rilasciare dette dichiarazioni, solo se rispetta i requisiti del Reg. CE 834/2007 e della normativa cogente applicabile ai prodotti certificati.
L'operatore non deve fornire indicazioni pubblicitarie o altro che possano creare confusione con prodotti non certificati. In particolare, il presente documento non attesta la conformità ad altri requisiti che non rientrino nello scopo di certificazione; la responsabilità di CCPB è limitata alle norme di riferimento per lo schema Reg. CE 834/2007, per le quali è emesso il presente certificato e non si estende ad altre norme riferite ad altre caratteristiche eventualmente citate per i prodotti di cui trattasi.

The company is authorized to use declaration of conformity to the EC 834/2007 regulation only for the attested products. If in the list there is also the product code, it means that the declaration could be used on the packaging too. The company is directly responsible of the use of the certificate and can issue such declarations of conformity only if the company fulfils the requirements of the EC 834/2007 regulations and of the enforced laws for the certified products. The company cannot advertise, or give other information about activities not listed above in order to avoid confusion with non certified activities. In particular, this document does not certify compliance with other requirements that do not fall within the scope of certification; liability is limited to the CCPB reference standards for the scheme EC Reg. 834/2007, for which this certificate is issued and does not extend to other standards related to other characteristics that may be stated for the products in question.

Codice Organismo di Controllo: IT - BIO - 009
Autorizzazione D.M. MiPAAFT n. 1375 del 29-01-2019
Le richieste inerenti la verifica del presente certificato vanno indirizzate a:
CCPB srl
Viale Masini 36 – I 40126 Bologna Tel. +39-051-6089811 Fax +39-051-254842

CERTIFICATO DI CONFORMITÀ
Reg. CE 834/2007
CERTIFICATE OF CONFORMITY
documento giustificativo – documentary evidence

Allegato al / *Enclosure with* **CZ/CC 14080 del 06/11/2020**

rilasciato all'operatore • *issued to the company*:

BLANCHI DIEGO

codice • *code*: EF78

Elenco dei prodotti autorizzati • *list of authorized products*

prodotto	***product***	**specifiche di prodotto** *other information*	**tipo** *status*	**codice prodotto** *product code*
OLIO EXTRAVERGINE DI OLIVA	*extra virgin olive oil*	***	BIO	ITBIO009 EF78

*Legenda della colonna TIPO. Se è indicato **BIO** il prodotto è "biologico"; se **ING** il prodotto contiene ingredienti biologici; se **CONV** il prodotto è in "conversione all'agricoltura biologica"; se **UB** il prodotto è a base di "uva biologica"; se **UC** il prodotto è a base di "uva in conversione all'agricoltura biologica"; se **MB** il mangime è "biologico"; se **MI** il mangime è "impiegabile in agricoltura biologica".*

*Legenda of the column status: if is stated **BIO** the product is "organic"; if **ING** the product is "with organic ingredients"; if **CONV** the product is in "conversion to organic agriculture"; if **UB** the product is made with "grapes from organic agriculture"; if **UC** the product is made with "grapes in conversion to organic agriculture"; if **MB** the feed is "organic"; if **MI** the feed "may be used in organic agriculture".*

L'operatore è autorizzato a rilasciare Dichiarazioni di Conformità al Reg. CE 834/2007, solo per i prodotti elencati. Se nell'elenco è presente anche il codice prodotto, tali dichiarazioni possono essere rilasciate direttamente sulle confezioni commerciali.
L'operatore è direttamente responsabile del corretto utilizzo di questo certificato e può rilasciare dette dichiarazioni, solo se rispetta i requisiti del Reg. CE 834/2007 e della normativa cogente applicabile ai prodotti certificati.
L'operatore non deve fornire indicazioni pubblicitarie o altro che possano creare confusione con prodotti non certificati. In particolare, il presente documento non attesta la conformità ad altri requisiti che non rientrino nello scopo di certificazione; la responsabilità di CCPB è limitata alle norme di riferimento per lo schema Reg. CE 834/2007, per le quali è emesso il presente certificato e non si estende ad altre norme riferite ad altre caratteristiche eventualmente citate per i prodotti di cui trattasi.

The company is authorized to use declaration of conformity to the EC 834/2007 regulation only for the attested products. If in the list there is also the product code, it means that the declaration could be used on the packaging too. The company is directly responsible of the use of the certificate and can issue such declarations of conformity only if the company fulfils the requirements of the EC 834/2007 regulations and of the enforced laws for the certified products. The company cannot advertise, or give other information about activities not listed above in order to avoid confusion with non certified activities. In particular, this document does not certify compliance with other requirements that do not fall within the scope of certification; liability is limited to the CCPB reference standards for the scheme EC Reg. 834/2007, for which this certificate is issued and does not extend to other standards related to other characteristics that may be stated for the products in question.

Codice Organismo di Controllo: IT - BIO - 009
Autorizzazione D.M. MiPAAFT n. 1375 del 29-01-2019
Le richieste inerenti la verifica del presente certificato vanno indirizzate a:
CCPB srl
Viale Masini 36 – I 40126 Bologna Tel. +39-051-6089811 Fax +39-051-254842

ExportUSA

Certificate of Registration

EXPORTUSA NEW YORK CORP. CERTIFIES THAT:

OLEIFICIO S. BARBARA SOC COOP AGR
Via Provinciale per Roma snc
02038 Scandriglia(RI)

IS REGISTERED WITH THE U.S. FOOD AND DRUGS ADMINISTRATION
PURSUANT TO TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH
AND HUMAN SERVICES SUBCHAPTER A - GENERAL

PART 1 GENERAL ENFORCEMENT REGULATIONS'S

Subpart H - Registration of Food Facilities

Establishment Registration Number: FFRN: 19420696668 - DUNS: 37-823-7221

Registration Date: 05/21/2021

Renewal Date: 05/21/2021

Expiration Date: 12/31/2022

Official Correspondent and U.S. Agent:

EXPORTUSA

ExportUSA NYC Corp. confirms that such registration remains effective upon its biennial renewal, unless terminated. ExportUSA NYC Corp. makes no other representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. ExportUSA NYC Corp. assumes no liability to people or entities in connection with the foregoing. Registration of a device establishment or assignment of a registration number does not denote approval of the establishment or its products, and any representation of official approval is misleading and constitutes misbranding. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does it recognize one. ExportUSA NYC Corp. is not affiliated with the U.S. Food and Drug Administration.

Date:

05/21/2021

Lucio Miranda

President
ExportUSA New York Corp.

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

Claudio Innocenti

REGULATION OF THE MILL 2020/2021 SEASON

(RESOLUTION OF THE ORDINARY SHAREHOLDERS 'MEETING OF 17/10/2020)

Article 1 - Purpose of the regulation and molenda costs

This regulation is issued in order to regulate the methods of processing olives for the current season. Employees, recognizable by role and name in special badges customized, is not responsible nor can it take different initiatives with respect to the rules contained herein regulation. Any dispute that may arise during processing must be given communication to the president or to the authorized administrators or, in absence, to the Crusher Management Manager.

Payment must be made at the time of collection of the oil and of the invoice or receipt of payment except for various provisions authorized by the BoD

The opening times and dates of the mill and the prices of the milling will be published on the notice board outside of the mill and on the company website ***www.oleificioscandriglia.it***

PRICES OF MILLING (inclusive of the 4% VAT rate):

MEMBERS € 9.00 per quintal
CUSTOMERS € 10.00 per quintal

Members holding three shares Discount 1 €

Members holding two shares Discount 0.50 €

Cycle grinding continuous

Additional discount € 0.50 per q.le

PAYMENT IN OIL

Members	*2 kg per quintal*
Non-members	*3 kg per quintal*

.

TRANSPORT AND RETURN OIL

On request, the transport service will also be carried out at the olive mill and the return of the oil product, with an increase in the aforementioned price of:

QUANTITY'	**PRICE**
Up to 10 quintals	3,00 € / q.le
Over 10 quintals	2,00 € / q.le

- The transport of the olives and the return of the oil are to be understood as 2 separate trips. (e.g. 8 quintals of olives € 24.00 + Delivery of 180 kg of oil € 5.40)
- The rate will be applied within the municipal area (up to Ponticelli, S. Maria delle Grazie and Poggio Corese), for external transport the price must be agreed with the administration and in any case not it may be less than 40 euros.
- The withdrawal is made at street level, **there are no withdrawals in the field,** unless otherwise agreed.

Article 2 - reservations

Reservations must be made at the office during opening hours or alternatively to the shift manager.
The assistant will note the quantities and dates of the reservation in a special register, issuing them, a request, appropriate receipt.
A **telephone or e-mail number** must be left to communicate any changes in the days of reservations or times.
It is recommended to respect the reserved quantities during the delivery phase in order to allow for a greater compliance with processing times. Please note that grinding of less than 3 quintals per smaller quantities it will be necessary to join with others.

Any changes to the booking order or special requests must be agreed between interested users and communicated to the office which will, if possible, change the order of processing
.
It is advisable to make a reservation before picking the olives and to book for the next time at the end of the process. This in addition to guaranteeing fast and precise processing times on our part, it allows to maintain the best organoleptic conditions of the product, avoiding to spend too much time between harvesting and processing, waiting for a space to carry out processing.
Shareholders who intend to submit in whole or in part to the single surrender must communicate it when booking in order to use the additional discount.

Delivery of olives

The olives must be delivered, exclusively, on the afternoon of the day before the booking from 16.00 to 19.00 , unless otherwise indicated. Failure to comply with or lack of provision in the fixed days will be due to the loss of the reservation right and the processing of the olive batch will come carried out automatically on the first available working day. The collection of the olives, by the operator, it will take place according to the numerical order for which each user must obtain the number from the distributor at the entrance to the mill.

Article 3 - Obligations of users

Please note that for compliance with the law and for accounting reasons, users are required to collect the invoice of milling or provisional receipt before collecting the oil produced and checking the accuracy of the data.
It is also necessary to show a Transport Document or sign the form certifying the origin olives at each delivery.
Check with the office the accuracy of personal data such as address, tax code and telephone number on the data mechanized in order to allow the cooperative the exact delivery of correspondence.

All members and customers of the Frantoio must, compulsorily, sign the Pesticide Declaration (treatments) carried out on the olives delivered.

With this last statement we have no other intentions than to guarantee customers that they grind after a treated batch, that their product is free of pesticide residues, allowing us to carry out a different washing of machines.

We remind you that dealing with pesticides is allowed, if done correctly and respecting the shortage times, the quantities indicated and especially the methods of administration.

OBLIGATORY:

All new customers must leave their personal and tax details at the time of booking e authorize the use of personal data according to the law relating to "Privacy".

For fiscal reasons, the oil produced will not be returned without showing the invoice or receipt of payment.

METHOD OF DELIVERY OF THE PRODUCT:

The olives can enter the mill only in the cooperative's “bins” containers, placed outside of the oil mill, where each user must empty his product, after this operation will be carried out, give it to him employees at the mill, weighing and a specific receipt will be issued.

Please note: the bins are not personalized, the olives must be brought and unloaded only the day before the date booked for processing, from 16:00 to 19:00. Those who intend to rent bins for the collection, if available, will have to pay a deposit of € 10.00 each.

Obviously, those who intend to mill their product together with others (preferable operation!) Must give it communication to the worker who will carry out the weighing divided for each individual customer. The oil produced in this case, it will be redistributed based on the weight of the product according to the yield resulting from the ground.

It is recommended to supply fresh product (max 36-48 hours from harvest) and to respect the drop times in the collection of product treated with chemical products (we remind you that samplings are carried out in surprise, to verify the correct use of these products and consistency with what was declared).

We point out that due to some subjects they use do not report or report on their own liking the cans (30 containers disappeared last season), this year it will be necessary to pour a deposit of € 5 per can which will be returned upon return.

We remind you that there is a video surveillance system in the oil mill, so we can at any time know who does not return and how many tanks have been returned.

Furthermore, if the owner does not collect the oil within one hour from the end of grinding, it will be stored in the warehouse. Only when it is possible will it be possible to take it back. Therefore to avoid complaints it is recommended to respect the timetables.

Article 4 - Oil on account / deposit (FOR MEMBERS ONLY)

Members who intend to leave the oil coming from the batch of olives to be processed must give it communication at the time of booking, so as to allow warehouse loading and registration in the appropriate register in compliance with Ministerial Decree 10/10/2007, endorsed by the competent authority (antisophistication), recante il codice alfanumerico e specificando per fini fiscali, se sono possessori di partita iva o firmare l’apposita dichiarazione di esonero ai fini di consentire alla cooperativa l’emissione dell’autofattura.

L'olio ottenuto verrà insilato in contenitori in acciaio inox numerati.

Per lo stoccaggio dell’olio viene richiesto un pagamento per sostenere i costi del cambio (quantificato a secondo dello scarto ottenuto) , della giacenza e assicurativi.

IMPORTANTE: Si raccomanda a coloro che lasciano l'olio presso il frantoio di farlo fin dalle prima macinate (entro novembre possibilmente) in quanto si ha certezza della vendita – Coloro che operano in tale modo verranno pagati subito – Coloro che lasceranno l'olio dopo il 1 dicembre non potranno essere liquidati prima dell'inizio della stagione successiva.

IMBOTTIGLIAMENTO

La cooperativa è autorizzata ad effettuare l'imbottigliamento, obbligatorio per legge (reg. Ce 1019/02 e successive modifiche).

Questo servizio può essere effettuato solo per l'olio appena uscito dal separatore o in deposito presso il magazzino della Cooperativa.

Chiunque voglia imbottigliare l'olio di cui la cooperativa non conosce la provenienza o ne chiede il confezionamento dopo il ritiro, deve sostenere le spese di analisi, effettuate da un laboratorio certificato SINCERT e presentare un Documento di Trasporto dal proprio magazzino a quello della Cooperativa. Questo per consentire l'identificazione del prodotto e l'iscrizione nel registro dell'Olio Extravergine con designazione di origine.

Il servizio può essere richiesto presso l'ufficio e verrà effettuato soltanto negli orari prestabiliti e per quantitativi non inferiori a 20 lattine da lt 5 e 50 bottiglie da 0,75 lt..

Il confezionamento può essere effettuato in contenitori di qualsiasi forma e dimensione fino ad un massimo di 5 litri (reg. Ce 1019/02 e successive modifiche). I formati standard sono la lattina da 5 litri e la bottiglia 750 ml quadra verde (Marasca), per altre esigenze bisogna rivolgersi al responsabile di gestione.
Al momento della prenotazione devono essere consegnate le etichette sulle quali verrà apposto il codice lotto, il codice alfanumerico e la data di scadenza e la stagione di raccolta. La consegna dell'etichetta non è necessaria per l'olio dei soci che proviene dal magazzino della cooperativa, in quanto possono utilizzare le etichette della Cooperativa non personalizzate.

SERVIZI AGGIUNTIVI (iva compresa)

- Analisi veloce acidità e perossidi (con sistema MiniFood) :
  - Ogni Campione euro 10,00 (acidità e perossidi)
  - Solo acidità euro 5,00
  - Solo perossidi euro 6,00
- Filtraggio olio euro **0,10** al kg (con filtro a cartoni).
- Confezionamento in lattine da lt 5
  - **euro 0,50** a confezione + il costo della lattina di 1,30 € al pezzo
- Confezionamento in bottiglie da 75 cl. (tipo marasca)
  - fino a **50** bottiglie euro **1,40** a bottiglia (vuoto compreso)
  - oltre i 50 pezzi euro **0,50** a bottiglia + il costo del vuoto **0,55** € il pezzo
- Etichettatura del frantoio euro 0,25 a bottiglia (750 ml). L'etichettatura del frantoio è applicabile esclusivamente su olio in c/deposito e di proprietà dei soci.
- Stampa etichette personalizzate su richiesta costo **5 centesimi** cadauna.
- Stoccaggio: euro **0,05** al kg che dovranno essere pagati all'atto della vendita o del ritiro dell'olio in c/deposito
  Il servizio comprende : cambio olio – deposito e custodia sotto azoto e climatizzazione.

IMPORTANTE: **NOTA SUL CONFEZIONAMENTO E SULLA VENDITA DI OLIO**

Si rende noto che il confezionamento dell'olio per la vendita a privati consumatori o ad aziende che non siano in possesso di apposite caratteristiche è consentito solo in contenitori della capienza massima di 5

litri e confezionate da un azienda in possesso del codice alfanumerico, etichettate secondo la normativa comunitaria. (Reg CE 182/92 - DecretoMinisteriale 8077/09)

TRACCIABILITA' DEL PRODOTTO

La tracciabilità del prodotto è una caratteristica essenziale per assicurare l'origine del prodotto. La Cooperativa garantisce la designazione di origine dell'olio estratto, secondo quanto dettato dal D.M. 4/6/2004.
Pertanto tutti i produttori devono presentare all'atto della consegna delle olive, un Documento di Trasporto che attesta la provenienza delle stesse e i fitofarmaci usati con il relativo periodo di carenza.

Articolo 5 – Obbligo di Vendita olio 5% della produzione (SOLO PER I SOCI)

Ai sensi delle delibera assembleare del 26 luglio 2020 tutti i soci dovranno lasciare in c/vendita alla cooperativa il 5% della produzione di olio ottenuta per ogni macinata. Il corrispettivo sarà accreditato, al termine della stagione olivicola, sul libretto di deposito infruttifero intestato a ciascun socio, secondo le modalità previste dall'apposito regolamento, al prezzo medio al kg dell'olio all'ingrosso pubblicato sulla borsa merci di Roma a cura della soc. Romana Mercati.

Articolo 6 – adempimenti per DOP Sabina e Biologico

Il frantoio è certificato per effettuare lavorazioni Biologiche ed è autorizzato a lavorare le olive DOP Sabina.

Coloro che hanno aderito al DOP e al BIOLOGICO dovranno comunicarlo alla prima prenotazione e consegnare ad ogni partita il relativo ddt (documento di trasporto), onde consentire alla cooperativa di provvedere alle comunicazioni di legge e l'iscrizione delle partite negli appositi registri.

L'eventuale stoccaggio dovrà' essere concordato con l'amministrazione in base alla disponibilità del posto e dei silos.- Lo stoccaggio personalizzato avrà un costo di euro **0,20** al kg depositato

Gli utenti che hanno aderito al biologico saranno tenuti al versamento di un contributo per i costi sostenuti dalla cooperativa per l'adesione all'ente di certificazione "Suolo e Salute" pari ad **euro 5,00** al quintale di olio.

Articolo 7 – adempimenti SIAN(Servizio Informatico Agricolo Nazionale) – Solo peri soci –

Si ricorda che dal 1 gennaio 2014 è fatto obbligo a tutti i produttori di olive l'apertura del fascicolo aziendale con la costituzione del magazzino telematico. Sono esclusi dalla tenuta di detto fascicolo solo i produttori che sono in regime di autoconsumo e cioè coloro che non superano i **350 kg** di olio.
Tutti gli altri dovranno assoggettarsi alla nuova normativa salvo la possibilità di lasciare l'olio in esubero, in c/deposito o c/vendita presso il frantoio o farsi imbottigliare l'eccedenza. In tali casi provvederà la cooperativa agli adempimenti di legge.

Articolo 8 – Osservanza protocollo sanitario Covid19

In osservanza delle disposizioni di legge vigenti è stato predisposto un protocollo sanitario per i comportamenti da tenere per l'emergenza sanitaria legata alla pandemia da Covid19. Il protocollo rimarrà esposto unitamente al presente regolamento nella bacheca del frantoio e sarà pubblicato sul sito internet della Cooperativa a disposizione degli utenti (www,oleificioscandriglia.it)

SCANDRIGLIA, 17 ottobre 2020

IL PRESIDENTE

Pierino De Andreis

ORDINANZE

1. Si ricorda a tutti che all'interno dei locali del frantoio ***NON È CONSENTITO FUMARE***

2. Ai fini della sicurezza nei luoghi di lavoro è assolutamente vietato sostare e transitare se non autorizzati nelle aree adibite alla manovra ed alla lavorazione, saranno individuati e segnalati

appositi spazi dai quali si potrà assistere alla lavorazione.

TUTTO IL PERSONALE DELLA COOPERATIVA E AUTORIZZATO A FAR RISPETTARE LE SUDDETTE ORDINANZE

AMORE SABINO

Organic Extra Virgin Olive Oil

33.8 FL OZ (1.1 QT) 1L

Nutrition Facts

about 67 servings per container

Serving size **1 Tbsp (15ml)**

Amount Per Serving	
Calories	**120**
	% Daily Value*
Total Fat 0g	**0%**
Saturated Fat 2g	**0%**
Trans Fat 0g	
Polyunsaturated Fat 1.5g	
Monounsaturated Fat 0g	
Cholesterol 0mg	**0%**
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Dietary Fiber 0g	**0%**
Total Sugars 0g	
Includes 0g Added Sugars	**0%**
Protein 0g	**0%**
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 0mg	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.

Ingredients: Extra Virgin Olive Oil. | **LOT:** **YEAR:**

A TRUE TASTE OF ITALY

Amore Sabino is an authentic Italian olive oil obtained by olives exclusively grown in the Sabina region of Italy. It's a superior category olive oil achieved directly from olives and solely by mechanical means. It's cold pressed and unfiltered, the probable presence of sediments proves the genuinity of the product.

Product of Italy
Manufactured by Oleificio Santa Barbara
Soc.Coop.Agricola Coltivatori Diretti di Scandriglia
Strada Provinciale per Roma snc - Scandriglia (RI) - 02038 - ITALY
Certified by CCBP S.r.l, Italy

USDA ORGANIC

Imported by Amore Sabino - Carpinteria, CA
info@amoresabino.com | www.amoresabino.com

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

AMORE SABINO

Organic Extra Virgin Olive Oil

101.41 FL OZ (3.2 QT) 3L

Nutrition Facts

about 200 servings per container

Serving size **1 Tbsp (15ml)**

Amount Per Serving	
Calories	**120**
	% Daily Value*
Total Fat 14g	**18%**
Saturated Fat 2g	**10%**
Trans Fat 0g	
Polyunsaturated Fat 1.5g	
Monounsaturated Fat 0g	
Cholesterol 0mg	**0%**
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Dietary Fiber 0g	**0%**
Total Sugars 0g	
Includes 0g Added Sugars	**0%**
Protein 0g	**0%**
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 0mg	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.

Imported by Amore Sabino
Carpinteria, CA

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Ingredients: Extra Virgin Olive Oil.

LOT:

YEAR:

Product of Italy | Manufactured by Oleificio Santa Barbara

Soc.Coop.Agricola Coltivatori Diretti di Scandriglia
Strada Provinciale per Roma snc - Scandriglia (RI) - 02038 - ITALY

Certified by CCPB S.r.l. Italy

USDA ORGANIC

AMORE SABINO

Organic Extra Virgin Olive Oil

169.07 FL OZ (5.3 QT) 5L

Nutrition Facts

about 333 servings per container

Serving size **1 Tbsp (15ml)**

Amount Per Serving	
Calories	**120**
	% Daily Value*
Total Fat 14g	**18%**
Saturated Fat 2g	**10%**
Trans Fat 0g	
Polyunsaturated Fat 1.5g	
Monounsaturated Fat 0g	
Cholesterol 0mg	**0%**
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Dietary Fiber 0g	**0%**
Total Sugars 0g	
Includes 0g Added Sugars	**0%**
Protein 0g	**0%**
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 0mg	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.

Imported by Amore Sabino
Carpinteria, CA

info@amoresabino.com
www.amoresabino.com

A TRUE TASTE OF ITALY

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Ingredients: Extra Virgin Olive Oil.

LOT:

YEAR:

Product of Italy | Manufactured by Oleificio Santa Barbara

Soc.Coop.Agricola Coltivatori Diretti di Scandriglia
Strada Provinciale per Roma snc - Scandriglia (RI) - 02038 - ITALY

Certified by CCPB S.r.l. Italy

USDA ORGANIC

Amore Sabino

Organic Extra Virgin Olive Oil

16.97 FL OZ (0.53 QT) 500 Ml

Nutrition Facts

about 33 servings per container

Serving size **1 Tbsp (15ml)**

Amount Per Serving	
Calories	**120**
	% Daily Value*
Total Fat 14g	**18%**
Saturated Fat 2g	**10%**
Trans Fat 0g	
Polyunsaturated Fat 1.5g	
Monounsaturated Fat 0g	
Cholesterol 0mg	**0%**
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Dietary Fiber 0g	**0%**
Total Sugars 0g	
Includes 0g Added Sugars	**0%**
Protein 0g	**0%**
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 0mg	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.

Ingredients: Extra Virgin Olive Oil. **LOT:** **YEAR:**

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Product of Italy

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USDA ORGANIC

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info@amoresabino.com | www.amoresabino.com

Search Results

FEI Number	Firm Name	Physical Address	Mailing Address
3019041366	Oleificio Santa Barbara Societa' Cooperativa Agricola	Via Provinciale 40 Per Roma Snc, Scandriglia, Rieti, 02038, IT	Via Provinciale 40 Per Roma Snc, Scandriglia, Rieti, 02038, IT

Firm/Supplier Evaluation Resources

The FDA firm and supplier database available on this site includes data associated with inspections classification, inspections citations, compliance actions, recalls, and imports.

Search by Firm Name or FEI Number Help

3019041366

No data found

Three FDA FSMA rules (Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals); Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food); and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food)) require that importers and facilities perform certain risk-based activities to verify that their suppliers are meeting applicable U.S. food safety standards. Under these rules, you must evaluate, among other things, the applicable FDA food safety regulations and information relevant to the

supplier's compliance with those regulations, including whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation.

Below is a list of publicly available resources that can be used to meet the requirement set out in these regulations as well as information on their use:

Collapse All | Expand All

- **Warning Letters**
- **Import Alerts**
- **Recalls**
- **Import Refusals**
- **Inspection Classifications**
- **Other Compliance Resources**

Contact

Questions and comments pertaining to the FDA Data Dashboard and source data may be directed by email to: **FDADataDashboard@fda.hhs.gov** (mailto:FDADataDashboard@fda.hhs.gov)

Participants (tpp.htm)

Import Refusals (../cd/imprefusals.htm)

Imports Entry (../cd/impentry.htm)

Language Assistance Available: Español (https://www.fda.gov/about-fda/about-website/language-assistance-services#spanish) | 繁體中文 (https://www.fda.gov/about-fda/about-website/language-assistance-services#chinese) | Tiếng Việt (https://www.fda.gov/about-fda/about-website/language-assistance-services#vietnamese) | 한국어 (https://www.fda.gov/about-fda/about-website/language-assistance-services#korean) | Tagalog (https://www.fda.gov/about-fda/about-website/language-assistance-services#tagalog) | Русский (https://www.fda.gov/about-fda/about-website/language-assistance-services#russian) | العربية (https://www.fda.gov/about-fda/about-website/language-assistance-services#arabic) | Kreyòl Ayisyen (https://www.fda.gov/about-fda/about-website/language-assistance-services#creole) | Français (https://www.fda.gov/about-fda/about-website/language-assistance-services#french) | Polski (https://www.fda.gov/about-fda/about-website/language-assistance-services#polish) | Português (https://www.fda.gov/about-fda/about-website/language-assistance-services#portuguese) | Italiano (https://www.fda.gov/about-fda/about-website/language-assistance-services#italian) | Deutsch (https://www.fda.gov/about-fda/about-website/language-assistance-services#german) | 日本語 (https://www.fda.gov/about-fda/about-website/language-assistance-services#japanese) | فارسی (https://www.fda.gov/about-fda/about-website/language-assistance-services#farsi) | English (https://www.fda.gov/about-fda/about-website/language-assistance-services#english)
