UNITED SAFETY AGENTS

# FSVP

## COMPLIANCE PLAN

P&L IMPORTS LLC

*Name of FSVP Importer*

LA GALVANINA SPA

*Name of Foreign Supplier*

ITALIAN SPARKLING MINERAL WATER

*Name of Product*

NOVEMBER 03, 2019 / NOVEMBER 04, 2021

*Date of Initial Verification / Reverification*

NOVEMBER 05, 2022

*Date of FSVP Plan Expiration*

VERIFICAITON COMPLETE | APPROVED FOR IMPORT

*Status of Review*

NUMBER 04

*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.

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## FOREIGN SUPPLIER VERIFICATION PROCEDURES

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

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

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


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

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

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

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

*Continued onto next page.*

## FOREIGN SUPPLIER VERIFICATION PROCEDURES

*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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 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: La Galvanina SpA | Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) | Review Start: Oct. 11, 2021 | Review End: Nov. 03, 2021

## DESIGNATION *of* ROLES & SUMMARY *of* REVIEW

### FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: P&L Imports LLC | FDA FEI:

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

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

Mailing Address: 10051 E Dynamite Blvd. Suite 160

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

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

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

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

Company Name: La Galvanina SpA | FDA FFR:

Manufacturing Address: Via della Torretta N. 2 | FDA FEI: 3003097690

City: Rimini | Province/Territory: Rimini, 47923 | Country: Italy

Office Address: Via della Torretta N. 2

City: Rimini | Province/Territory: Rimini, 47923 | Country: Italy

Phone Number: +39 0541 751315 | Email Address: galvanina@galvanina.com

Name *of* Representative*(s)*: Luca Bertozzi | Title: Production Manager

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

Agent/QI Name: Claudio Innocenti | Signature: Claudio Innocenti

Title: Partner & Preventive Controls Qualified Individual. | Date: Nov. 03, 2021

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

Title: Preventive Controls Qualified Individual. | Date: Nov. 03, 2021

### SUMMARY *of* REVIEW

| **Details *of* Product**(s) | *Is foreign supplier expected to implement controls for* | | | **Comments** |
|---|---|---|---|---|
| | **Biological Hazards** | **Chemical Hazards** | **Physical Hazards** | |
| Italian Sparkling Mineral Water with Carbonation Added. 16.9 Fl Oz or 500 mL. Branded under: Kirkland Signature. | ☑ Yes ☐ No ☐ *Undetermined* | ☑ Yes ☐ No ☐ *Undetermined* | ☑ Yes ☐ No ☐ *Undetermined* | Verified & Approved. — See Addendum. |
| | ☑ 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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## REGISTER *of* SUBSTANTIATING DOCUMENTS

### HAZARD ANALYSIS

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

NOTES La Galvanina SpA's HACCP Plan and various related procedures received.
Dated: January 10, 2011.
Prepared By: Luca Bertozzi, and Dott. Matteo Matassoni.
CCP(s): 02. Starblend, Deareation/ Saturation and Filling.
Plan and Accompanying Documentation Contain Information On: Analysis of Hazards, Identification of Critical Control Points, Validation of Critical Control Points (for both CCP No. 01 and CCP No. 02.), Process Flow Chart, Etc.
La Galvanina SpA's Food Safety Plan received.
Dated: October 20, 2019.

### ON-SITE AUDIT

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

NOTES La Galvanina SpA's BRC Global Standard Issue 7: July 2015 audit report received.
Dated: January 24, 2019. Audit Grade: AA.
Expires: February 02, 2020.
Independent research indicates that La Galvanina S.p.A. currently holds FSMA Regulatory Certification.
FSMA Regulatory Certification - Not Confirmed.

| No. | Dated. | Exp. | Scope. |
|---|---|---|---|
| C2019-02209 | 07/05/2019 | 07/04/2020 | Manufacture and bottling of mineral water. |

Note: We respectfully request that a full copy of the supplier's annual on-site audit report be provided.

### SAMPLING OR TESTING RESULTS

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

NOTES Certificate of Analysis not received from supplier.

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

### OTHER FOOD SAFETY RECORDS

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

NOTES La Galvanina SpA has provided various (not HACCP) food safety documents. List follows: Cleaning and Sanitation Procedure, Environmental Air Check, Environmental Air Quality Check, Bioluminator Checks, Assessment, Accreditation and Monitoring of Suppliers, and Plan of Checks (includes comprehensive list of utilized CGMPs and the frequency of their oversight).
Dates: Vary, but appear to indicate that supplier created modern system in or around 2011.

### 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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 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:* _____

### LABORATORY TESTING RESULTS

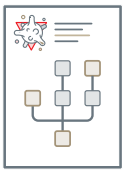
- ☑ if positive results are returned
- ☑ if recall or import refusal occurs
- ☑ if inspection occurs
- ☑ on an annual basis
- ☐ on a per-batch/shipment basis
- ☑ Chemical ☑ Biological
- ☐ *other:* _____


### 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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 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 |
|---|---|
| October 29, 2013 | FDA FACILITY INSPECTION<br>Inspection Id: 853158<br>Project Area: Foodborne Biological Hazards<br>Classification: VAI<br><br>NOTE: We suggest that P&L Imports inquire about supplier's corrective measures and obtain all relevant documents including copy of full EIR for review. |
| | FDA Data Dashboard search results indicate that supplier's compliance history does not include FDA Warning Letters, Import Alerts, or other applicable compliance actions. |

Covers: La Galvanina SpA FEI: 3003097690 Date: Nov. 03, 2021

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

Supplier: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## REVISION LOG *for* FSVP PLAN

| Version No. | Date *of* Change | Description *of* Revision |
|---|---|---|
| No. 01 | November 03, 2018. | Product and supplier underwent initial FSVP verification. |
| No. 02 | February 13, 2019 – November 03, 2019 | La Galvanina SpA's BRC Global Standard Issue 7: July 2015 audit report, and Food Safety Plan was received, reviewed, and added to FSVP.<br><br>Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification. |
| No. 03 | November 04, 2020 | Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification. |
| No. 04 | November 03, 2021 | Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification. |

Supplier: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## ANALYSIS & DETERMINATION *of* BIOLOGICAL HAZARDS

| FDA Identified Hazard(s) | P. | S. | Control Measure(s) | Hazard(s) Controlled |
|---|---|---|---|---|
| ☐ ***Bacillus cereus***<br>☐ ***Clostridium botulinum***<br>☐ ***C. perfringens***<br>☐ ***Brucella spp.***<br>☐ ***Campylobacter spp.***<br>☒ ***Pathogenic E. coli***<br>☐ ***Salmonella spp.***<br>☐ ***S. aureus***<br>☐ ***L. monocytogenes***<br>☐ ***Trichinella spiralis***<br>☐ ***Giardia lamblia***<br>☐ ***Shigella spp.***<br>☐ ***Other*** | 1 | 3 | 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.<br><br>——— SUPPLIER CONTROL MEASURES ———<br><br>01. La Galvanina SpA utilizes extensive raw material assessment and accreditation procedures to ensure that hazards posed by biological agents are controlled prior to receipt of raw material (water).<br>Details: Procedure is applicable to all goods and services that have an effect of the quality and legality of the products supplied to customers.<br><br>02. La Galvanina SpA utilizes chemical sanitation controls prior to bottling to ensure that bottles are free from biological contaminants.<br><br>03. La Galvanina SpA utilizes laboratory testing of rinsing water and samples finished product for microbiological analysis.<br>Details: Acceptable Levels<br>Yeasts: 0 ufc/mL.<br>Moulds: 0 ufc/mL.<br>Total Coliforms: absent.<br>Ps. aeruginosa: absent.<br>Str. fecalis: absent.<br><br>04. All product is positively released by QC.<br><br>----------NOTE----------<br>-- ADDITIONAL SUBSTANTIATION REQUESTED --<br><br>We respectfully request recent laboratory testing results for FDA identified biological hazards. In the absence of laboratory testing results. We would recommend that FSVP Importer conduct independent testing to confirm that product is free from on FDA-identified biological hazards on a regular basis. | 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.<br><br>USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified biological hazards.<br><br>---<br>----- HAZARD PROFILE -----<br>---------- SOURCE ----------<br><br>Appendix 1 (Hazards Tables)<br>Category: Ready-to-Drink.<br>Category No.: 02.<br>Subcategory: Bottled Water.<br>Storage: Shelf-Stable.<br>--- |

### 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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## ANALYSIS & DETERMINATION *of* CHEMICAL HAZARDS

| FDA Identified Hazard(s) | P. | S. | Control Measure(s) | Hazard(s) Controlled |
|---|---|---|---|---|
| ☒ ***Drug residues***<br>☒ ***Heavy metals***<br>☐ ***Industrial chemicals***<br>☐ ***Pesticides***<br>☐ ***Mycotoxins/Toxins***<br>☐ ***Radiological***<br>☒ ***Unapproved colors & additives***<br>☐ ***Chemical hazards due to mis-formulation***<br>☐ ***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.<br><br>——— SUPPLIER CONTROL MEASURES ———<br><br>01. La Galvanina SpA utilizes laboratory testing to ensure that raw material is free from Drug residues, Heavy Metals and/or Unapproved Colors and Additives.<br><br>Details: Checked every year for every supplier. Contract specifications for external lab. IST. 8.2.24 and IST. 8.2.25<br><br>----------NOTE----------<br>-- ADDITIONAL SUBSTANTIATION REQUESTED --<br><br>Laboratory testing is an acceptable method to ensure that a specific shipment/batch of raw material is free from a given hazard. We respectfully request recent laboratory testing results for Heavy metals, Drug residues, and Unapproved colors/additives.<br><br>In the absence of laboratory testing results. We would recommend that FSVP Importer conduct independent testing to confirm that product is free from on FDA-identified chemical hazards on a regular basis. | 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.<br><br>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.<br><br>----- HAZARD PROFILE -----<br>---------- SOURCE ----------<br><br>Appendix 1 (Hazards Tables)<br>Category: Ready-to-Drink.<br>Category No.: 02.<br>Subcategory: Bottled Water.<br>Storage: Shelf-Stable. |

### 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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## ANALYSIS & DETERMINATION *of* ALLERGENIC HAZARDS

| FDA Identified Hazard(s) | P. | S. | Control Measure(s) | Hazard(s) Controlled |
|---|---|---|---|---|
| ☐ ***Undeclared allergens - Incorrect label***<br>☐ ***Undeclared allergens - Cross-contact***<br><br>**ALLERGENS**<br>☐ ***Milk***<br>☐ ***Eggs***<br>☐ ***Fish***<br>☐ ***Shellfish*** *(Crustacean)*<br>☐ ***Tree nuts***<br>☐ ***Peanuts***<br>☐ ***Wheat***<br>☐ ***Soybeans***<br>☐ ***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.<br><br>——— SUPPLIER CONTROL MEASURES ———<br>01. Supplier certifies that:<br>A) there are NO allergens handled on site.<br>B) a documented allergen control program is in use.<br>C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination.<br>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.<br><br>---------- NOTE ----------<br>---------- Labeling Requirements ----------<br>- Food Allergen Labeling and Consumer Protection Act -<br>----------<br>- Nutritional information (not appliance to bulk).<br>- Name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5).<br>- Quantity of contents (21 CFR 101.7).<br>- Statement of identity (21 CFR 101.3).<br>- Presence of artificial flavoring, artificial coloring, or chemical preservative ( 21 CFR 101.22).<br>- Ingredient statement if the product has two or more ingredients (21 CFR 101.4).<br>- Presence of major food allergens (21 U.S.C. 343(w)).<br>- 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.<br><br>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.<br><br>_____<br>----- HAZARD PROFILE -----<br>---------- SOURCE ----------<br><br>Appendix 1 (Hazards Tables)<br>Category: Ready-to-Drink.<br>Category No.: 02.<br>Subcategory: Bottled Water.<br>Storage: Shelf-Stable.<br>_____<br>_____ |

### 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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## ANALYSIS & DETERMINATION *of* ENVIRONMENTAL HAZARDS

| FDA Identified Hazard(s) | P. | S. | Control Measure(s) | Hazard(s) Controlled |
|---|---|---|---|---|
| ☒ ***Recontamination with environmental pathogens.***<br>☐ ***Bacterial pathogen survival of a lethal treatment.***<br>☐ ***Bacterial growth and/or toxin formation due to lack of time / temperature control.***<br>☒ ***Recontamination due to lack of container integrity.***<br>☐ ***Bacterial growth and/or toxin formation due to poor formulation control.***<br>☐ ***Bacterial growth and/or toxin formation due to reduced oxygen packaging.***<br>☐ ***Other*** | 1 | 2 | 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.<br><br>——— SUPPLIER CONTROL MEASURES ———<br><br>01. Hazard posed by recontamination with environmental pathogens are controlled through Current Good Manufacturing Practices and a wide array of environmental condition controls.<br><br>Details: La Galvanina SpA has provided various (not HACCP) food safety documents. List follows: Cleaning and Sanitation Procedure, Environmental Air Check, Environmental Air Quality Check, Bioluminator Checks, Assessment, Accreditation and Monitoring of Suppliers, and Plan of Checks (includes comprehensive list of utilized CGMPs and the frequency of their oversight).<br>Dates: Vary, but appear to indicate that supplier created modern system in or around 2011.<br><br>02. La Galvanina SpA utilizes chemical sanitation controls prior to bottling to ensure that bottles are free from biological contaminants.<br><br>03. La Galvanina SpA utilizes laboratory testing of rinsing water and samples finished product for microbiological analysis.<br><br>Details: Acceptable Levels<br>Yeasts: 0 ufc/mL.<br>Moulds: 0 ufc/mL.<br>Total Coliforms: absent.<br>Ps. aeruginosa: absent.<br>Str. fecalis: absent.<br><br>04. All product is positively released by QC. | 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.<br><br>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.<br><br>———————<br>----- HAZARD PROFILE -----<br>---------- SOURCE ----------<br><br>Appendix 1 (Hazards Tables)<br>Category: Ready-to-Drink.<br>Category No.: 02.<br>Subcategory: Bottled Water.<br>Storage: Shelf-Stable.<br>———————<br>——————— |

### 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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## ANALYSIS & DETERMINATION *of* PHYSICAL HAZARDS

| FDA Identified Hazard(s) | P. | S. | Control Measure(s) | Hazard(s) Controlled |
|---|---|---|---|---|
| ☒ ***Metal***<br>☒ ***Glass***<br>☐ ***Extraneous Matter***<br>☐ ***Plastics***<br>☐ ***Stones***<br>☐ ***Wood***<br>☐ ***Natural Component of Food***<br>☐ ***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.<br><br>——— SUPPLIER CONTROL MEASURES ———<br><br>01. Supplier utilizes a filtration system prior to bottling to control hazards posed by physical agents.<br><br>Details: Filter mesh specifications were not provided by supplier. Filer is overseen and monitored by trained personal.<br><br>02. Supplier has sufficient raw material supplier approval procedures in place.<br><br>Details: see "Accreditation and Monitoring of Suppliers."<br><br>03. Supplier has sufficient broken glass protocols and procedures in place.<br><br>----------NOTE----------<br><br>We respectfully request a copy of La Galvanina SpA's Filter mesh specifications and any other metal control details. | 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.<br><br>----- HAZARD PROFILE -----<br>---------- SOURCE ----------<br><br>Appendix 1 (Hazards Tables)<br>Category: Ready-to-Drink.<br>Category No.: 02.<br>Subcategory: Bottled Water.<br>Storage: Shelf-Stable. |

### 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: La Galvanina SpA Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

# ASSESSMENT *of* FOREIGN SUPPLIER

## 1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: La Galvanina SpA

1.2. Supplier address: Via della Torretta, 2, 47923 Rimini RN, Italy.

1.3. Products manufactured/supplied: Soft and fruit drinks, cola, ice creams, and carbonated and mineral waters.

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

*GFSI Standard:* BRC Global Standard for Food Safety Issue 7: July 2015

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)*

## 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)*

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: La Galvanina SpA Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Oct. 11, 2021 Review End: Nov. 03, 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)*

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)*

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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## REVIEW *of* GENERAL FOOD SAFETY PROGRAM

### Claims Made Against Product

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

### Overview *of* Foreign Supplier's Commercial Operation

La Galvanina Societa' Per Azioni produces non-alcoholic beverages and manufactures a wide range of soft and fruit drinks, cola, ice creams, and carbonated waters for private label and other customers. La Galvanina SpA employs between 51-200 people.

Unverified statement from supplier: La Galvanina is an outstanding producer of pure mineral water and of an impressive range of sodas and ice teas. The company owns two mineral water sources located in Central Italy, and is recognized worldwide for its high quality, uncompromised production standards and innovative force. La Galvanina operates own bottling plants that offer both glass and PET bottles, and serves all countries with its branded products as well as with a very significant amount of private labels.

### Testing Program & Accreditation

Suppliers are constantly monitored and assessed according to the quality of supplies delivered and documented in MOD. 36 A "Checklist for Incoming Raw Materials". In case of checks with positive results, the accreditation already obtained is confirmed, and the respective accreditation attributions are updated. Incase of checks with negative results, the Assessment Team will oblige the supplier to observe a state of "suspension". Any state of suspension of a supplier will be noted in the List of Accredited Suppliers. Accreditation may be obtained again only after a new accreditation process has been successfully completed, which a supplier may commence only after the expiry of a "period of prohibition" of twelve months.

### 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 (glass and PET bottles) is accredited for food use. Ambient shipping and handling requirements.

Supplier: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## REVIEW *of* GENERAL FOOD SAFETY PROGRAM

### Supplier GFSI Status & Historical Performance

La Galvanina SpA has not provided a copy of their onsite audit report or any other form of substantiation. Independent research indicates that La Galvanina S.p.A. currently holds FSMA Regulatory Certification.
FSMA Regulatory Certification - Not Confirmed.
No. C2019-02209.
Dated: 07/05/2019.
Exp: 07/04/2020.
Scope: Manufacture and bottling of mineral water.
---
We respectfully request a copy of La Galvanina SpA's onsite audit report or similar.

### Close Supplier Monitoring

No. Supplier follows CGMPs and utilizes an established food safety program. 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

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.

----------NOTE----------

We respectfully request:

A copy of La Galvanina SpA's onsite audit report or similar.
A copy of recent laboratory testing results, conducted by a 17025-accredited laboratory, for FDA-identified chemical and biological hazards – or similar.
A completed version of United Safety Agents' Foreign Supplier FSVP Questionnaire (DOCSAAQ02212019).

Supplier: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 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.

---

FSVP IMPORTER

In the absence of laboratory testing results. We recommend that FSVP Importer conduct independent testing to confirm that product is free from on FDA-identified biological and chemical hazards on a regular basis.

We respectfully request:

- A copy of recent laboratory testing results, conducted by a 17025-accredited laboratory, for FDA-identified chemical and biological hazards – or similar.
- A completed version of United Safety Agents' Foreign Supplier FSVP Questionnaire (DOCSAAQ02212019).

## ADDENDUM

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Supplier: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## ADDENDUM

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Supplier: La Galvanina SpA | Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) | Review Start: Oct. 11, 2021 | Review End: Nov. 03, 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: La Galvanina SpA | Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) | Review Start: Oct. 11, 2021 | Review End: Nov. 03, 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

ifpti International Food Protection Training Institute

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: La Galvanina SpA Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Oct. 11, 2021 Review End: Nov. 03, 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

05/31/2018

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

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AFDO

Certificate # d2e9c287

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

09/14/2017

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

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AFDO

Certificate # d2e9c287

Supplier: La Galvanina SpA Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Oct. 11, 2021 Review End: Nov. 03, 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:

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

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AFDO

Certificate # 2d697331

Supplier: La Galvanina SpA | Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) | Review Start: Oct. 11, 2021 | Review End: Nov. 03, 2021

## CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

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

ifpti

Certificate # ed6f0b58

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

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

Certificate # 917b0241

AFDO

## CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

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

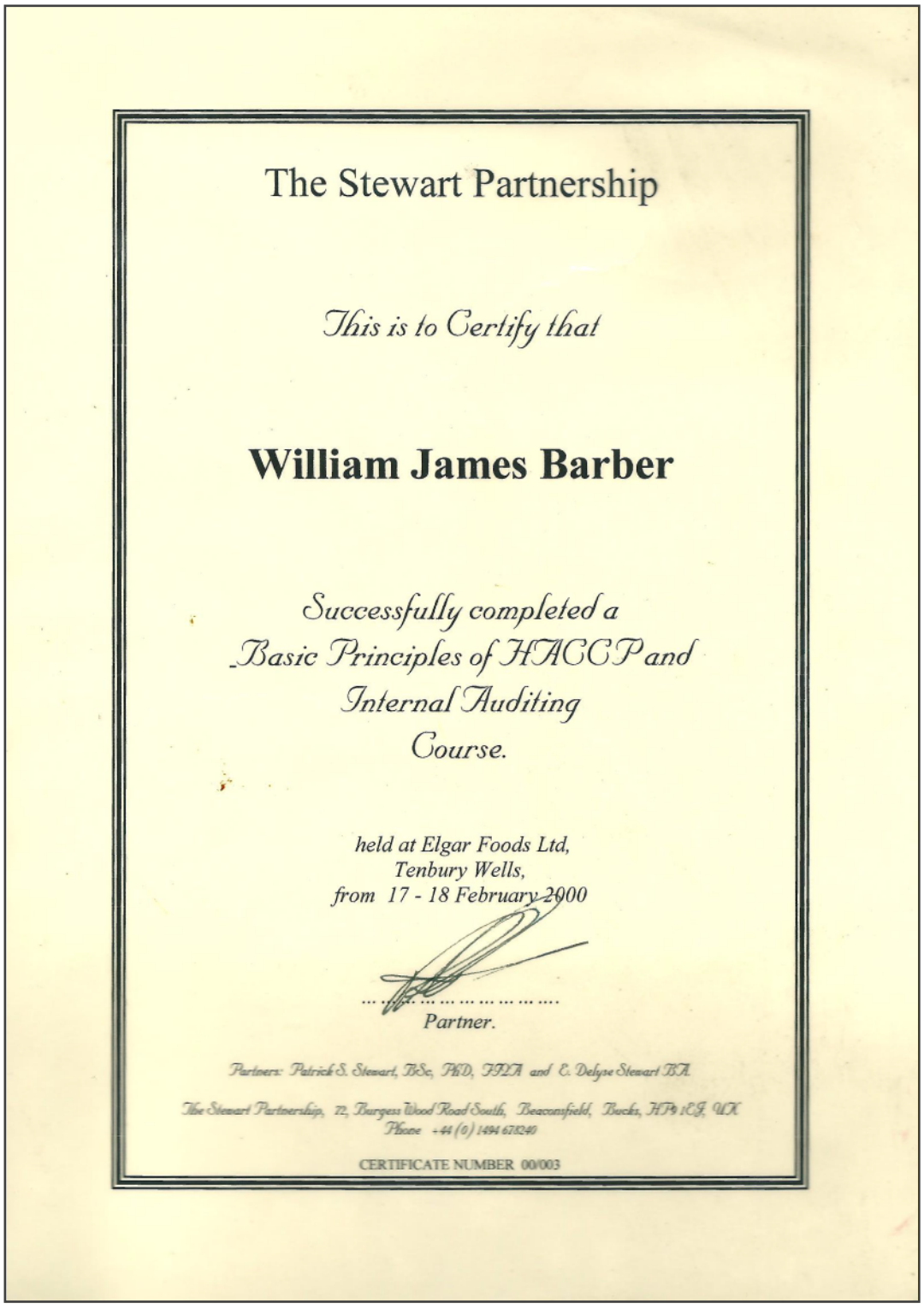
526405 101116 1107147

RSPH

Supplier: La Galvanina SpA Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Oct. 11, 2021 Review End: Nov. 03, 2021

## CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT



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: La Galvanina SpA | Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) | Review Start: Oct. 11, 2021 | Review End: Nov. 03, 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: La Galvanina SpA | Product: Italian Sparkling Mineral Water

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) | Review Start: Oct. 11, 2021 | Review End: Nov. 03, 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: La Galvanina SpA

Product: Italian Sparkling Mineral Water

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

Review Start: Oct. 11, 2021 Review End: Nov. 03, 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.

**INTERESTED MANAGERS:**
Production Manager: Luca Bertozzi
Quality Control Manager: Dott. Matteo Matassoni

**ACTIVITY:**
**CCP1 VALIDATION** (MONITORING OF THE WORKING PARAMETERS SET FOR FILLING MACHINE DETERSION-SANIFICATION-RINSING OPERATIONS).

**OBJECT OF VALIDATION**:

| DATE | CONDUCTED OPERATIONS | FROM: | RESULTS | | NOTE |
|---|---|---|---|---|---|
| 18/09/2016 | **PLC:** complete cycle execution | QCM/PM | The correct and complete execution of the cleaning cycle has been verified as set by the programmer | | |
| 18/09/2016 | **DETERGENT SOLUTION:** temperature recording | Lab Technician | Measured value: 79°C<br>Target value: 77-80°C | | |
| 18/09/2016 | **DETERGENT SOLUTION:** Detergent chemical analysis | Lab Technician | Measured value: 2,0%<br>Target value: 1,8 – 2,2% | | |
| 18/09/2016 | **DETERGENT SOLUTION:** Conductivity analysis | Lab Technician | Measured value: 94 mS/cm<br>Target value: 90 – 95 mS/cm | | |
| 18/09/2016 | **SANITAZER SOLUTION:** Sanitizer chemical analysis | Lab Technician | Measured value:100 ppm peracetic acid to room temperature<br>Target value:50-150 ppm peracetic acid to room temperature | | |
| 18/09/2016 | **RINSING WATER:** Detergent chemical analysis | Lab Technician | Measured value: 0%<br>Target value: 0% | | |
| 18/09/2016 | **RINSING WATER:** Conductivity analysis | Lab Technician | Measured value: 0 mS/cm<br>Target value: 0 mS/cm | | |
| 18/09/2016 | **RINSING WATER:** Sanitizer chemical analysis | Lab Technician | Measured value: 0 ppm peracetic acid<br>Target value:0 ppm peracetic acid | | |
| 18/09/2016 | **RINSING WATER:** Microbiological analysis after drainage | Lab Technician | **Yeasts** | 0 ufc/mL | |
| | | | **Moulds** | 0 ufc/mL | |
| | | | **Total Coliforms** | absent | |
| | | | **Ps. aeruginosa** | absent | |
| | | | **Str. fecalis** | absent | |

| **GOAL:** | **RESULT** |
|---|---|
| CHECK OF FILLING MACHINE DETERSION-SANIFICATION- RINSING OPERATIONS EFFECTIVENESS. | POSITIVE |

**ATTACHMENTS:** TECHNICAL SHEET + SAFETY DATA SHEET

**APPROVED BY QCM:**_____

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

Claudio Innocenti

**INTERESTED MANAGERS:**
Production Manager: Luca Bertozzi
Quality Control Manager: Dott. Matteo Matassoni

**ACTIVITY:**
**CCP2 VALIDATION** (MONITORING OF THE WORKING PARAMETERS SET FOR PREMIX-DEAERATOR /SATURATOR DETERSION-SANIFICATION-RINSING OPERATIONS).

**OBJECT OF VALIDATION**:

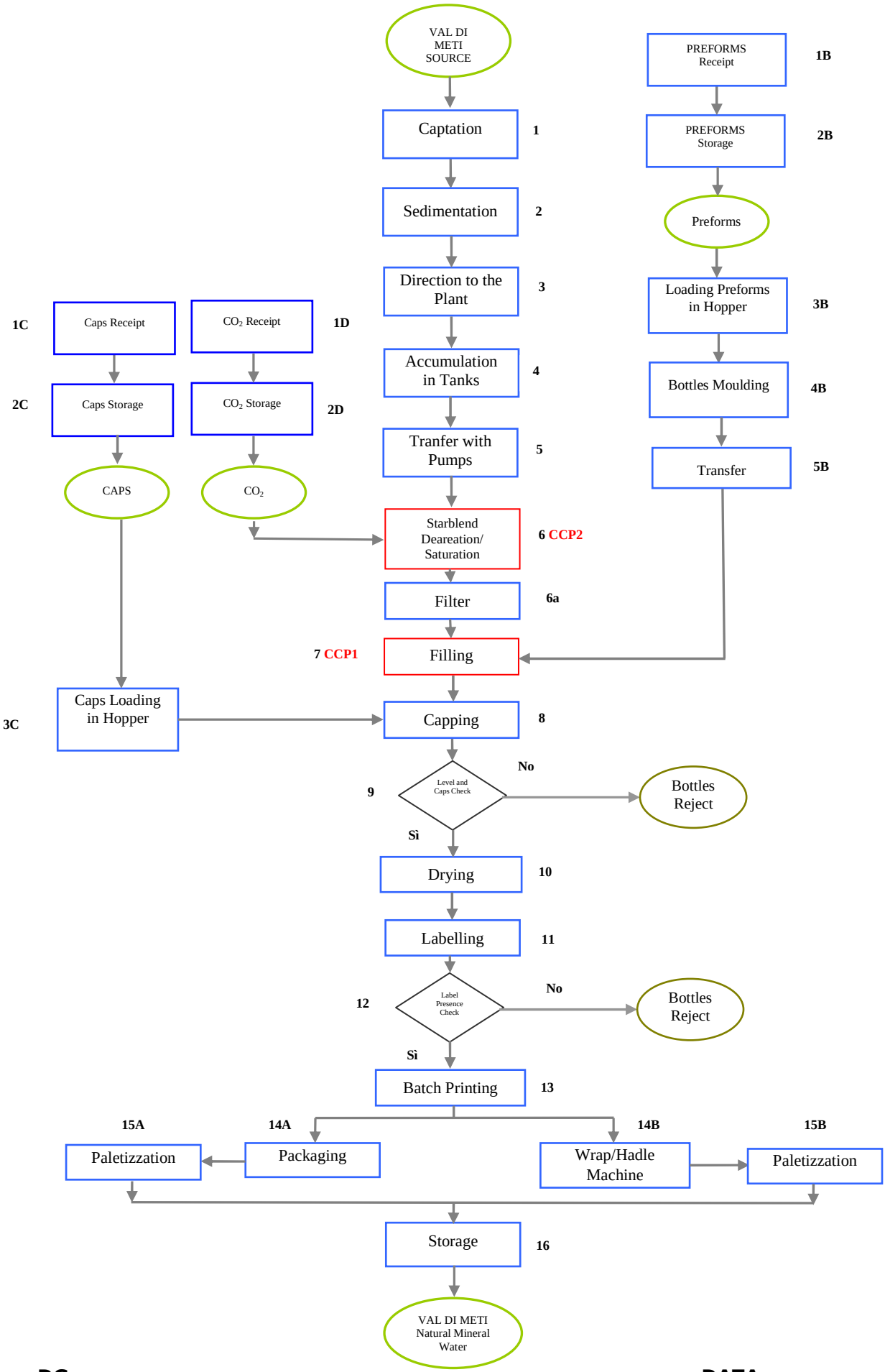
| DATE | CONDUCTED OPERATIONS | FROM: | RESULTS | | NOTE |
|---|---|---|---|---|---|
| 18/09/2016 | **PLC:** complete cycle execution | QCM/PM | The correct and complete execution of the cleaning cycle has been verified as set by the programmer | | |
| 18/09/2016 | **DETERGENT SOLUTION:** temperature recording | Lab Technician | Measured value: 78°C<br>Target value: 77-80°C | | |
| 18/09/2016 | **DETERGENT SOLUTION:** Detergent chemical analysis | Lab Technician | Measured value: 2%<br>Target value: 1,8 – 2,2% | | |
| 18/09/2016 | **DETERGENT SOLUTION:** Conductivity analysis | Lab Technician | Measured value: 93 mS/cm<br>Target value: 90 – 95 mS/cm | | |
| 18/09/2016 | **SANITAZER SOLUTION:** Sanitizer chemical analysis | Lab Technician | Measured value:100 ppm peracetic acid to room temperature<br>Target value:50-150 ppm peracetic acid to room temperature | | |
| 18/09/2016 | **RINSING WATER:** Detergent chemical analysis | Lab Technician | Measured value: 0%<br>Target value: 0% | | |
| 18/09/2016 | **RINSING WATER:** Conductivity analysis | Lab Technician | Measured value: 0 mS/cm<br>Target value: 0 mS/cm | | |
| 18/09/2016 | **RINSING WATER:** Sanitizer chemical analysis | Lab Technician | Measured value: 0 ppm peracetic acid<br>Target value:0 ppm peracetic acid | | |
| 18/09/2016 | **RINSING WATER:** Microbiological analysis after drainage | Lab Technician | **Yeasts** | 0 ufc/mL | |
| | | | **Moulds** | 0 ufc/mL | |
| | | | **Total Coliforms** | absent | |
| | | | **Ps. aeruginosa** | absent | |
| | | | **Str. fecalis** | absent | |

| **GOAL:** | **RESULT** |
|---|---|
| CHECK OF PREMIX-DEAERATOR /SATURATOR DETERSION-SANIFICATION-RINSING OPERATIONS EFFECTIVENESS. | POSITIVE |

**ATTACHMENTS:** TECHNICAL SHEET + SAFETY DATA SHEET

**APPROVED BY QCM:**_____

| GALVANINA ANTICA FONTE ROMANA | **Flow Chart: Sparkling Mineral Water"VAL DI METI" PET** | TAB. 7.5.01 VDM<br>Rev. 0<br>10/05/10<br>Pag. 1 di1 |
|---|---|---|




**DG**_____ **DATA**_____

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

Claudio Innocenti

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

Claudio Innocenti

GALVANINA
ANTICA FONTE ROMANA

# PLAN OF CHECKS

TAB.7.5.06 VDM Rev. 9 dated 12/20/2018

| *PHASE* | CCP | PARAMETERS TO BE CHECKED | SAMPLING FREQUENCY | METHOD OR INSTRUMENT | CRITICAL LIMIT | CORRECTIVE ACTION | PERSON RESPONSIBLE | REFERENCE DOCUMENT | REGISTRATION |
|---|---|---|---|---|---|---|---|---|---|
| Receipt andStorage of packings/caps | | Original packing undamaged<br>Transport conditions<br>Conformant to order | With every supply | Visual check | Presence of pests<br>Presence of breakages<br>Not conformant to order | Isolate product<br>Return product | RP/RCQ | Transport document | Mod. 36<br>Mod. 07 NC |
| Caps | | Conformity of color/wordings<br>Presence of foreign bodies | Every lot | Visual check | Not conformant to specifications | Isolate product<br>Return product | Warehouse function supervisor | Transport document<br>Supplier tag | Mod. 36<br>Mod. 07 NC |
| Caps | | Microbiological check (Total Coliforms) | Once every 3 months | Swab and smear on selective culture media | Absence | Interrupt production Isolate product and identificate like NC | RCQ | MOD. 415 | MOD. 415 |
| Caps | | Overall and Specific migration tests | Annual | Official method performed by third party accredited lab | Presence of substances not permitted by law | Isolate product<br>Return product | RCQ | / | Test report |
| Preforms | | Original packing undamaged<br>Transport conditions<br>Conformant to order | With every supply | Visual check | Presence of pests<br>Presence of breakages<br>Not conformant to order | Isolate product<br>Return product | RP/RCQ | Transport document | Mod. 36<br>Mod. 07 NC |
| Formed PET bottles | | Weight/Color/Deformations | Twice every shift | Visual check/ micrometer/weigher | Not conformant to specifications<br>Presence of deformations | Isolate product lot<br>Eliminate product<br>Work on bottle blower | Bottle blower function supervisor | PRO 7.5.01 PET, GLASS<br>PRO 7.5.04 PET, GLASS | Mod.158 VDM |
| Formed PET bottles | | Overall and Specific migration tests | Annual | Official method performed by third party accredited lab | Presence of substances not permitted by law | Isolate product<br>Return product | RCQ | / | Test report |
| Labels | | Conformity with specifications | Every lot | Visual check | Not conformant to specifications | Isolate product<br>Return product | RS/Warehouse function supervisor | Transport document<br>Supplier tag | Mod. 36<br>Mod. 07 NC |
| Cardboard cases | | Conformity with specifications | Every lot | Visual check | Not conformant to specifications | Isolate product<br>Return product | RP/Warehouse function supervisor | Transport document<br>Supplier tag | Mod. 36<br>Mod. 07 NC |
| Receipt of Aromas/Flavors | | Original packing undamaged<br>Transport temperature<br>Transport conditions<br>Conformant to order<br>Conformity with specifications | With every supply | Visual check | Presence of pests<br>Presence of breakages<br>Not conformant to order<br>Not conformant to specifications | Isolate product<br>Return product | Warehouse function supervisor | Transport document | Mod. 36 A<br>Mod. 07 NC |

GALVANINA
ANTICA FONTE ROMANA

PLAN OF CHECKS

TAB.7.5.06 VDM Rev. 9 dated 12/20/2018

| *PHASE* | CCP | PARAMETERS TO BE CHECKED | SAMPLING FREQUENCY | METHOD OR INSTRUMENT | CRITICAL LIMIT | CORRECTIVE ACTION | PERSON RESPONSIBLE | REFERENCE DOCUMENT | REGISTRATION |
|---|---|---|---|---|---|---|---|---|---|
| Aromas/Flavors | | **Chemical:** alcohol levels / heavy metals;<br>**Microbiological:** yeasts / molds / lactic bacteria | Every year for every supplier | Contract specifications for external lab.<br>IST. 8.2.24<br>IST. 8.2.25 | Technical info sheet | Isolate lot<br>Return product | Lab technician/RCQ | / | Mod. 111<br>Mod. 07 NC<br>Test report |
| Storage of Aromas/Flavors | | Absence of pests<br>Absence of breakages<br>Absence of order | Every day | Visual check | Presence of pests<br>Presence of breakages<br>Absence of order | Isolate lot | Production function supervisor | PRO 7.5.04 PET, GLASS | Mod. 07 NC |
| RECEIPT AND STORAGE OF CARBON DIOXIDE | | Check conformity of test report | With every supply | / | Not conformant to legal requirements:<br>Min. Decree 209 02/27/97, Min. Decree 356 08/04/97, Min. Decree 02/19/66 | Isolate lot<br>Return product | RS | PRO 7.5.04 PET, GLASS | Mod. 07 NC |
| WATER COLLECTION FROM SPRINGS | | Smell, color, taste | Every week | Sensorial tests | Presence | • Temporary interruption of use<br>• Notification to competent authorities of harmful activities by third parties<br>• Elimination of causes of contamination<br>• Sanitization (IST.7.5.01) | Lab technician | PRO. 8.2.00<br>IST. 8.2.12<br>IST.8.2.13<br>IST.8.2.14 | Mod.46 VDM |
| | | Conductivity | Every week | Conductivity meter | See Mod.46 | | Lab technician | PRO. 8.2.00<br>IST. 8.2.05 | Mod.46 VDM |
| | | Temperature | Every week | Thermometer | See Mod.46 | | Lab technician | PRO. 8.2.00<br>IST. 8.2.23 | Mod.46 VDM |
| | | pH | Every week | pH meter | See Mod.46 | | Lab technician | PRO. 8.2.00<br>IST. 8.2.08 | Mod.46 VDM |
| | | Water hardness | Every week | Volumetric method | See Mod.46 | Temporary interruption of use<br>• Notification to competent authorities of harmful activities by third parties<br>• Elimination of causes of contamination<br>• Sanitization (IST.7.5.01) | Lab technician | PRO. 8.2.00<br>IST. 8.2.15 | Mod.46 VDM |

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# PLAN OF CHECKS

TAB.7.5.06 VDM Rev. 9 dated 12/20/2018

| *PHASE* | CCP | PARAMETERS TO BE CHECKED | SAMPLING FREQUENCY | METHOD OR INSTRUMENT | CRITICAL LIMIT | CORRECTIVE ACTION | PERSON RESPONSIBLE | REFERENCE DOCUMENT | REGISTRATION |
|---|---|---|---|---|---|---|---|---|---|

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| WATER COLLECTION FROM SPRINGS | | Chlorides | Every week | Volumetric method | See Mod.50 | | Lab technician | PRO. 8.2.00<br>IST. 8.2.11 | Mod.46 VDM |
| | | Total dissolved solids | Every week | Weighing method | See Mod.46 | Temporary interruption of use<br>• Notification to competent authorities of harmful activities by third parties<br>• Elimination of causes of contamination<br>• Sanitization (IST.7.5.01) | Lab technician | PRO. 8.2.00<br>IST. 8.2.06 | Mod.46 VDM |
| | | Bicarbonates | Every week | Volumetric method | See Mod.46 | | Lab technician | PRO. 8.2.00<br>IST. 8.2.03 | Mod.46 VDM |
| | | Plate count at 20°C | Every week | Culture | > 20 CFU/mL | • Temporary interruption of use<br>• Notification to competent authorities of harmful activities by third parties<br>• Elimination of causes of contamination<br>• Sanitization (IST.7.5.01) | Lab technician | PRO. 8.2.00<br>IST. 8.2.16 | Mod.46 VDM |
| | | Plate count at 37°C | Every week | Culture | > 5 CFU/mL | | Lab technician | PRO. 8.2.00<br>IST. 8.2.16 | Mod.46 VDM |
| | | Pseudomonas aeruginosa | Every week | Culture | Presence | | Lab technician | PRO. 8.2.00<br>IST. 8.2.20 | Mod.46 VDM |
| | | Coliform bacteria | Every week | Culture | Presence | | Lab technician | PRO. 8.2.00<br>IST. 8.2.18 | Mod.46 VDM |
| | | Streptococcus faecalis | Every week | Culture | Presence | | Lab technician | PRO. 8.2.00<br>IST. 8.2.19 | Mod.46 VDM |
| | | Staphylococcus aureus | Every week | Culture | Presence | | Lab technician | PRO. 8.2.00<br>IST. 8.2.04 | Mod.46 VDM |
| | | Sulfite-reducer clostridiums | Once every month | Culture | Presence | | Lab technician | PRO. 8.2.00<br>IST. 8.2.21 | Mod.46 VDM |

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# PLAN OF CHECKS

TAB.7.5.06 VDM Rev. 9 dated 12/20/2018

| *PHASE* | CCP | PARAMETERS TO BE CHECKED | SAMPLING FREQUENCY | METHOD OR INSTRUMENT | CRITICAL LIMIT | CORRECTIVE ACTION | PERSON RESPONSIBLE | REFERENCE DOCUMENT | REGISTRATION |
|---|---|---|---|---|---|---|---|---|---|
| MIXING IN MASSBLEND /DEAERATION/SATURATION | YES | Check on presence of sanitization agent in detersion | End of production/every change of production | Indicator papers | Absence of sanitization agent | • Repeat sanitization procedures | Function operative | IST. 7.5.03 VDM | Mod. 48 VDM CCP1-2 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| MIXING IN MASSBLEND /DEAERATION/SATURATION | YES | Check on absence of sanitization agent in rinsing water | Start of production/every change of production | Indicator papers | Presence of sanitization agent | • Repeat rinsing procedures | Function operative | IST. 7.5.03 VDM | Mod. 48 VDM CCP1-2 |
| MIXING IN MASSBLEND /DEAERATION/SATURATION | | Carbon dioxide pressure | Every production of sparkling water | Pressure gauge | IST. 7.5.115 | Eliminate non-conformant lot<br>• Interrupt production<br>• Return to correct values | Function operative | / | Mod. 54 VDM |
| MIXING IN MASSBLEND /DEAERATION/SATURATION | | Temperature | Every production of sparkling water | Thermometer | IST. 7.5.115 | Eliminate non-conformant lot<br>• Interrupt production<br>• Return to correct values | Function operative | / | Mod. 54 VDM |
| DEAERATION/SATURATION | YES | Presence of sanitization agent in detersion | End of production/every change of production | Indicator papers | Absence of sanitization agent | Check machine<br>Check supply of sanitization agent | Function operative | IST. 7.5.03 VDM | Mod. 48 VDM CCP1-2 |
| DEAERATION/SATURATION | YES | Check on absence of sanitization agent in rinsing water | Start of production/every change of production | Indicator papers | Presence of sanitization agent | • Repeat rinsing procedures | Function operative | IST. 7.5.03 VDM | Mod. 48 VDM CCP1-2 |
| DEAERATION/SATURATION | | Carbon dioxide pressure | Every production lot of sparkling water | Pressure gauge | Values out of correct range | Eliminate non-conformant lot<br>• Interrupt production<br>• Return to correct values | Function operative | / | Mod. 54 VDM |
| DEAERATION/SATURATION | | Temperature | Every production of sparkling water | Thermometer | Values out of correct range | Eliminate non-conformant lot<br>• Interrupt production<br>• Return to correct values | Function operative | / | Mod. 54 VDM |
| FILLING | YES | Presence of sanitization agent in detersion | End of production/every change of production | Indicator papers | Absence of sanitization agent | • Repeat sanitization procedures | Function operative | IST. 7.5.03 VDM | Mod. 48 VDM CCP1-2 |
| FILLING | YES | Absence of sanitization agent in rinsing water | Start of production/every change of production | Indicator papers | Presence of sanitization agent | • Repeat rinsing procedures | Function operative | IST. 7.5.03 VDM | Mod. 48 VDM CCP1-2 |

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# PLAN OF CHECKS

TAB.7.5.06 VDM Rev. 9 dated 12/20/2018

| *PHASE* | CCP | PARAMETERS TO BE CHECKED | SAMPLING FREQUENCY | METHOD OR INSTRUMENT | CRITICAL LIMIT | CORRECTIVE ACTION | PERSON RESPONSIBLE | REFERENCE DOCUMENT | REGISTRATION |
|---|---|---|---|---|---|---|---|---|---|
| FILLING | | Number of broken bottles | During production | Visual | > 1 out of 3000 | Interrupt production<br>Identify non-conformant lot<br>Inform RS | Function operative | IST. 7.5.29 | Mod. 54 VDM |
| PET FILLING | | Volumetric capacity | 80 bottles every hour | Graduated cylinder and weigher | Values lower than capacity shown on label | • Interrupt production<br>• Extraordinary maintenance • Reject finished product with incorrect filling level | Function operative | | Mod. 229 VDM |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| CAP APPLICATION | | Resistance to cap opening | Every day for every cap type | Dynamometer | Values out of correct range See Mod.47 | • Interrupt production<br>• Extraordinary maintenance • Reject finished product incorrectly capped | Function operative | IST. 8.2.07 | Mod. 47 VDM |
| LABELING | | Check on lot and labeling | Every HOUR for every production | Visual | Non-conformant lot labeling | Isolate non-conformant product<br>Destroy product | Labeling operative<br>RCQ | / | Mod. 07 NC<br>Mod. 52 VDM |
| PACKING (case packer, multipacker) | | Check on packaging conformity | Every HOUR | Visual | Defective packaging | Isolate non-conformant product<br>Destroy product | Case packer operative | / | Mod. 07 NC<br>Mod. 51 VDM |
| PACKING | | Conformity of bar code | Every hour for productions where bar code is applied by inkjet machine | Scanner for bar code identification | Failure to read bar code | • Interrupt packing<br>• Reset correct operation of inkjet machine | Case packer operative | / | Mod. 230 VDM |
| Mineral Water Storage | | Smell, color, taste | For every production lot | Organoleptic test | Presence | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.12<br>IST.8.2.13<br>IST.8.2.14 | See Form 45 |
| Mineral Water Storage | | Conductivity | For every production lot | Conductivity meter | Values out of correct range See Form 45 | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.05 | See Form 45 |
| Mineral Water Storage | | pH | For every production lot | pH-meter | Values out of correct range See Form 45 | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.08 | See Form 45 |
| Mineral Water Storage | | Nitrates | For every production lot | Spectrophotometer | Values out of correct range See Form 45 | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.09 | See Form 45 |
| Mineral Water Storage | | Chlorides | For every production lot | Volumetric method | Values out of correct range See Form 45 | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.11 | See Form 45 |

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# PLAN OF CHECKS

TAB.7.5.06 VDM Rev. 9 dated 12/20/2018

| *PHASE* | CCP | PARAMETERS TO BE CHECKED | SAMPLING FREQUENCY | METHOD OR INSTRUMENT | CRITICAL LIMIT | CORRECTIVE ACTION | PERSON RESPONSIBLE | REFERENCE DOCUMENT | REGISTRATION |
|---|---|---|---|---|---|---|---|---|---|
| Mineral Water Storage | | Hardness | For every production lot | Volumetric method | Values out of correct range See Form 45 | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.15 | See Form 45 |
| Mineral Water Storage | | Total dissolved solids at 180°C | For every production lot | Weighing method | Values out of correct range See Form 45 | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.06 | See Form 45 |
| Mineral Water Storage | | g/L $CO_2$ | For every production lot | Pressure gauge | Out of range | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.10 | See Form 45 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Mineral Water Storage | | carica batterica a 20°C | For every production lot | Culture | > 10000 UFC/mL | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.16 | See Form 45 |
| Mineral Water Storage | | carica batterica a 37°C | For every production lot | Culture | > 10000 UFC/mL | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.16 | See Form 45 |
| Mineral Water Storage | | Coliform bacteria | For every production lot | Culture | Presence | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.18 | See Form 45 |
| Mineral Water Storage | | Pseudomonas aeruginosa | For every production lot | Culture | Presence | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.20 | See Form 45 |
| Mineral Water Storage | | Streptococcus faecalis | For every production lot | Culture | Presence | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.19 | See Form 45 |
| Mineral Water Storage | | Staphylococcus aureus | For every production lot | Culture | Presence | • Isolate product<br>• Destroy product | RCQ | PRO. 8.2.00<br>IST. 8.2.04 | See Form 45 |
| Surface Air System (SAS) | | Microorganisms research in the air (Yeasts, Moulds, Pseudomonas a., Streptococcus faecalis, Staphylococcus a., Total plate count, Coliform Bacteria) in defined zones (Filling area, Syrup room, Lab) | every month | Active Air Sampler | Values out of correct range See Mod. 73 | treatment with fumigants | ADQ | PRO. 8.2.00 | See mod. 73 See mod. 73 A |
| Effectiveness of cleaning | | Effectiveness of cleaning | weekly | Bioluminator Swab | C/NC | perform new cleaning | RCQ | PRO. 7.5.07 | see mod. 59 |

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# PLAN OF CHECKS

TAB.7.5.06 VDM Rev. 9 dated 12/20/2018

| *PHASE* | CCP | PARAMETERS TO BE CHECKED | SAMPLING FREQUENCY | METHOD OR INSTRUMENT | CRITICAL LIMIT | CORRECTIVE ACTION | PERSON RESPONSIBLE | REFERENCE DOCUMENT | REGISTRATION |
|---|---|---|---|---|---|---|---|---|---|
| Pest check | | Pests presence | monthly (from october to march) twice a month (from april to september) | Illuminated "Flytrap" traps | Low > 60 6 traps inside factory<br>Media > 90 4 traps inside factory<br>Critica > 120 1 trap inside factory | Increase number of trapping stations in area.<br>Request additional operations by specialized company. | ADQ | PRO. 7.5.04 | see mod. 107 |
| Pest check | | Pests presence | every month | Glue Traps | Presence | Increase of number of temporary traps in the area.<br>Increase cleaning operations in area. | Specialized Company Personnel RCQ/RAQ | PRO. 7.5.04 | Pest control register |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Pest check | | Bait nibbled | every month | External traps with solid poisonous bait | Bait nibbled on 3 consecutive checks | Increase number of trapping stations in area.<br>Action by specialized company.<br>Increase cleaning operations in area. | Specialized Company Personnel RCQ/RAQ | PRO. 7.5.04 | Pest control register |

| | |
|---|---|
| *RCQ SIGNATURE* | *Date* |

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

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# HACCP PLAN Line 1 (Mineral Water PET)

| CCP n° | Step | Phase | Risk # | Risk description | Control Misure | Critical Limit / Target | Monitoring How, frequency, who? | Corrections/ Corrective actions/ Responsibility | Records | Verify |
|---|---|---|---|---|---|---|---|---|---|---|
| CCP n°2 | 6 | Starblend Deareation/ Saturation | Chemical | Sanitizing presence | Test with indicator strips | Sanitizing present in the process of sanitization (≥ 100 ppm) | The system is tested at every stage of sanitizing with indicator strips. Operator | If during Sanitizing the test does not succeed the step is repeated until the indicator strips give a value ≥ 100 ppm / PM-QCM | MOD. 48 VDM CCP1/CCP2 | Internal inspection and forms control. |
| | | | | Sanitizing absence | Test with indicator strips | Sanitizing absent after the rinsing phase ( 0 ppm) | The system is tested at every stage of rinsing with indicator strips. Operator | If after the step of rinsing the test does not succeed it is repeated rinsing until the indicator strips indicate 0 ppm / PM-QCM | | |
| CCP n°1 | 7 | Filling | Chemical | Sanitizing presence | Test with indicator strips | Sanitizing present in the process of sanitization (≥ 100 ppm) | The system is tested at every stage of sanitizing with indicator strips. Operator | If during Sanitizing the test does not succeed the step is repeated until the indicator strips give a value ≥ 100 ppm / PM-QCM | MOD. 48 VDM CCP1/CCP2 | Internal inspection and forms control. |
| | | | | Sanitizing absence | Test with indicator strips | Sanitizing absent after the rinsing phase ( 0 ppm) | The system is tested at every stage of rinsing with indicator strips. Operator | If after the step of rinsing the test does not succeed it is repeated rinsing until the indicator strips indicate 0 ppm / PM-QCM | | |

**RCQ**_____ **DATA**_____



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| HAZARD | | | | PREVENTIVE ACTIVITIES | | | | RISK ASSESSMENT | | |
|---|---|---|---|---|---|---|---|---|---|---|
| PHASE | CHEMICAL | PHYSICAL | MICROBIOLOGICAL | TECHNICAL MEASURES | MATERIALS | METHODS | PERSONAL | GRAVITY | PROBABILITIES | RISK |
| Captation<br>**1** | Chemical contamination of water (sanitazing residual after cleaning operations) | / | / | | Stainless Steel pipeline<br>Tiled environment | Geological study and definition of the respect area<br><br>Weekly check at the source<br><br>IST. 7.5.01 VDM Captation pipeline cleaning | Personnel trained for the cleaning operations in this area | 2 | 1 | 2 |
| | / | / | Microbiological contamination of water | | Stainless Steel pipeline<br>Tiled environment | Geological study and definition of the respect area<br><br>Weekly check at the source<br><br>IST. 7.5.01 VDM Captation pipeline cleaning | Personnel trained for the cleaning operations in this area | 2 | 1 | 2 |
| Sedimentation<br>**2** | Chemical contamination of water (sanitazing residual after cleaning operations) | / | / | | Stainless Steel tank<br><br>Unbreakable glass cover that permits visual inspection<br><br>Tiled environment | IST. 7.5.01 VDM Captation pipeline cleaning<br><br>Weekly check at the source | Personnel trained for the cleaning operations in this area | 2 | 1 | 2 |
| | / | Physical contamination of water (potential sand microparticles could be naturally contained in the source water) | / | Sendimentation process is a natural kind of filtration (for the italian law the water can never be treated) | Stainless Steel tank | IST. 7.5.01 VDM Captation pipeline cleaning<br><br>Weekly check at the source | Personnel trained for the cleaning operations in this area | 2 | 1 | 2 |
| Direction to the plant<br>**3** | / | / | / | | | | | / | / | / |
| Accumulation in tanks<br>**4** | Chemical contamination of water (sanitazing residual after cleaning operations) | / | / | | Stainless Steel tank | IST. 7.5.01 VDM Captation pipeline cleaning<br><br>Weekly check at the source | Personnel trained for the cleaning operations in this area | 2 | 1 | 2 |
| Transfer with pumps<br>**5** | / | / | / | | | | | / | / | / |



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| HAZARD | | | | PREVENTIVE ACTIVITIES | | | | RISK ASSESSMENT | | |
|---|---|---|---|---|---|---|---|---|---|---|
| PHASE | CHEMICAL | PHYSICAL | MICROBIOLOGICAL | TECHNICAL MEASURES | MATERIALS | METHODS | PERSONAL | GRAVITY | PROBABILITIES | RISK |
| Starblend Deareation/ Saturation **6** | Chemical contamination of water (sanitizing residual after sanitation operations) | / | / | CIP | Stainless steel equipments | Pro 7.5.07 Cleaning procedure<br>Pro 6.3.01 Maintenance | Trained personnel about CIP, CCPs and cleaning procedures | 4 | 2 | 8 CCP2 |
| Filtration **6a** | / | Physical contamination | / | Filters | Filters | Cleaning and maintenance | Trained personnel about GMP, GHP | 2 | 1 | 2 |
| Filling **7** | Chemical contamination of water (sanitizing residual after sanitation operations) | / | / | CIP | Stainless steel equipments | IST. 7.5.03 VDM<br>Pro 6.3.01 Maintenance | Trained personnel about CIP, CCPs and cleaning procedures | 4 | 2 | 8 CCP1 |
| Capping **8** | / | Physical contamination: foreign bodies | / | Caps loaded in a closed hopper Capping machine completely cover | | Pro 6.3.01 Maintenance | | 2 | 1 | 2 |
| Level and Caps check **9** | / | / | / | Electronic check | | Equipment set-up | Personnel trained | / | / | / |
| Drying **10** | / | / | / | PET Bottles electronic drying | | Pro 6.3.01 Maintenance | Personnel trained | / | / | / |
| Labelling **11** | / | / | / | | | Mod. 78 production order<br>Pro 6.3.01 Maintenance | Trained personnel | / | / | / |
| Label presence check **12** | / | / | / | Electronic check | | Pro 6.3.01 Maintenance | Trained personnel | / | / | / |
| Batch printing **13** | / | / | / | Laser Electronic printer | | ISTR. 7.5.07 VDM<br>Pro 6.3.01 Maintenance | Trained personnel | / | / | / |
| Packaging **14A** | / | / | / | Machine set up regarding cardboard size | | Mod. 78 production order<br>Pro 6.3.01 Maintenance | Trained personnel | / | / | / |



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| HAZARD | | | | PREVENTIVE ACTIVITIES | | | | RISK ASSESSMENT | | |
|---|---|---|---|---|---|---|---|---|---|---|
| PHASE | CHEMICAL | PHYSICAL | MICROBIOLOGICAL | TECHNICAL MEASURES | MATERIALS | METHODS | PERSONAL | GRAVITY | PROBABILITIES | RISK |
| Paletizzation **15A / 15 B** | / | / | / | Machine set up regarding palletization size | | IST. 7.5.07 VDM<br>Mod. 78 production order<br>Pro 6.3.01 Maintenance | Trained personnel | / | / | / |
| Wrap/Handle machine **14B** | / | / | / | Machine set up regarding palletization size | | Mod. 78 production order<br>Pro 6.3.01 Maintenance | Trained personnel | / | / | / |
| Storage **16** | / | / | / | | | IST.7.5.00 GMP, GHP<br>FIFO (first in – first out) | Trained personnel about correct handling | / | / | / |
| PREFORMS receipt **1B** | / | Physical contamination: not intact packaging | / | | Preforms Data Sheets and Terms of Delivery | IST.7.5.00 GMP, GHP | Trained personnel about incoming ckecks | 2 | 1 | 2 |
| PREFORMS storage **2B** | / | Physical contamination: not intact packaging | / | | | IST.7.5.00 GMP, GHP<br>FIFO (first in - first out) | Trained personnel about GMP, GHP | 2 | 1 | 2 |
| Loading of preforms into hopper **3B** | / | / | / | | | IST.7.5.00 GMP, GHP | Trained personnel about correct handling | / | / | / |
| Formatura bottiglie **4B** | Physical contamination: foreign bodies | / | / | The preforms have warmed by a kiln The formed bottles with a foreign body are automatically discarded | | Pro 6.3.01 Maintenance | Trained personnel | 1 | 1 | 1 |
| Transfer **5B** | / | / | / | Pro 7.5.07 Cleaning<br>Positive pressure environment | | Pro 7.5.07 Cleaning<br>Pro 6.3.01 Maintenance | | / | / | / |



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| HAZARD | | | | PREVENTIVE ACTIVITIES | | | | RISK ASSESSMENT | | |
|---|---|---|---|---|---|---|---|---|---|---|
| PHASE | CHEMICAL | PHYSICAL | MICROBIOLOGICAL | TECHNICAL MEASURES | MATERIALS | METHODS | PERSONAL | GRAVITY | PROBABILITIES | RISK |
| Caps receival **1C** | / | Physical contamination: not intact packaging | / | | Caps meet applicable legislation – product data sheets | IST.7.5.00 GMP, GHP<br>FIFO (first in – first out) | Trained personnel about GMP, GHP | 2 | 1 | 2 |
| Caps Storage **2C** | / | Physical contamination: not intact packaging | / | | | IST.7.5.00 GMP, GHP<br>FIFO (first in – first out) | Trained personnel about correct handling | 2 | 1 | 2 |
| Loading of caps into hopper **3C** | / | Physical contamination: caps loading operations | / | Caps transportation with air in pressure that removes potential foreign bodies | | IST.7.5.00 GMP, GHP<br>Pro 6.3.01 Maintenance | Trained personnel about correct handling | 1 | 1 | 1 |
| $CO_2$ receival **1D** | Product receival with chemical pollutants | / | / | | Natural $CO_2$ from geothermal sources | CoA check | Lab trained personnel regarding raw materials receival | 1 | 1 | 1 |
| $CO_2$ storage **2D** | / | / | / | Under pressure tank | | | | / | / | / |



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- **Probability** of occurence (evaluation of frequency of occurence).

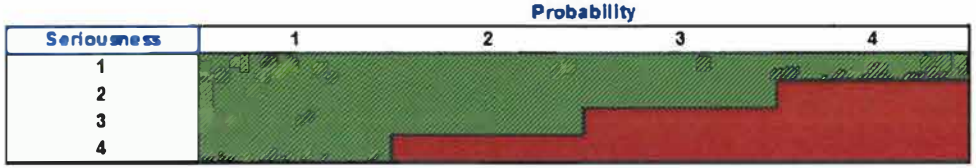
| Probability | | | |
|---|---|---|---|
| **Unlikely** | **Low** | **Moderate** | **High** |
| **1** | **2** | **3** | **4** |
| Never happened | Events with very low probability of occurrence | Some possibilities of occurence are known | Probability of high occurence with important consequences |

- **Significantly serious negative effects on health** that can be caused

| Seriousness | | | |
|---|---|---|---|
| **1** | **2** | **3** | **4** |
| Void Damage | Slight illness | Important damage | Extensive damage |

The risk is determined by the result of correlation between probability and seriousness

**Risk (R) = Probability (P) x Seriousness (G)**




**With R ≥ 8 the risk must be controlled CCP**

| DATE | QAM SIGNATURE |
|---|---|
| 2015/09/03 | |



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

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## 1. SCOPE AND AIM

La Galvanina SpA uses only the best suppliers and is bound to their with a strong relationship. Thanks to a loyal relationship La Galvanina SpA is able to guarantee an high quality supply chain. This procedure defines the general criteria and aids, the responsibilities and the operative methods applied by La Galvanina SpA to manage and control all phases of the system of assessment and accreditation of suppliers, according to their capacity in technical, quality, productive and service terms to supply products/services that conform to the needs and specifications of La Galvanina SpA.
To maintain control over the progress of quantity in supplies over time, developing specific quality indicators for each supplier and for each product purchased, and keeping the same updated.

This objective is guaranteed:
- by the assessment and accreditation of suppliers (**TAB. 7.4.00** "List of Accredited Suppliers"), so as to limit the procurement of supplies to suppliers that the company considers to be capable of fully satisfying its specifications in a constant manner;
- by the collection of specific technical documentation for the supplies requested;
- by the assessment of raw material risks (**TAB. 7.4.01** "Assessment of Raw Material Risks");
- by the checking, approval and issue of orders;
- by checks on the products supplied.

## 2. APPLICABILITY

This procedure is applicable to all goods and services that have an effect of the quality and legality of the products supplied to customers (critical supplies).
The indications of this procedure are applicable from supplier accreditation through to checks on the supply or service delivered, and for both production facilities at Rimini (RN) and Apache (PU).

## 3. REFERENCES

BRC Standard: point **3.6**
IFS Standard: point **4.4**
UNI EN ISO 9001:08 Standard: section **7.4**
UNI 10854 Standard: point **5.2**
Quality Manual: chap. **7**
**PRO. 7.4.00** "Procurement Process and Procedure"
**TAB. 7.4.00** "List of Accredited Suppliers"
**TAB. 7.4.01** "Assessment of Raw Material Risks"
**TAB. 7.5.06** "Plan of Checks".

## 4. RESPONSIBILITIES - ABBREVIATIONS

**DG** = General Management
**RC** = Sales Manager
**RAQ** = Quality Assurance Manager
**RCQ** = Quality Control Manager

DG / RC

- Responsibility for collaborating in technical/commercial aspects of supplier assessment;

RAQ Quality Assurance Manager:

- Responsibility for the assessment, accreditation and monitoring of suppliers and for management of the List of Accredited Suppliers;

RCQ Quality Control Manager:

- Responsibility for collaborating in quality control aspects, and for verification of compliance with the procedure by means of Internal Audits.

## 5. IMPLEMENTATION METHODS

The attached flow chart describes activities in general terms. Specific activities are described in greater detail below.

### *5.1 General information*

Suppliers are accredited for the raw materials for which assessment has been performed.
Every supplier of raw materials has an assessment form (**MOD. 333** "Supplier Assessment and Accreditation Report"), which in addition identification data also indicates any complaints and the overall annual assessment.
Suppliers are an integral part of the productive and organizational process of the company, and therefore must be selected so as to offer the greatest possible guarantees.
Assessment methods are decided by the Assessment Team, composed of RAQ, DG and RCQ.

### *5.2 Initial assessment*

Assessment is made by the Assessment Team, the work of which culminates in the **MOD. 333** "Supplier Assessment and Accreditation Report" document, which indicates the results of assessment and the proposal for inclusion in the list in a standardized, coherent and motivated manner.
All historical and current suppliers are subjected to an initial assessment indicated on the assessment report.
In addition, suppliers must not only supply products, services and work that are adequate to and compliant with particular specification. They must also demonstrate that they are in possession of an organization and structure (Quality System) such as to ensure the maintenance and respect of the minimum quality levels established for their products and services.
This assessment is made annually, and takes into consideration all the supplies made in recent years, with particular attention to:

- assessment of the corporate Quality System of the supplier
- assessment of the characteristics and competitiveness of the products supplied
- consistency of quality in supplies
- respect of delivery times
- cost (for the same quality as similar products/services)
- availability of technical/quality consultancy
- sales service

### *5.2.1 Quality System*

This assessment takes into consideration all supplies received in recent years, with particular attention to:
- historical data;
- assessment of the corporate quality system of the supplier.

For the assessment of the corporate quality system of the supplier the following criteria are applied:

- corporate quality system certified for at least 2 years: 3
- corporate quality system certified less than 2 years: 2
- certification of corporate quality system envisaged within 1 year: 1
- no existing corporate quality system: 0

### *5.2.2 Assessment of the characteristics and competitiveness of the products supplied*

For the assessment of the characteristics of the products supplied, the following criteria are applied:

- the products supplied have far better characteristics than comparable products supplied by competitors: 3
- the products supplied have better characteristics than comparable products supplied by competitors: 2
- the products supplied have the same characteristics as comparable products supplied by competitors: 1
- the products supplied have poorer characteristics than comparable products supplied by competitors: 0

### *5.2.3 Consistency of supply quality*

For the assessment of the consistency of supply quality, the following criteria are applied:

- no non-conformities found in products supplied in the last two years: 3
- a non-conformity has been found in products supplied over the last year, but only of a minor nature
- a non-conformity of a serious nature has been found in products supplied over the last year: 1
- two serious non-conformities have been found in products supplied over the last year: 0

### *5.2.4 Availability of technical/quality consultancy*

For the assessment of the technical service provided by the supplier, the following criteria are applied:

- the supplier proactively anticipates possible quality and/or technical problems: 3
- the supplier collaborates in solving quality and/or technical problems only if solicited by action taken by La Galvanina SpA: 2
- the supplier collaborates only if serious quality non-conformities are found in products: 1
- the supplier does not willingly collaborate in solving quality and/or technical problems: 0

### *5.2.5 Sales service*



For the assessment of the sales service provided by the supplier, the following criteria are applied:

- the supplier collaborates in solving problems of delivery, availability and costs*:* 3
- the supplier does not willingly collaborate in solving problems of product delivery, availability or costs: 2
- the supplier collaborates only partially and in particular conditions to solve problems of product delivery, availability and costs: 1
- the supplier does not collaborate in solving these problems: 0

#### *5.2.6 Respect of delivery times*

For the assessment of the respect of delivery times, the following criteria are applied:

- delivery times and quantities have always been respected over the last two years: 3
- the envisaged delivery times or quantities have not been respected for two orders over the last year: 2
- the envisaged delivery times or quantities have not been respected for more than two and less than five orders over the last year: 1
- the envisaged delivery times or quantities have not been respected for more than five orders over the last year: 0

#### *5.2.7 Cost*

For the assessment of the cost (for the same quality as similar products/services), the following criteria are applied:

- the price of sale is lower than competitors: 3
- the price of sale is the same as competitors: 2
- the price of sale is higher than competitors: 1
- the price of sale is far higher than competitors: 0

In the case of raw materials supplied at a cost that cannot be compared, due to rarity and/or of a special nature, this indicator is not taken into consideration.

### *5.3 QUESTIONNAIRES*

It is the responsibility of RAQ to prepare a list of suppliers to which the supplier assessment questionnaire (**MOD. 14 A** "Supplier Accreditation Questionnaire-General Information" and **MOD. 14 B** "Supplier Accreditation Questionnaire-Delivery Methods and Requirements") is to be sent.
Suppliers undertake to provide correct and truthful information, and La Galvanina SpA reserves the right to verify the truthfulness of the information given in assessment questionnaires.

#### *5.3.1 MOD. 14 A "Supplier Accreditation Questionnaire-General Information"*

This questionnaire consists in several questions, for each of which there are two possible replies; points are awarded as follows:

- 0 points for every *NO* reply;
- 2 points for every *YES* reply;

The points obtained in this way must be converted into a ternary score using this formula:

$$\text{Assessment points} = \frac{\text{Questionnaire points} \times 3}{\text{Number of applicable items} \times 2}$$

If suppliers fail to return the completed assessment questionnaire, they cannot be accredited.
It is the responsibility of RAQ to solicit a reply or to exclude suppliers in the List of Accredited Suppliers.

#### 5.3.2 *MOD. 14 B "Supplier Accreditation Questionnaire-Delivery Methods and Requirements"*

This questionnaire consists in several questions, for each of which there are three possible replies; points are awarded as follows:

- 0 points for every *NO* reply;
- 2 points for every *YES* reply;
- 1 point for every reply where the envisaged implementation is indicated.

The points obtained in this way must be converted into a ternary score using this formula:

$$\text{Assessment points} = \frac{\text{Questionnaire points x 3}}{\text{Number of applicable items x 2}}$$

If suppliers fail to return the completed assessment questionnaire, they cannot be accredited.
It is the responsibility of RAQ to solicit a reply or to exclude suppliers in the List of Accredited Suppliers.

### *5.4 CERTIFIED SUPPLIERS*

Suppliers certified to UNI EN ISO 9001:2008, BRC, IFS or equivalent standards are considered to be accredited and are included in the list.
Certified suppliers are given the following point ratings:

- Suppliers with more than 2 internationally recognized certifications: 3 points
- Suppliers with more than 1 internationally recognized certification: 2 points
- Suppliers con 1 quality certification: 1 point
- Suppliers without certification: 0 points

### *5.5 INSPECTION AUDITS*

Together with DG, RAQ decides the suppliers on which inspection audits will be made following a predetermined program (**MOD. 37 A** "Plan of Audits on Suppliers"), and establishes the date of the visit, which is communicated to the supplier, together with an indication of the company personnel who must be available on the day of the visit. The visit will be made by an audit team.
The inspection audit visit is performed with **MOD. 334** "Checklist for Supplier Audits". Failure to perform the audit activity at the supplier facility must be motivated by an adequate risk assessment. If the risk assessment indicates that the third-party certification of a food standard is deemed to be sufficient, RAQ must request and have access to the currently valid certificate, the audit report and a summary of the corrective actions taken by the supplier, to demonstrate that the certification has been reviewed.
The results of the audit visit may be sufficient to accredit the supplier. It will be the task of RAQ to assess the results recorded and to formulate the final outcome, choosing between the following ratings:

- Insufficient: 0 points
- Acceptable: 1 point
- Quite good: 2 points
- Good: 3 points

At this point, the supplier may be:
- accredited if the rating is good or quite good;
- approved with reservations if the rating is only acceptable;
- not approved if the rating is insufficient.

If the supplier is approved, RAQ fills in the Supplier Assessment and Accreditation Report and adds it to the List of Accredited Suppliers.
The documentation collected during audits is conserved by RAQ.

### *5.6 CHECKS ON FIRST SUPPLY*

In case of urgency, the accreditation process can be performed by means of the supply of a sample or the first supply.
In this case, the supply is subjected to the quality checks envisaged by **TAB. 7.5.06** "Plan of Checks". The supplier is accredited with reservations if all the planned checks give positive results, and is later subjected to the accreditation process established by La Galvanina SpA for possible inclusion in the List of Accredited Suppliers.

### *5.7 ACCREDITATION*

For all items considered above (Supplier Assessment and Accreditation Report, Questionnaire A, Questionnaire B, Certified Supplier, Inspection Audit) a points rating from 0 to 3 will be assigned. The arithmetic average of the points assigned (considering only the items assessed) gives the overall value with which the supplier is classified. All this information is recorded on **MOD. 336** "Supplier Accreditation Form".
The supplier classification is then subdivided into three groups indicated with the letters *A*, *B* and *C*:

- group *A*: suppliers with a point rating higher than 2 (accredited suppliers);
- group *B*: suppliers with a point rating from 1 to 2 (suppliers accredited with reservations);
- group *C*: suppliers with a point rating lower than 1 (non-accredited suppliers).

This classification is used to choose the suppliers that can guarantee the company quality and reliability over time.
Supplier classifications may however be subject to modifications over time, according to periodic classification reviews.

### *5.8 LIST OF ACCREDITED SUPPLIERS*

Son the basis of the information described above, RAQ compiles **TAB. 7.4.00** "List of Accredited Suppliers".

### *5.9 ASSESSMENT UPDATES*

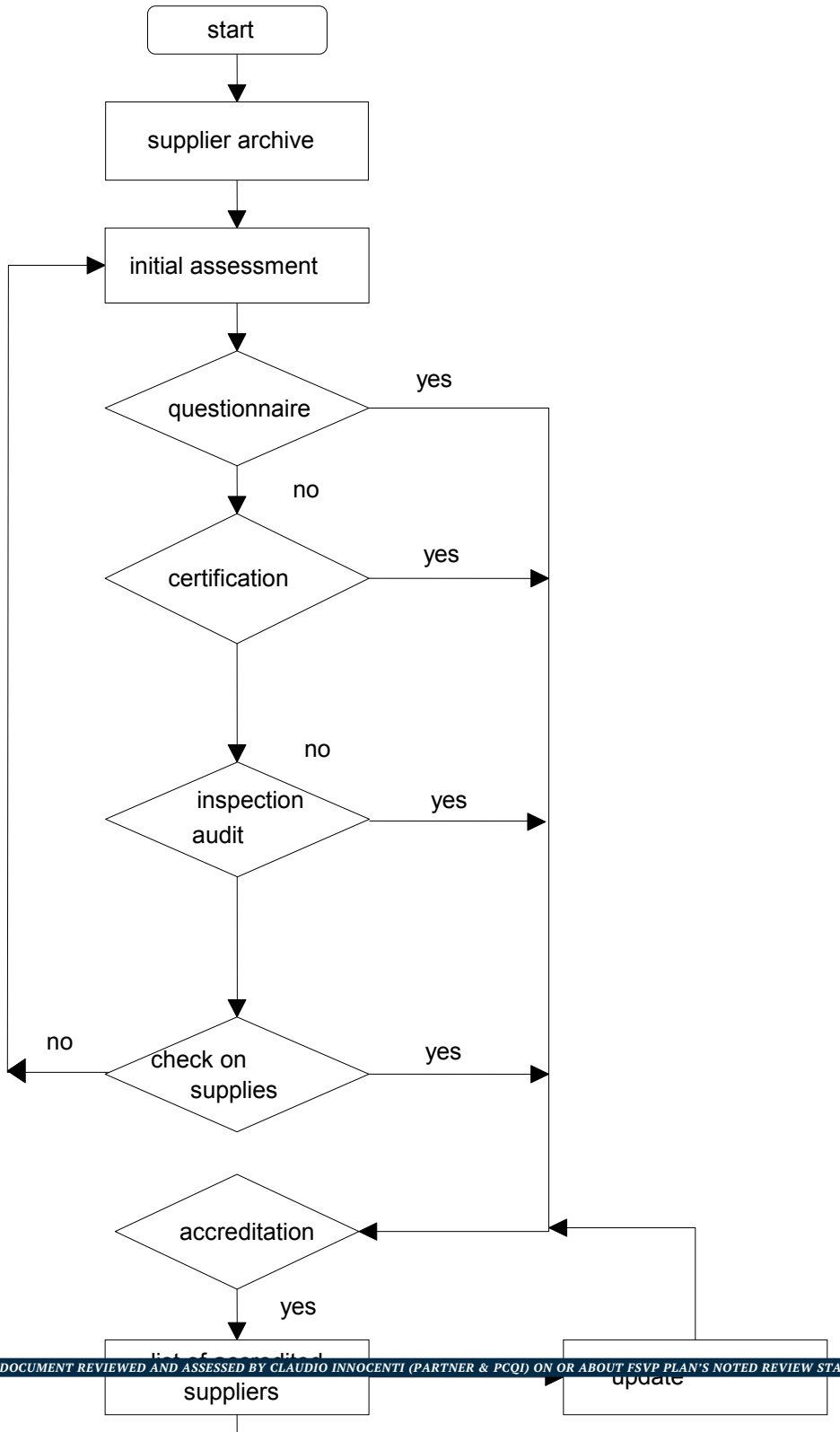
Supplier accreditations are valid for one year. Before the end of this period, RAQ arranges for the accreditation process to be reopened. RAQ informs suppliers in writing of the accreditation results, specifying the general parameters necessary to maintain or improve the accreditation obtained.
If supplies are found to have non-conformities on three consecutive occasions, RAQ decides whether accreditation must be immediately withdrawn, or if the supplier can maintain accreditation for a specific period, establishing times and methods for an inspection audit.
Withdrawal of accreditation, together with the reasons for the same, is notified by e-mail or fax to the supplier in question.

Suppliers are constantly monitored and assessed according to the quality of supplies delivered and documented in **MOD. 36 A** "Checklist for Incoming Raw Materials".
In case of checks with positive results, the accreditation already obtained is confirmed, and the respective accreditation attributions are updated. Incase of checks with negative results, the Assessment Team will oblige the supplier to observe a state of "suspension". Any state of suspension of a supplier will be noted in the List of Accredited Suppliers.
For a limited period of time ("observation period"), established as being six months, the supplier may continue to supply goods for which signed contracts already exist, but may not agree new contracts.
Within this period, the supplier must make the improvements necessary to restore conformity to the accreditation requirements, and must be subjected to another verification.
If this ulterior verification also gives negative results, the accreditation of the supplier will be withdrawn (non-accredited supplier). Accreditation may be obtained again only after a new accreditation process has been successfully completed, which a supplier may commence only after the expiry of a "period of prohibition" of twelve months.

## 6. FILING

All documentation referred to in the procedure is stored in the corporate IT system and on hard copy. All accreditation documents and supply quality indicators are filed by RAQ in the supplier files. Documents are kept for a period of five years from the most recent update.

**Attachment 1:** Flow chart of supplier assessment activities



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Claudio Innocenti

## 1. AIM OF THE DOCUMENT

The instruction defines how to use the active air sampler (SAS) in order to evaluate the environments microbiological quality.

## 2. FIELD OF APPLICATION

A careful monitoring of the air quality in the processing departments is essential to guarantee the healthiness of the raw materials being processed and the finished product.

## 3. PROCEDURE

The microbiological quality control of the air is carried out with the appropriate SAS (Surface Air System) in the following specific company areas: filling area, syrup room and laboratory.
Samples are taken by a laboratory tecnichian once a month.

The air to be sampled is aspirated at constant speed through a head equipped with holes and conveyed to the surface of a petri dish containing the selective culture media for the microbiological research that is to be carried out.

Then, one by one, the plates dedicated to the search for: Yeasts, Muold, Total Plate Count at 20 ° C, Total Plate Count at 37 ° C, Pseudomonas Aeruginosa, Fecal Streptococci, Staphilococcus Aureus, Total Coliform Bacteria, Bacteria Fecal Coliforms.

At the end of the single samples, the petri dishes are placed in the appropriate incubation stoves at a controlled temperature according to the microbial development optimality characteristic of the microorganism to be searched, for a given period of time.
The results obtained, as well as date / time of start and end of analysis, are recorded on the MOD. 73 " ENVIRONMENTAL AIR QUALITY CHECK (S.A.S.)".

If the results are higher than the guide values indicated on the form, a fumigation treatment is carried out which will be recorded on the MOD. 73 / A "Environmental disinfection register".

At the end of the treatment with fumigant, a further sampling is carried out with the microbiological air sampler to evaluate the effectiveness of the treatment.
Fumigation treatments for environmental disinfection are carried out on a quarterly basis in the company premises mentioned above, regardless of the results obtained from the monthly samples. Operations are recorded on the MOD. 73 / A "Environmental disinfection intervention register".

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| 1 | 10/09/14 | | |
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GALVANINA
ANTICA FONTE ROMANA

# Bioluminator Checks

Mod. 59
Rev.1
dated 06/10/2011

| WEEK NUMBER | | |
|---|---|---|

| SYRUP PASTEURIZER | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| SUGAR HOPPER | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| MIXER | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| JUICE PUMP | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| OPERATIVE HANDS | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| TANK | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| TANK | D | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| TANK | F | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| FILLER PIPES L1 | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| FILLER PIPES L2 | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| CAP HOPPER L1 | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| CAP HOPPER L2 | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| LOWER CHANNELS L1 | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

| LOWER CHANNELS L2 | | | | | | | |
|---|---|---|---|---|---|---|---|
| DATE | | TIME | | Operative | | | |
| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

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| BIOLUMINATOR RESULT | | | | | | C | NC |
| Corrective action | | | | | | | |

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| Corrective action | | | | | | | |

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# ENVIRONMENTAL AIR QUALITY CHECK (S.A.S.)

| ZONE #1 | | | External weather conditions | | | |
|---|---|---|---|---|---|---|
| Date and time of sampling | | | Environmental Temperature | | | |
| N° Operators on site | | Analysis technician | | | | |
| | Result (CFU/m$^3$) | start analysis | date/time | end analysis | date/time | LIMITS (CFU/m$^3$) |
| Yeasts | | | | | | 0 - 40 |
| Molds | | | | | | 0 - 100 |
| Total plate count at 20°C | | | | | | 0 - 600 |
| Total plate count at 37°C | | | | | | 0 - 300 |
| Pseudomonas aeruginosa | | | | | | 0 |
| Fecal streptococci | | | | | | 0 |
| Staphilococcus aureus | | | | | | 0 |
| Total coliform bacteria | | | | | | 0 |
| Fecal coliform bacteria | | | | | | 0 |

| ZONE #2 | | | External weather conditions | | | |
|---|---|---|---|---|---|---|
| Date and time of sampling | | | Environmental Temperature | | | |
| N° Operators on site | | Analysis technician | | | | |
| | Result (CFU/m$^3$) | start analysis | date/time | end analysis | date/time | LIMITS (CFU/m$^3$) |
| Yeasts | | | | | | 0 - 40 |
| Molds | | | | | | 0 - 100 |
| Total plate count at 20°C | | | | | | 0 - 600 |
| Total plate count at 37°C | | | | | | 0 - 300 |
| Pseudomonas aeruginosa | | | | | | 0 |
| Fecal streptococci | | | | | | 0 |
| Staphilococcus aureus | | | | | | 0 |
| Total coliform bacteria | | | | | | 0 |
| Fecal coliform bacteria | | | | | | 0 |

| ZONE #3 | | | External weather conditions | | | |
|---|---|---|---|---|---|---|
| Date and time of sampling | | | Environmental Temperature | | | |
| N° Operators on site | | Analysis technician | | | | |
| | Result (CFU/m$^3$) | start analysis | date/time | end analysis | date/time | LIMITS (CFU/m$^3$) |
| Yeasts | | | | | | 0 - 40 |
| Molds | | | | | | 0 - 100 |
| Total plate count at 20°C | | | | | | 0 - 600 |
| Total plate count at 37°C | | | | | | 0 - 300 |
| Pseudomonas aeruginosa | | | | | | 0 |
| Fecal streptococci | | | | | | 0 |
| Staphilococcus aureus | | | | | | 0 |
| Total coliform bacteria | | | | | | 0 |
| Fecal coliform bacteria | | | | | | 0 |

| ZONE #4 | | | External weather conditions | | | |
|---|---|---|---|---|---|---|
| Date and time of sampling | | | Environmental Temperature | | | |
| N° Operators on site | | Analysis technician | | | | |
| | Result (CFU/m$^3$) | start analysis | date/time | end analysis | date/time | LIMITS (CFU/m$^3$) |
| Yeasts | | | | | | 0 - 40 |
| Molds | | | | | | 0 - 100 |
| Total plate count at 20°C | | | | | | 0 - 600 |
| Total plate count at 37°C | | | | | | 0 - 300 |
| Pseudomonas aeruginosa | | | | | | 0 |
| Fecal streptococci | | | | | | 0 |
| Staphilococcus aureus | | | | | | 0 |
| Total coliform bacteria | | | | | | 0 |
| Fecal coliform bacteria | | | | | | 0 |

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Claudio Innocenti

# CLEANING AND SANITIZATION PROCEDURE

**CONTENTS**



**DOCUMENT STATUS**

| REV. | PAR. | PAGE | REASON | DATE |
|---|---|---|---|---|
| 0 | / | / | Document issue | 05/27/04 |
| 1 | All | All | General revision | 04/03/06 |
| 2 | All | All | Revision for compliance with BRC / IFS standard | 09/25/06 |
| 3 | All | All | General revision | 03/21/08 |
| 4 | All | All | Revision for improvements to procedure and respective reference documentation | 06/10/11 |

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## 1. SCOPE

The following procedure defines responsibilities, criteria and operative methods for the management and implementation of cleaning and sanitization performed inside the company, with the aim of guaranteeing the quality and wholesomeness of foodstuffs products.

## 2. APPLICABILITY

The instructions of this procedure are applicable to all cleaning and sanitization operations performed in the premises of the production facility and in water collection facilities, to machinery and to systems.
This procedure is applicable to both production sites of the company.

## 3. REFERENCES

BRC Standard
IFS Standard
UNI EN ISO 9001:08 Standard
UNI 10854 Standard
EC Regulation 852/2004
**TAB. 7.5.05** "Program of Cleaning and Checks"
**TAB. 7.5.06** "Plan of Checks"

## 4. RESPONSIBILITIES

RCQ is responsible for the monitoring plan, the supervision of cleaning functions and the purchase of products for the sanitization and cleaning of the systems and equipment of the company. Safety information sheets for these products are kept in the laboratory. Information sheets on their use are displayed in the areas where they are used. Cleaning operations are carried out by operatives of a specialized external company. Sanitization operations are the responsibility of Function Supervisors.

## 5. MANAGEMENT OF CLEANING AND SANITIZATION ACTIVITIES

The products, methods, times, frequency and temperatures used in the various operative phases of cleaning and sanitization are chosen by RCQ according to the following criteria:

- ✓ Analysis of risks;
- ✓ Results of analysis checks;
- ✓ Technical knowledge and knowledge of specific hygiene problems of the facility;
- ✓ Information on companies working in the bottling industry;
- ✓ Technical and safety information sheets in which the conditions of use and dosages of the various products used are defined;
- ✓ Indications provided by suppliers of products for cleaning and sanitization.

To prevent the deterioration of the active principles contained in chemical products, they are kept away from sunlight and direct heat sources and in well-closed and identifiable packs. Storage facilities, equipped with specific containment tubs, are clearly identified and are located in external factory areas, closed and managed by authorized personnel.
For any product used, whether detergent or disinfectant, careful consideration is given to the instruction provided on the package with regard to dilution methods (mixing of product with water), contact times with surfaces, and the use of any necessary safety equipment (protective

glasses, mask and gloves). Dilution proportions are specified in the various operative instructions for cleaning.
**Different products are never mixed together**, unless in accordance with the instructions for use indicated on the label. In general, acidic and disencrustants are used in the clean areas, given that machines are made completely in steel. For all other machines, instead, basic or neutral products are used. Chemical cleaning products must be used in accordance with the instructions given by the supplier, and are stored in well-identified areas assigned for this purpose inside the factory (see location plans).
The operatives of the specialized external company dilute the products needed for cleaning activities. Every container used to dilute chemical products used for cleaning is correctly identified and is used only for that specific purpose.
All cleaning operatives are trained by technicians of the company supplying chemical products, defining the methods of use of the products and on any associated risks.

## 6. MANAGEMENT OF CLEANING EQUIPMENT

The operatives of the specialized external company are responsible for the cleaning of equipment and for its storage, and must replace it when necessary.
Equipment for routine cleaning is managed by the operatives of the specialized external company in a dedicated area of the factory, well ventilated and with restricted access, where good hygiene conditions are maintained to guarantee the suitable conservation of equipment. Cleaned equipment must be returned to this area after cleaning operations, avoiding contact with the floor, and is identified with a color code system according to the area of use inside the factory, using adhesive labels positioned in a visible position to facilitate the separation of equipment from equipment used in other factory areas.

The zoning scheme for the entire company is defined in this chart:

| | Zone | Color |
|---|---|---|
| Internal areas | Raw materials storage warehouse; packaging materials, pacing department, finished product warehouse, boiler room. | Yellow |
| External areas | Yards, green areas | White |
| Food departments | Filling hall, syrup room | Red |
| Personnel area | Quality laboratory, personnel changing rooms, hygiene facilities and offices. | Blue |

## 7. CLEANING OF MACHINERY AND SYSTEMS

Cleaning and sanitization are carried out on machines and systems by operatives of the specialized external company and by Function Supervisors, who are responsible for the correct performance and results of cleaning and sanitization activities.
Cleaning of the machines/systems used in the production process has been defined in a series of operative instructions indicating operative methods and the records to be compiled:

**IST. 7.5.03 "SANITIZATION AND RINSING WITH CIP"**
**IST. 7.5.01 "CLEANING OF COLLECTION SYSTEMS AND TANKS"**
**IST. 7.5.28 "SANITIZATION OF SYRUP ROOM"**
**IST. 7.5.28/A "CLEANING AND SANITIZATION OF SPACES AND EQUIPMENT"**

In general, cleaning and sanitization are carried out at the end of the working day. Rinsing operations are normally performed with every product change. If a change if made from a sugar-containing drink to a flavored water during the production day, sanitization operations are carried out.
Internal components of systems that can be dismantled are cleaned with every production change, ensuring that the components are reassembled only after having been sanitized and subsequently rinsed. Operative methods are defined in **IST. 7.5.28/A** "Cleaning and Sanitization of Spaces and Equipment".
External parts of systems and machines are cleaned by the operatives of the specialized external company, at weekly intervals for the Red Area, and by rotation at least once a week for the Yellow Area.

## 8. CLEANING OF INTERNAL SPACES

Operatives in departments are responsible for keeping their department in suitable conditions of hygiene, and to remove bulky refuse as soon as possible, such as:

- Packing materials in the syrup room;
- Packing materials in the labeling/case packing department;
- Non-conformant bottles and glass in the bottling department.

Cleaning operations for internal spaces are planned and defined in **MOD. 12** "Programming and Registration of Cleaning Operations" by RCQ, who verifies their effectiveness.
Cleaning operations performed by the specialized external company regard:

- Cleaning of factory floors;
- Cleaning of windows/glass panels;
- Ceilings and walls;
- Entrances (main and secondary doors);
- Offices, laboratory, changing rooms and hygiene facilities;
- Warehouses for materials and finished products.

The following operative methods are used:

- Clean away glass and production residues from machines, conveyor belts, labelers, case packers and floors;
- Empty and wash the bottle washer tubs;
- Rinse machine surfaces and floors with water;
- Wash floors with single-brush cleaning machines using the specific product;
- Always leave products to act for 15 minutes, then rinsing with abundant water.

The products used for cleaning of the offices are supplied directly by the external company. In production spaces, only products approved by RCQ are used.
All cleaning operations are planned and recorded in **MOD. 12** "Programming and Registration of Cleaning Operations" and are checked in **MOD. 335** "Checklist for Cleaning of Spaces".
The equipment used by the external company is kept in closed storerooms.

## 9. PLANNING

**TAB. 7.5.05** shows the general programming of cleaning and sanitization activities performed in the factory. Sanitization operations for filling systems are planned weekly by RCQ and are recorded on **MOD. 212**. "Planning of Sanitization Operations".
The performance of these operations is registered by the operative who carried them out on the specific forms indicated by **TAB. 7.5.05**.

## 10. VERIFICATION OF EFFECTIVENESS OF CLEANING AND SANITIZATION OPERATIONS

The effectiveness of cleaning and sanitization operations is verified by the quality control operative, who takes surface swabs as envisaged by **TAB. 7.5.06** "Plan of checks". Samples are taken at weekly intervals, and are recorded on **MOD. 59** "Bioluminator Checks". Swabs are taken after cleaning and sanitization operations and subsequent rinsing operations. Effectiveness is assessed using a bioluminator, making reference to biovalues expressed in RLU (Relative Light Units):

**RLU BIOVALUE GUIDELINES:**

Very clean surface < 200
Clean surface from 200 to 500
Dirty surface > 500

Samples must be taken on a surface area of about 100 cm² (10 cm x 10 cm). If the surface is found to be dirty (>500 RLU), the cleaning and sanitization operations must be repeated, followed by another swab test on the surface. In case of a trend of negative results, if the cause cannot be attributed to incorrectly performed procedures but to the ineffectiveness of the cleaning and sanitization program itself, the program must be appropriately reviewed and updated, noting the steps taken on the NON-CONFORMITIES form.

## 11. FILING AND CONSERVATION OF DOCUMENTATION

All registrations for cleaning and sanitization operations are collected and filed by RCQ. The results of checks on the effectiveness of cleaning operations are recorded on **MOD. 59** "Bioluminator Checks", which is used to compile annual statistics on **MOD. 59 B** "Bioluminator Statistics", allowing the trend in cleaning and sanitization operations to be monitored.

## 12. ATTACHMENTS

**MOD. 12** "Programming and Registration of Cleaning Operations";
**MOD. 59** "Bioluminator Checks";
**MOD. 59 B** "Bioluminator Statistics";
**MOD. 212** "Planning of Sanitization Operations";
**MOD. 335** "Checklist for Cleaning of Spaces".

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

Claudio Innocenti

12,1mm overlap 5

210 mm (8.267")

1,5

65 mm (2.559")

10

1,5

3 5 15mm

RETRO

Cyan Magenta Yellow

12

12,1mm overlap 5

210 mm (8.267")

1,5

**Nutrition Facts** Servings: 1, **Serv. size: 1 Bottle (500 mL),** Amount per serving: **Calories 0, Total Fat** 0g (0% DV), **Sodium** 10mg (0% DV), **Total Carb.** 0g (0% DV) **Protein** 0g, Calcium (4% DV)

ITM. / ART. 9262015

0 96619 40197 0

17KS06107a

BEST BEFORE: SEE DATE ON BOTTLE. CT #846 - NV 09367

**INGREDIENTS:** MINERAL WATER, CARBON DIOXIDE.

TOTAL DISSOLVED SOLIDS: 330 mg/L With carbonation added

Distributed by: Costco Wholesale Corporation
P.O. Box 34535, Seattle, WA 98124-1535 USA
1-800-774-2678 • www.costco.com

**CAUTION:** Do not store in direct sunlight. Store in a cool, dry, odorless place. Do not freeze. Contents under pressure.

PLEASE RECYCLE

BOTTLED AT METI SOURCE, APECCHIO, PU, ITALY

Every Kirkland Signature product is guaranteed to meet or exceed the quality standards of the leading national brands. If you're not completely satisfied, your money will be refunded.

CA CRV
CT-HI-IA-MA
ME-NY VT ref5,
OR-MI ref10

*From the heart of Italy's pristine Apennine Mountains, our sparkling mineral water is a true gift from Mother Nature. Perfect for every day, or your favorite moments with family and friends. From Italy with love.*

For water quality and information
1-800-209-1670
waterquality@ksspkwater.com

KIRKLAND Signature™

Low mineral content

# Italian Sparkling™ Mineral Water

With Carbonation Added

PRODUCT OF ITALY

16.9 FL OZ - 500 mL

65 mm (2.559")

10

1,5

3 5 15mm

FRONTE

Black PANTONE 349 C PANTONE 185 C BIANCO BIANCO BIS

12

VISTO SI STAMPI

ATTENZIONE: La verifica è a cura del cliente. Non si risponde di eventuali errori contenuti e non rilevati in questa bozza. Prima di procedere con il file finale per la stampa aspettiamo la vostra conferma definitiva a questa bozza. Grazie.



novembre november 2017 23.

met.studio

FILE IN BASSA DEFINIZIONE NON VALIDO PER LA STAMPA ALLEGATO PER CONTROLLO E APPROVAZIONE TOTALE

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Claudio Innocenti

# Warning Letters

**Learn about the types of warning letters on FDA's website.** (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters)

- Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the letter recipient that may have changed the regulatory status of issues discussed in the letter.
- To obtain additional available information, contact FDA. Requests to FDA for agency records should be sent to: Food and Drug Administration Division of Freedom of Information (HFI-35), 5630 Fishers Lane, Rockville, MD 20857. Instructions for how to submit an FOI request can be found at How to Make a FOIA Request. (/how-make-foia-request)

**Search**

Galvanina

Showing 0 to 0 of 0 entries (filtered from 3,272 total entries)

**Filters**

**Issuing Office**

**Letter Issue Date** **Letters with Response or Closeout**

**Posted Date** **Year**

Clear Filters

Show 10 entries Export Excel

| Posted Date | Letter Issue Date | Company Name | Issuing Office | Subject | Response Letter | Closeout Letter |
|---|---|---|---|---|---|---|

No matching records found

Showing 0 to 0 of 0 entries (filtered from 3,272 total entries)

Previous Next



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Certificate IT14/0174

This is to certify that

# LA GALVANINA Spa

Località Pian di Molino snc
61042 Apecchio (Pesaro Urbino), Italy
**BRC SITE CODE 1435271**

has been assessed and certified as meeting the requirements of

# Global Standard for Food Safety

**Issue 7: January 2015**
**Achieved Grade AA**
**Audit Programme: Announced**

For the following activities

**Exploitation and bottling of mineral water in glass and PET bottles.**
**Production of flavoured water in glass and PET bottles.**

**Product Categories: 12**
**Exclusions from scope: None**

Date of Evaluation: 23 January 2019
Certificate Issue Date: 08 March 2019
Re-Evaluation Due Date: From 05 January 2020 to 02 February 2020
Certificate Expiry Date: 15 March 2020

This certificate supersedes all other certificates bearing this certificate number with earlier certificate issue dates.

If you would like to feedback comments on the BRC Global Standard or the audit process directly to BRC, please contact tellus@brcglobalstandards.com
Visit the BRC Directory www.brcdirectory.com to validate certificate authenticity

AUDITOR NUMBER
176131

Authorised by

UKAS PRODUCT CERTIFICATION
0005

This certificate remains the property of
SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS BRC FOOD 1218





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

Claudio Innocenti

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# Audit Report

**Global Standard for Food Safety Issue 7: July 2015**

| 1.Audit Summary | | | |
|---|---|---|---|
| Company name | LA GALVANINA spa | BRC Site Code | 1435271 |
| Site name | LA GALVANINA spa | | |
| Scope of audit | Exploitation and bottling of mineral water in glass and PET bottles. Production of flavoured water in glass and PET bottles. | | |
| Exclusions from scope | None | | |
| Justification for exclusion | None | | |
| Audit Finish Date | 2019-01-24 | | |
| Re-audit due date | 2020-02-02 | | |

| Voluntary modules included | | |
|---|---|---|
| Modules | Result | Details |
| Choose a module | Choose an item | |
| Choose a module | Choose an item | |
| Choose a module | Choose an item | |

| 2. Audit Results | | | | | |
|---|---|---|---|---|---|
| Audit result | Certificated | Audit grade | AA | Audit type | Announced |
| Previous audit grade | AA | Previous audit date | 2018-01-17 | | |

| Number of non-conformities | | |
|---|---|---|
| | Fundamental | 0 |
| | Critical | 0 |
| | Major | 0 |
| | Minor | 4 |

## 3.Company Details

| | | | |
|---|---|---|---|
| Address | Località Pian di Molino snc<br>61042 Apecchio (Pesaro Urbino) | | |
| Country | Italy | Site Telephone Number | 0039 0722986086 |
| Commercial representative Name | Rino Mini | Email | rino.mini@galvanina.com |
| Technical representative Name | Matteo Spinozzi | Email | matteo.spinozzi@galvanina.com |

## 4.Company Profile

| | | | | | |
|---|---|---|---|---|---|
| Plant size (metres square) | 10-25K sq.m | No. of employees | 1-50 | No. of HACCP plans | 1-3 |

| | |
|---|---|
| Subcontracted processes | No |
| Other certificates held | Organic 834/07, Kosher, Fair Trade, UNI 10854, UNI EN ISO 9001:2008, IFS, ISO 14001, ISO 18001, ISO 50001, AEO, HACCP |
| Regions exported to | North America<br>Europe<br>Choose a region<br>Choose a region<br>Choose a region<br>Choose a region |
| Company registration number | 11370456596 |
| Major changes since last BRC audit | 1 new PET line, 1 new glass line, enlargement of offices and warehouse |

Company Description
Volume of production: 59.500.000 bottles.
Health authorization n° 985 dated 16.05.2013.
US FDA number: 11370456596
Rimini Head Office audited by SGS Auditor Bianca Francia on 13-14-15/03/2018.
On site 25 employees are engaged on 3 shifts (06:00-14:00, 14:00-22:00, 22:00-06:00) for 6 days/week.
The site of Apecchio occupies 30000 square meters (covered 14.000).
Clients are major retailers and retailers.
The company has been bottling "Galvanina" Mineral Water since 1901, but it is also known as an Ancient Roman Spring. Since 2008, the company acquired the new source site on Apecchio (PU) - Val di Meti.
The production process consists of pipelines and storage tanks of mineral water, discharge hopper for preforms, blow moulding of PET bottles, rinser, filler, capper, control for caps presence, labeller, printing the lot number and expiry date, wrapping and palletizing.

## 4.Company Profile

For the line of glass bottles there are depalletizer for empty bottle, rinser, filling, capping machine, check for presence of the caps, labeller, printing the lot number and expiry date, case packing and palletizing bottles. For the preparation of flavoured waters: dissolvers are used to warm for the ingredients, mixing, storage tanks, filtration plant and pipes for sending the drink to the fillers.
There are 2 HACCP studies (2 main products: mineral water, flavoured water in PET and GLASS).
The finished products are also bottles private label products for some foreign customers.
Sales are 96% for foreign markets and 4% for Italy.

| 5.Product Characteristics | | | | | |
|---|---|---|---|---|---|
| Product categories | 12 - Beverages<br>Category<br>Category<br>Category<br>Category<br>Category | | | | |
| Finished product safety rationale | Ambient stable products, Microbiological pure, CO2 | | | | |
| High care | No | High risk | No | Ambient high care | No |
| Justification for area | Microbiological low risk area due to ambient stable product (eg. CO2, microbiological pure products) | | | | |
| Allergens handled on site | None<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen | | | | |
| Product claims made e.g. IP, organic | Organic and Kosher | | | | |
| Product recalls in last 12 Months | No | | | | |
| Products in production at the time of the audit | Mineral water 0,75lt PET | | | | |

| 6.Audit Duration Details | | | |
|---|---|---|---|
| On-site duration | 14 man hours | Duration of production facility inspection | 7 man hours |
| Reasons for deviation from typical or expected audit duration | 2.0MD – 0,25 multisite audit (MULTISITE WITH RIMINI AS HEAD OFFICE AND APECCHIO AS PRODUCTION SITE) + 0.5MD Integrated audit with IFS = 2,25MD | | |
| Next audit type selected | Announced | | |

| Audit Duration per day | | | |
|---|---|---|---|
| Audit Days | Audit Dates | Audit Start Time | Audit Finish Time |
| 1 (start date) | 2019-01-23 | 1000 | 1930 |
| 2 (end date) | 2019-01-24 | 0900 | 1830 |

| | Auditor (s) number(s) | Names and roles of others |
|---|---|---|
| Auditor Number | 176131 | ALFREDO STEFANI<br>Lead Auditor |
| Second Auditor Number | N/A | |

| Present at audit | | | | |
|---|---|---|---|---|
| Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.9)<br>Name / Job Title | Opening Meeting | Site Inspection | Procedure Review | Closing Meeting |
| Patrizia Mini/General Manager | X | | | X |
| Matteo Spinozzi/QAM | X | X | X | X |
| Ubaldo Bertozzi/ Production Plant Manager | X | X | X | X |
| Luigi Inthiar/ Quality Control | X | X | X | X |
| Matteo Pagnetti/ Warehouse Manager | | X | | |
| Michele Smacchia/Operator | | X | | |

# Non-Conformity Summary Sheet

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

| Critical | | | |
|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Anticipated re-audit date** |
| | | | |
| | | | |

| Major | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Correction** | **Proposed preventive action plan (based on root cause analysis)** | **Evidence provided document, photograph, visit/other** | **Date reviewed** | **Reviewed by** |
| | | | | | | | |
| | | | | | | | |

| Minor | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No.** | **Clause** | **Details of non-conformity** | **Correction** | **Proposed preventive action plan (based on root cause analysis)** | **Evidence provided document, photograph, visit/other** | **Date reviewed** | **Reviewed by** |
| 1 | 3.4.1 | Programme of internal audits of 2019 is not scheduled throughout the year. | The internal audits were better scheduled throughout the year | The BRC guidelines were not correctly interpreted. A meeting has been arranged together with the Quality Control Manager and Quality Assurance Manager to better understand BRC Standard requirement | A new annual internal audit planning has been formalized. (See MOD. 37 VDM attached) | 2019-02-03 | Alfredo Stefani |
| 2 | 4.9.3.1 | In bottling area there is a plastic not detectable pen. | The non detectable plastic pen in the bottling area was | Although the quality control operators | New detectable pen. (See | 2019-02-03 | Alfredo Stefani |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | substituted with a new detectable pen | were trained on the correct use of pens in the bottling area a mistake was made | pictures here enclosed). A new personnel training on the correct use of pens in the bottling area has been carried out. (See MOD. 35 attached) | | |
| 3 | 4.9.3.3 | In bottling area there is a plastic box for defective pet preform, cracked. | The cracked plastic box in the bottling area was substituted with a new one in stainless steel | During the customary inspections, the quality control operators didn't notice that a plastic box for defective PET preforms in the bottling area was cracked. The quality control operators were invited to pay more attention during the inspections | A new stainless steel box was placed in the bottling area. (See pictures here enclosed) | 2019-02-03 | Alfredo Stefani |
| 4 | 5.6.2.4 | Test for peroxides used in production area is expired since 08/2018. | Expired test for peroxides in the bottling area was substituted with an updated new one | Although the quality control operators were trained on the correct use of the test for peroxides in the bottling area, they didn't notice that the test for peroxides had expired | A new updated test for peroxides was placed in the production area. (See pictures here enclosed) A new personnel | 2019-02-03 | Alfredo Stefani |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | training on the correct use of test for peroxides in the bottling area has been carried out. (See MOD. 35 attached) | | |

| Comments on non-conformities |
|---|
| |

# Detailed Audit Report

## 1. Senior management commitment

### 1.1 Senior management commitment and continual improvement

There is an integrated Company policy: Quality, environment and food safety dated Jan 2018 which is signed by the Company President Mr Mini is displayed both at the site entrance and other points of the factory, furthermore presented at all levels during training.
PRO 5.6.01 "Responsabilità della direzione" issue 5 dated 20/08/2010. Management review last dated 19.12.2018. Clear targets are set on document enclosed to management review: increase in sales and clients; decrease of complaints.
Quality, legality and food safety parameters are monthly monitored by top management consulting updated results supplied by QA Department and HACCP team. Monitoring shows levels on targets. HACCP plan review base on analysis record- supplier change- R&D activity- processing changes - external alert and new law- recall/withdrawal, sanitization and pest procedures efficiency, with discussion and evaluation outputs as management decisions.
Meeting programme is in place and properly communicated.
Seen all monthly records of 2018 and 2019, e.g. that of 09.01.2019, 19.12.2018, 15.11.2018, 17.10.2018.
The objectives are analysed at least quarterly
The company's senior management thanks to Food Companies Association is kept informed of scientific and technical developments, industry codes of practice and all relevant legislation applicable in the country of raw material supply, production and, where known, the country where the product will be sold.

Previous minor CAR and non-conformities related to suppliers were solved.

### 1.2 Organisational structure, responsibilities and management authority

Overview of Management Structure verified. Monitoring shows levels on targets. KPI are related to HACCP plan review base on analysis record- supplier change- R&D activity- processing changes- external alert and new law- recall/withdrawal, sanitization and pest procedures efficiency, with discussion and evaluation outputs as management decisions. Es. Kpi ppm of complaint, analysis results, NC ecc..
Operators are sensitized and aware of their own skills and responsibilities, all staff have access to relevant procedures.
TAB 5.5.01 "Organigramma nominativo" dated 09.04.2018. Job description in place for all managers and supervisors and responsibilities, substitutes in a dedicated attachment with all signs including substitutes. Job descriptions were in place. Duties are defined in job descriptions.
Appropriate documented arrangements are in place to cover for the absence of key staff.

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

| Clause reference | Justification |
|---|---|
| // | // |

## 2 The Food Safety Plan – HACCP

HACCP Study and Manual last updates (now version 10) 2018.12.19. PRO7.5.03 VDM “Sistema di autocontrollo” issue 14 dated 03.09.2015 updated 09.05.2017.
The program prerequisites discussed in the Manual and HACCP procedures. Prerequisite programs defined and adequately demonstrate that basic conditions are being provided for the safe production of food. Prerequisite are: cleaning and sanitation of equipment, acceptance of raw materials and correct storage of raw materials and finished products.
HACCP Team led by Matteo Spinozzi who is trained in and experienced with HACCP, member of team . The multi-disciplinary team comprises members from the following departments: Direction, Production, Maintenance.
Competencies documented.

A full description of process and products are developed and documented in the HACCP Manual, which includes all relevant information on food safety. The inquiry involves mainly the hygienically and sanitary risks.
Verified the description of products: Mineral water and flavoured water in PET.
The intended use of the products and consumer categories are defined and specified in the HACCP Manual and specifically " product indicated for all consumer types ". No allergens on site.

Flowcharts are present to different types of products. The flow diagram of the various types of products are reviewed once a year during the Management Review.
Verified the 4 process flow diagrams have been defined:
- 1 for Mineral Water in glass and 1 for Mineral Water in PET, brand Val di Meti;
- 1 for Flavoured Water in glass and 1 for Flavoured Water in PET;
Flow diagram verified on 19.12.2018.
Process steps; Disinfection after cleaning and filtration below 10 micron for aromatized products on contrite solution; filling and Bottling.

All the potential hazards are identified and recorded, the scope of the HACCP plan has been confirmed MHACCP.
Each identified hazard was reviewed and given a risk rating to define the severity and likeliness of hazard occurring.
Suitable controls for each hazard were documented, in many cases these formed part of the prerequisite programs.
Significant hazards considered in hazard analysis identified as pathogen microorganism; chemical as heavy metals; physical as foreign bodies. The team have used a 4 step decision tree. Last hazard analysis dated 19.12.2018

HACCP plan with clear reference to EU Reg. and IFS/BRC standards, is generally developed and comprehensive with Codex principles applied in sequenced chapters.
CCPs identified are as follow with relative critical limits:
CCP1: During filling, chemical hazard: sanitizer presence for PET and Glass fillers’ disinfection. Action: Litmus test. Critical limits: concentration from 30 to 100 ppm of Peracetic acid;
CCP2: During saturation, chemical hazard: sanitizer presence for PET and Glass fillers’ disinfection. Action: Litmus test. Critical limits: concentration from 30 to 100 ppm of Peracetic acid;
CCP3: During bottling, physical hazard: foreign bodies presence (filling strau and parts of the filler of glass bottles line). Action: Magnet control. Critical limits: rejection of samples of glass bottles containing taps and filler spare parts;
CCP4: sanitizer presence in rinsing empty glass bottles and into second step of glass bottles rinse (microbiological and chemical hazard), critical limits concentration from 30 to 100 ppm or absence of Peracetic acid.

The critical limits for CCPs are clearly defined as above mentioned.
Monitoring procedure defined as follows:
CCP1: Checked every batch by QC at the at the end of rinsing process, monitored with coloured litmus paper, records provided and signed. CA in case of loss of check: repeated analysis and rejection of the batch;
CCP2: Checked every batch by QC at the at the end of rinsing process, monitored with coloured litmus paper, records provided and signed. CA in case of loss of check: repeated analysis and rejection of the batch;
CCP3: Checked every batch by QC. at start and end of filling process or in case of changing of product. CA in case of loss of check: rejection of the batch;
CCP4: Checked every batch by QC at the at the end of rinsing process, monitored with coloured limits paper, records provided and signed. CA in case of loss of check: repeated analysis and rejection of the batch.
All records are signed by responsible for the monitoring and verified by an authorized person.
Records of monitoring were available and properly managed. The method of monitoring and corrective actions to be

| |
|---|
| taken in case of deviation. HACCP verification during management review. |
| Every CCP and relative critical limits were validated on 2018.12.19. Validation method of CCPs: Critical limits had been agreed and signed off by team. All CCPs are validated taking into account legislation, validation studies, industry best practice and commissioning studies. The company's HACCP plan is based on following updated and comprehensive information:<br>-scientific literature and known hazards associated with water bottling<br>-complaints and customer requirements<br>-food-safety European legislation<br>-codes of practice of packing process (Manual of good practices). Manual of good practices on the transport)<br>The critical limits were validated with bibliographic study, for litmus control phase (Control Point) was dated December 2018. |
| Procedures of verification are established to confirm that the HACCP plan, including CCPs are effective.<br>HACCP plan is reviewed every year during Management Review and/or in case of a production change in ingredients or technology.<br>Last HACCP review dated 2018.12.19. |

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

| Clause reference | Justification |
|---|---|
| // | // |

## 3. Food safety and quality management system

### 3.1 Food safety and quality manual

The company has implemented a Quality Management System in conformity to UNI EN ISO 9001:2008 and documented in the Quality Management System (manual issue 0 dated 03.03.2018) with department specific work instruction manuals available on the company intranet; this was certified on refer UNI EN ISO 9001.08. Main Quality Management System with department specific work instruction manuals available on a shared drive within the company's network system. Evidence of compliance of documents clearly legible in sufficient detail and in appropriate languages.

### 3.2 Documentation control

Verified the procedures for the Documentation and Registrations Management: PRO 4.2.01 "Gestione documentazione sistema integrato aziendale" issue 6.
Collection, review, maintenance, storage and retrieval of all records relating to product safety, legality and quality are properly managed. Manuals and procedures available in the IT company system and by means of controlled paper copies signed for receipt. Folders had limited write access to designated personnel. Access to documentation is controlled with video surveillance.

### 3.3 Record completion and maintenance

Records retained for a time consistent with the shelf life of products as indicated on technical sheets: Shelf life Still Mineral Water in glass and PET is 24 months, Sparkling Mineral Water in glass and PET is 12 months and 15 months for Italian Market, Flavoured Water and Soft drinks have a shelf life from 9 to 12 months.

Records retained for a time consistent with the shelf life of products as indicated on technical sheets (from 6 to 60 months months), record keeping 4 years. Electronic records are automatically backed up every month to an external server to prevent loss.

## 3.4 Internal audit

There is a program of internal audits of the quality systems carried out by the QA Team on refer procedure QMS Manual. Procedures and Audit plan defined in order to guarantee that audits are conducted on those systems and procedures which cover the requirements of the Global Standard for Food Safety.
Audits are NOT scheduled throughout the year (see CAR below). More auditors are in place to assure independence.
Auditors are trained and has Food and Agronomy Degree. Internal audit programme is audited by external consultant.
Internal audits carried out for activities identified as critical to food safety and to product specifications such as sanification, bottling and magents; seen last one dated 2018.12.14, 13.11.2018, 31.05.2018, 04.12.2018.
NCs raised from last internal audit with due CA . In case of NCs, section managers are in charge for relative CARs implementation.
**MINOR CAR 3.4.1 RAISED.**

Dedicated report on purpose. BRC based check-list. Follow up of corrective action are properly monitored and reported.
QAM is in charge to assure that action are taken and actioned (responsibilities and timescale).

Furthermore, monthly site inspections based on structural and maintenance status check-list and GHPs, dedicated reports available e.g. inspections of December 2018: no observation raised. Non conformities are reported to the section manager and reviewed at monthly management meetings.

## 3.5 Supplier and raw material approval and performance monitoring

### 3.5.1 Management of suppliers of raw materials and packaging

Risk assessment dated 2018.12.19 is based on hygiene risk (definite on HACCP plan) and quality impact to the product with suppliers / raw materials: foreign-bodies risk, micro/chemical contamination, substitution or fraud are taken into account in suppliers risk assessment.
Raw materials identified as being at particular risk of adulteration or substitution appropriate assurance is in place to reduce the risk: such raw materials are Organic aromas which could be substituted with non organic: certification and analysis verified for every Organic aromas.

Verified the procedure PRO 7.4.00 “Approvvigionamento” issue 9 dated 25.01.2016 dealing with management of suppliers of raw materials, packaging and services and the procedure PRO 7.4.01 “Valutazione, qualificazione e monitoraggio fornitori” issue 9 dated 25.01.2016 relating to evaluation, qualification and monitoring of raw material, packaging and services suppliers.
A Qualified Suppliers List ( TAB 7.4.00 “Elenco fornitori qualificati”) updated 2018 based on risk analysis and a qualified raw materials suppliers list (TAB 7.4.00A “Elenco fornitori qualificati materie prime alimentari”) is available.
All suppliers of products and services have to be approved by the Technical Department and entered onto the authorized supplier list before they can be used.
Risk assessment is based on hygiene risk (definite on HACCP plan) and quality impact to the product with suppliers / raw materials: allergen contamination, foreign-bodies risk, micro/chemical contamination, substitution or fraud are taken into account in supplier’s risk assessment.
This is based on details from a raw material questionnaire.
No agents nor brokers are used.
Supplier classified low risk via certification or audits:

- Aromas: Giotti BRc site code 1904280 expiring on 28.01.2019 and Kerry FSSC 2000 expiring on 14.12.2020 and IFF Nederland expiring on 13.12.2019;
- CO2 and N2: R. FSSCC 22000 expiring on 06.04.2019;
- Packaging: Resilux BRC certified until 13.07.2019, Caps by Guala Closures FSSC expiring on 17.03.2021.

Brokers are not used. No high risk suppliers.

### 3.5.2 Raw material and packaging acceptance and monitoring procedures

Control in acceptance and controls on containers are effective following IST 7.5.08/C “Ispezione dei container – “Seven Point” issue 1 dated 25/01/2012. Raw materials are assessed on receipt.
Filled Schedule 36A with acceptance control verified: product sampling and testing; visual inspection on receipt; certificates of analysis – specific to the consignment; certificates of conformance.
Seen acceptance control dated 21.01.2018 on Resilux packaging and 16.01.2018 on Aromas: conforming values.

### 3.5.3 Management of suppliers of services

Service suppliers are managed through audit (seen last one dated November 2018 for pest control supplier) and questionnaire.
List of supplier of services: cleaning, pest control, lab analysis and transport. Contracts are available and yearly renewed. Complaints and issues monitored and used for a score card. Questionnaires are updated every three years, seen last compiled questionnaires sent by suppliers on 2018 (seen questionnaire of pest control and lab analysis suppliers).

### 3.5.4 Management of outsourced processing and packing

N/A

### 3.6 Specifications

The various kinds of specifications were verified for availability (dedicated files managed according to the rules defined in the Quality Manual). Specifications resulted being updated and available to interested staff. Specifications kept in SW system. The following specification were verified on site:
Raw materials
- “Aroma Naturale Giotti” dated 2015-04-08; citric acid dated 2015-03-18 and CO2 dated 13.02.2015.
- CO2 Rivoira 99% 17.01.2017 E290. Natural extraction 13.02.2015.
- Packaging PET updated 2017.
- Natural cucumber Flavoring W. 15.06.2015.

During document review the following specifications were verified:
Executive Water Natural 500ml code V100422 BB 24 months dated 11.12.2018 and Whole Food Market 500ml lime flavoured dated 27.12.2018.
These are reviewed minimum every three years or in the event of any change.
Rules are defined for the communication from supplier in the event of change/updating of characteristic.

### 3.7 Corrective and preventive actions

PRO 8.5.01 “NC/AC/AP” issue 5 dated 02/10/2009. There is a documented procedure for handling non-conformances identified within the scope of this Standard. Seen appropriate examples of CA management recorded on dedicated data base. All CA/PA sheets contain suitable root cause analysis and verification on effectiveness. Properly documented on company network dedicated Form. Action taken within short time. CAs properly implemented with identification of the cause and relative corrective action, positive trend observed. QAM is in charge for CA implementation. Regularly done as described in the procedure.
Seen records of CA in the last year: 1 dated 10.09.2018 from internal audits.

### 3.8 Control of non-conforming product

Procedure PRO 8.5.01 “NC/AC/AP” issue 5 dated 02/10/2009.NC managed by software and pc. Clear process well understood by staff interviewed during the audit according to procedure described. In general NC are detected directly during process controls and consequently managed real time. In case of NC product, the product is subject to physical separation and quarantine stock. Quality Control (after lab analysis check) has authority for releasing product. In 2018: 10 NCs were raised and in 2019 no NCs were raised. Seen last one dated 17.09.2018 for Pet colour mistake.

### 3.9 Traceability

Traceability Systems is defined in the dedicated procedure available and implemented for raw materials, finished products and packaging materials: PRO 7.5.06 “Procedura rintracciabilità” issue 8 dated 16/05/2011. Verified the IST 7.5.07 VDM “Predisposizione lotto di produzione” for lots control properly registered on production sheets. The

responsibilities were determined.
Traceability system operates through IT system enables trace of incoming, other production phase and ingredients and packaging from supplier through processes, to packing and despatch are traced by paper records. No rework. Upstream traceability tested regularly done, mass balance product to customer.

**Traceability test** carried out every year to cover both directions (from raw materials to finished product and vice versa).
A traceability test was conducted by the Company on 05.10.2018 on the product ACQUA FRIZANTE WEGMANS. Production date 17.09.2018, batch MW260A1800L1, expiring on 17.06.2019. Mass balance verified with quantity produced and sold (72576 lt). Time: 30 minutes.
Seen from raw materials to finished products: on 06.10.2018 for raw materials aroma strawberry batch 0008629464 code 5280 75kg and final productions (9 in total).

Suppliers approved by questionnaire sent a traceability test to be performed. Suppliers approved by questionnaire and sending of a traceability test to be performed.

A **traceability test conducted by the auditor** in the day of the audit was conducted on the product FLAVOURED LIME SPARKLING WATER for client S.. Production date 08.11.2018, batch FW312A1800L1, expiring on 08.11.2019. The auditor independently choose the sample for the test from warehouse. Mass balance verified with quantity produced and sold (26664lt). Seen transport doc from 21.11.2018 to 14.12.2018, seen recipe dated 19.01.2017. Seen lab analysis dated 08.11.2018 with conforming results. CCP1 and CCP2 control seen.
Time: 1h

## 3.10 Complaint handling

The procedure for the management of the complaint handling was defined. The responsibility was determined: 8.5.01 “NC/AC/AP” issue 5 on 2/10/09. In 2018, 3 complaints recorded. In 2019, no complaints raised from retailers. No complaints from consumers nor authorities; no complaints related to foreign material found in finished products.

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

Procedure defines the key personnel who manage the incident management team: PRO 9.00 VDM “Gestione sicurezza aziendale ed emergenza” issue 3 del 14/5/12.
In HACCP Manual key personnel who manage the incident management team is described. Crisis team defined including Matteo Spinozzi (QAM), Patrizia Mini (Dir). The responsibilities were determined.
The company has documented procedures described in HACCP Manual designed to report and effectively manage incidents and potential emergency situations that impact food safety, legality or quality such as disruption to key services such as water, energy, transport, refrigeration processes.
The procedure indicate, to call the certification body in 3 working days in case of real recall.

The process was tested on 10.07.2018 on Mineral sparkling water, batch MW146A1800L1 produced on 26.05.2018. Mock cause and scenario: chemical hazard which causes the recall of the product (decision making of the crisis team). Seen mail to client and mass balance (produced 7560 bottled and sold 5014, in warehouse 2544). Seen raw material provenance and batch. Seen traceability of batch, recall mail and crisis team summoned. Time: 40 minutes.

No recalls nor withdrawals in the last year.

## 3.12 Customer focus and communication

The Company has a correct management of customer focus and communication. Information are kept up to date and communicated out to relevant personnel and suppliers. No Specific requests by Clients so far.

Customer focus was clearly outlined in process specifications and outlined by staff interviewed during the production tour. This is clearly controlled through the supplier specification.

| Details of non-applicable clauses with justification | |
|---|---|
| **Clause reference** | **Justification** |
| 3.5.4.1 | No outsourced processing and packing |
| 3.5.4.2 | No outsourced processing and packing |
| 3.5.4.3 | No outsourced processing and packing |
| 3.5.4.4 | No outsourced processing and packing |
| 3.5.1.3 | No agents or brokers used |
| 3.9.4 | No rework used or reworking operations carried out |
| 3.12.1 | No specific customer policies or requirements in place |
| 3.12.2 | No specific customer policies or requirements in place |

## 4. Site standards

### 4.1 External standards

The building was on good condition.
In good repair and well maintained with investments regularly planned. Located in a large, light industrial estate with green fields around the plant. No local activities that would risk product contamination.
Adequate maintenance of the site and in relation to pests.
No additional buildings on site.

### 4.2 Security

Procedure is in place defined on refer risk assessment: PRO 11.00 VDM “Food Defence” issue 2 dated 31.05.2017.
Last security risk assessment dated 2018.12.19.
Sanitary authorization: “Provincia Pesaro and Urbino” Protocol 63151/2009, determination n° 3117 dated 30/09/2009.
Bottling authorization following “Ministero della Salute e delle Politiche Sociali” dated 18/06/2008.
FDA number: 11370456596.
Last training on food defence was carried out on 10.12.2018 to 17 operators.
Enclosed site with 24 hour security, by external evaluated supplier Vigilance service in continuous. A visitor was registered systematically.
Controlled access for all external people by approval only. Plant area is surrounded by fence.
Documented Food Defence on procedure The procedure to maintain the site security defined.

## 4.3 Layout, product flow and segregation

Site map in place which meets the requirement and define access points, personnel, waste, location of staff facilities and smoking areas.
Area present on site: production area and warehouse.
The layout of the plant is adequate and functional, updated map of the plant in HACCP Manual.
The local production and warehouse are adequately separated in order to minimize the risk of contamination. It was not detected any environmental risk. Storage areas are in line with the requirements of the standard.
The areas are all defined as low risk. The HACCP manual defines all areas at low risk because it is stable products.
No High risk/care area on site.

## 4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

The factory is suitable for the intended purpose. The walls are designed, constructed, finished and maintained to prevent the accumulation of dirt and to minimise condensation and mould growth. The cleaning operation is facilitated. The floors are adequate and maintained in good repair. Drainage doesn't pose risks for product contamination and not compromise product safety. Ceiling are proper managed and pipelines are under control. Windows have mosquito nets that prevent the ingress of pests properly maintained. External doors to raw material handling, processing, packing and storage areas are closed to prevent pest ingress. The lighting ensure a safe environment to carry out processes, inspection and cleaning operation: seen protection on light to avoid possible glass contamination.
NO high care/risk areas.

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

Procedure for water management in HACCP manual. Potable water in use available from public supply. A schematic plan of water is available dated 24.04.2018. Relevant records are maintained. Pluming system map detailing all sampling points was available. Water is tested every year for microbiological (including TMC, E.Coli, Coliforms and Enterococcus) and chemical (including heavy metals) parameters with reference to D. Lgs. 31/2001.
Analysis are carried out by internal and external accredited (micro and chemical) lab Università di Camerino and Neotron (Accredia 0026).
Seen analysis dated 26.07.2018 with conforming values.
No use of non- potable nor recycled water.
No other utilities that come into contact with food.

## 4.6 Equipment

The plants used in production are fit for purpose and well washed. SS used.
Main equipment was well maintained under routine maintenance systems.
Equipment contact surfaces all SS 316 but predate certification. Engineers aware of the requirement.
The production process provides 2 bottling lines, one for PET and the other one for one way glass bottle, equipment consist of pipelines and storage tanks of mineral water, discharge hopper for preforms, blow moulding of PET bottles, rinser, filler, capper, control for caps presence, labeller, printing the lot number and expiry date, wrapping and palletizing. For the line of glass bottles there are depalletizer for empty bottle, rinser, capping machine, check for presence of the caps, labeller, printing the lot number and expiry date, case packing and palletizing bottles. For the preparation of soft drinks dissolvers are used to warm for the ingredients, pasteurizer, storage tanks, filtration plant and pipes for sending the drink to the fillers. Fruits juice preparation is separated from filling areas.

## 4.7 Maintenance

PRO 6.3.01 "Manutenzione apparecchiature ed impianti" issue 8 dated 15/05/2012 .
2 maintenance workers who operates computerised maintenance plan and procedure, with workshop area which is maintained in good hygienic condition.
Refrigeration equipment subcontracted to specialists on case of breakdowns equipment.
The maintenance and cleaning operations activity was processed to ensure the safety of products.
The materials used for equipment and plant maintenance were conforming to use.

The good conditions are guaranteed during the maintenance programmed.
The Contractors involved in maintenance activity was monitored by the Responsible of the maintenance process.
The maintenance programs were verified.
Maintenance team regularly trained for proper GMPs and GHPs respect during maintenance activity. Operative instructions on purpose.
No major breakdowns during last 12 months.
Documented hygiene inspection on start-up completed by production supervisors.
Food grade lubricants are used: No allergens in food lubricants. Food Grade Oil NSFH1.
Engineering workshops are kept clean and tidy and controls are in place to prevent transfer of engineering debris to production or storage areas.
Last maintenance records seen dated 18.12.2018: on PET filling machine.

## 4.8 Staff facilities

IST 6.3.00 “Gestione Distribuzione bevande calde” issue 0 and IST 7.5.00A “Comportamento da tenere in stabilimento per gli appaltatori” issue 3.
Single large changing facility within main building maintained in clean condition by dedicated cleaning staff. Facilities for hand washing is sufficient. The canteen facilities were not present. The staff facilities are adequate. The cabinets are sufficient to receive the personal effects of the operators and are equipped with double compartment to separate work clothes from street clothes. Washing hands before entering the production departments. The number of sinks is adequate and the toilets are adequately separated from production areas. There is a refreshment room for short snacks through vending machine. Placards posted on proper hygiene. Toilets are adequately segregated and do not open directly into production, packing and storage areas. Toilets are provided with conforming hand washing.
Dedicate areas for smoking was identified on external perimeter of building.
No high care/risk facilities.
All food brought into manufacturing premises by staff is properly stored in a clean and hygienic state and is not permitted to brought food into storage, processing or production areas.

## 4.9 Chemical and physical product contamination control

### Raw material handling, preparation, processing, packing and storage areas

Chemical and physical product contamination control is described on HACCP plan and it is properly managed. The storage of the containers are segregated from the storage of raw materials, product or other packaging, even though containers are not made of glass. The procedure to prevent the risk of chemical or physical contamination of product was defined such as, chemicals control every month, audits to control label, correct packaging, MSDS. Regular audits are carried out every month on chemicals: last ones dated 22.01.2019, 15.01.2019 and 08.01.2019.

### 4.9.1 Chemical control

The storage, handling and use of chemical products is well managed to prevent chemical contamination. Chemical products are clearly identified and correctly segregated and locked. Cleaning chemicals stored in a locked room, restricted access on external storage area. A list of approved chemicals used at the facility was maintained for maintenance and cleaning chemicals. General Chemical awareness training was given to personnel at induction.
Food grade lubricants policy in place.

### 4.9.2 Metal control

The knives management is verified every day with the pre-operative control before the beginning of production day.
Documented knife policy. The knife is used on packaging area; the monitoring was documented on start up control.
Snap-off blades are not used. Staples, paper clips and drawing pins are not used in open product areas.

### 4.9.3 Glass, brittle plastic, ceramics and similar materials

The procedure of breaking glass on production area in glass was documented on HACCP Plan. In case of a glass breakage an “incident report” is opened and investigated following the operative instruction. Daily start up control and monthly glass and hard plastic audits. A list items detailing location, number, type and condition of glass is in place; recorded checks of condition of items and details on cleaning or replacing items to minimise potential for product

contamination are in place. During the audit, auditor has checked randomly windows and glasses present in the glass list. Seen glass of windows during audit: all conforming. Last ones dated 22.01.2019, 15.01.2019 and 08.01.2019.
MINOR CAR 4.9.3.1 ANF 4.9.3.3 RAISED.

### 4.9.4 Products packed into glass or other brittle containers

The procedures (PRO 7.5.00 "Gestione bottiglie vuote" issue 1 ; IST 7.5.29 issue 9 updated 11.01.2016 Gestione scoppio bottiglie) for handling glass, brittle or hard plastic, ceramic or other materials includes the requirement to inspect with a weekly frequency. Verified in production records check.
Bottles are cleaned using rinser before filling, mineral water and Peracetic acid are used for controlling foreign objects in empty bottles. A procedure is in place for filling phase checks: MOD 54 VDM-V "Controlli riempimento" issue 5.
The storage of the glass containers is segregated from the storage of raw materials, product and other packaging.
Even if no breakages occur, records are properly maintained, record are reviewed every year during management review to identified the trends.
The procedure of breaking glass on production area in glass was documented on HACCP Plan. In case of a glass breakage an "incident report" is opened and investigated following the operative instruction.
In more details, when a breakage occurs, the following action are taken: removal and disposal of at-risk products in the vicinity of the breakage; immediate and effective cleaning of the line; documented inspection of production equipment following the cleaning; authorisation for production to restart following cleaning.
The breakage accident is registered on a proper schedule and an "incident report" is opened with all the details of the line, the CA and the batch of product produced during the breakage.
The records are available and properly analysed by QC and QAM.

### 4.9.5 Wood

Control of wood properly managed. The presence of wood is allowed only at the end of the packaging line.

## 4.10 Foreign-body detection and removal equipment

### 4.10.1 Foreign-body detection and removal equipment

After risk assessment on 19.12.2018, the equipment to detect foreign materials were chosen as follows:
- Filters (50 µ) are used in 2 steps for filtering the juices for soft drinks production before filling the bottles and are regularly inspected and properly maintained; Seen record during traceability test.
- Magnet in the glass bottling line to detect missing part of filler as taps or screw and bolts testers are used to verify the detector as described in hazard analysis, managed as CCP.
Confirmed by risk analysis.

### 4.10.2 Filters and sieves

Filters (50 µ) are used in 2 steps for filtering the juices for soft drinks production before filling the bottles and are regularly inspected and properly maintained, checked every start/end of production.

### 4.10.3 Metal detectors and X-ray equipment

After hazard analysis no MD nor automatic foreign body detector was taken into account, the risk assessment defined monitoring procedure such as magnets (monitored as CCP).

### 4.10.4 Magnets

Magnet in the glass bottling line to detect missing part of filler as taps or screw and bolts, testers are used to verify the detector as described in hazard analysis, managed as CCP.
Test with Gauss meter.

### 4.10.5 Optical sorting equipment

N/A

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

Bottles in glass are cleaned with visual inspected.
Magnets in place verified by operator.
Records are available

## 4.11 Housekeeping and hygiene

Verified the procedure for Housekeeping and cleaning systems, was definite in accordance at the QMS (ref. 0877 AQ PR 010) and the procedure PRO 7.5.07 “Procedura pulizia e sanificazione” issue 4 dated 10/06/2011 to check the implementation for housekeeping and cleaning of production area, packaging area and storage.
Controls are carried out following IST 7.5.01 VDM “Pulizia impianti di captazione e serbatoi” and on IST 7.5.28 VDM “Igienizzazione sala sciroppi” issue 0. Cleaning registered on MOD 12 VDM “Registro interventi pulizia VDM” issue 1 dated 22/06/2012.
Bioluminescence once a week and registered on MOD 54 VDM “Controlli riempimento” issue 5.
Cleaning is carried out every day and it includes cleaning of equipment, floor and surfaces.
Chemical types and dilution rates available, checks of cleaning carried out with swabs every day.
Cleaning procedures have been developed and verified once a day production manager. Validation carried out yearly with machine manufacturers and have included extensive swabbing programme for TVC.
Seen swab carried out by Neotron on December 2018 and January 2019 with conforming result.

## 4.11.7 Cleaning in place (CIP)

CIP in place for storage tanks which are cleaned with spray balls and CIP system, as for production lines and pipeline, external part of equipment are manually cleaned by foam device and washed before production start.
Procedure IST 7.5.28 VDM issue 2 dated 22.04.2013 for flavouring area
CIP is used for sanitizing and cleaning, expected to wash with soda 1,5- 2 % at 80° C, Peracetic acid at 40° C and final rinsing with mineral water, all lines are subject to sanitization with variable frequency, both fillers, mixing room equipment, supply pipes and tanks, both internal and external. Weekly swab for cleaning monitoring of equipment cleaning with bioluminescence control.
Bioluminescence at every CIP, last one dated December 2018.
Schematic and validation of the CIP system are available.
Last inspection report on CIP concentration and temperature dated January 2019. Seen record also during traceability records of December 2018.

## 4.12 Waste / waste disposal

The system of waste is adequate: Operative Instruction IST 7.5.193 “Gestione rifiuti” issue 0 available and properly implemented. Waste collected in designated areas that respect all the standard requirements; was managed in conformity with the local regulations. Authorized Municipality Company and other qualified ones. No high risk/care area

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

There is no animal waste. Surplus of customer branded products is totally destroyed.

## 4.14 Pest Control

A specific procedure: PRO 7.5.04 VDM “Piano controllo e monitoraggio infestanti” issue 9 is clearly defined in HACCP Manual and in contract with external services company.
A contract with RENTOKILL dated 2012 and yearly renewed was in place with external provider to manage pest control on site 12 routine visits each year. No evidence of infestation was found or had recently been reported.
The baits are identified. External (using toxic products) and internal baits are used. Specifications and MSDS of pest control products are present (e.g. Rodent). Electrical lamps installed for the insects (mosquitos and flies) catching are correctly sited and they are inspected on a regular basis (every week). Pheromone traps are present for food insects such as moths, bugs, beetles. Schematic map of baits dated 11.10.2018. Last intervention dated 15.01.2019 and 10.12.2018, 06.11.2018, 05.10.2018 with bait control. In case of identification of pest: replacement of the trap and increase of the checks. An in-depth, documented pest control survey is undertaken quarterly, by a pest control expert to review the pest control measures in place: last one carried out on 10.12.2018. Trend analytical half-year. Monthly inspection, according to the model , it has not identified the other catches .Last trend in June 2018. Employees

understand the signs of pest activity and are aware of the need to report any evidence of pest activity to a designated manager.

## 4.15 Storage facilities

Storage of raw materials, packaging materials and finish products in dedicated warehouses, segregation of the different types of material is adequate.
There are 4 storage for mineral water coming from the source, 2 of which of 150.000 lt. Pipeline connect tanks with bottling lines.
There are 2 cells for storing aromas and juices (0-4 °C and <-18°C). Thermometers are correctly calibrated and checked, with alarm in case of temperature increasing.
The finished products are stable at room temperature and stored in warehouse, external loading area covered.
The stock rotation of raw and packaging materials and finished products is ensure by FIFO criteria and managed by managing system. No controlled atmosphere. Stock rotation formula is in place on a first-in first-out basis (FIFO) and inventory turnover ratio is calculated and properly monitored. Packaging is separately and correctly stored.

## 4.16 Dispatch and transport

The transport is carried out by several companies chosen by clients and the Operative Instruction 7.5.08 and PRO 7.2.03 “Programmazione della produzione e gestione ordini” specifies the activity.
The HACCP procedure of transport is defined for cleaning monitoring of vehicles level is ensured. A 7 point checklist for vehicles/containers inspection in preloading, loading and closure phases. IST 7.5.08/C “Ispezione container-“Seven Point”.
The temperature control during transport is not required. Checked the temperature of incoming fresh and frozen raw materials as fruit juices and flavours.
Documented maintenance and hygiene procedures maintained for equipment used for loading/unloading

## Details of non-applicable clauses with justification

| Clause reference | Justification |
|---|---|
| 4.3.5 | No high-risk areas defined |
| 4.3.6 | No high-care areas defined |
| 4.3.7 | No ambient high-care areas defined |
| 4.3.9 | No temporary structures constructed |
| 4.4.4 | No high-risk / high-care areas defined |
| 4.4.13 | No high-risk / high-care areas defined |
| 4.4.6 | No suspended ceilings or roof voids present |

| | |
|---|---|
| 4.5.3 | No legislation that specifically permits the use of water which may not be potable for initial cleaning. |
| 4.5.4 | No air, other gasses or steam used in direct contact, or as ingredient in, products. No compressed air used directly in contact with the product. |
| 4.7.3 | No temporary maintenance |
| 4.8.4 | No high-risk areas defined |
| 4.8.5 | No high-care areas defined |
| 4.8.10 | No catering facilities provided. No vending machines in place. |
| 4.10.3.2 | No metal detector or X-ray equipment in place |
| 4.10.3.3 | No metal detector or X-ray equipment in place |
| 4.10.3.4 | No metal detector or X-ray equipment in place |
| 4.10.3.5 | No metal detector or X-ray equipment in place |
| 4.10.5.1 | No optical sorting equipment in place |
| 4.12.1 | Licensing for the removal of waste isn't required by law |
| 4.13.3 | No products intended for animal feed |
| 4.14.3 | The site doesn't undertake its own pest control |
| 4.15.4 | No controlled atmosphere is required |
| 4.15.5 | No outside storage |
| 4.16.3 | No temperature control is required |

## 5. Product control

### 5.1 Product design/development

All new products/processes are submitted to specific R&D procedures including identification and assessment of potential safety hazard: 7.3.01 “Ricerca e Sviluppo” issue 7. New product projects are carried out by HQ in Rimini.
Labelling meets all legal requirements.

### 5.2 Product labelling

Labelling is in line with legal requirements and managed by HQ in Rimini.
Labelling information is reviewed whenever changes occur t: no recent changes to note.
During audit the label of product VALDIMETI OLIGOMINERALE NATURALE was checked during traceability: correct label.
Randomly checked the label of product KIRKLAND CARBONATED SPRING WATER in which ingredients and expiring date are present.

### 5.3 Management of allergens

There is TAB 10 AL “Materie prime contenenti allergeni” issue 0 and PRO 10 “Gestione rischio allergeni” issue 0. No allergens on site are. Risk assessment dated 2018.12.19.
Allergen policy on site communicated at induction – staff may not bring allergen containing products on site. Allergen risk assessment carried out during management review. All staff is properly trained on purpose: Seen training on purpose dated Dec 2018.

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

Vulnerability assessment of raw materials and packaging carried out on December 2018 (reviewed annually) on all food raw materials or groups of raw materials to assess the potential risk of adulteration or substitution.
The company have processes in place to access information on historical and developing threats to the supply chain which may present a risk of adulteration or substitution of raw materials.
Raw materials identified as being at particular risk of adulteration or substitution appropriate assurance is in place to reduce the risk. Organic aromas could be substituted with non organic: certification and analysis verified for every Organic aromas.

IST 7.5.112 “Gestione delle materie prime biologiche” issue 3 dated 26/1/2011. Following product authenticity:

- ORGANIC by Ecogruppo Italia ITBIO0081X06/12 issued on 14.12.2018 expiring on 13.12.2021;
- Kosher FRV-MGWF issued on 10.04.2018 expiring on 31.05.2019.

The facility maintains purchasing records, traceability of raw material usage and final product packing records to substantiate claims. ass balance exercise verified every 6 months. Last trace test on product with claims dated December 2018.

### 5.5 Product packaging

Packaging material used for the final products is:
- Glass and PET bottles. Size: 750ml, 335ml, 1 lt for Glass and 500ml, 1000ml, 1500ml for PET;
- Caps.

Packaging materials were stored and managed in a dedicated area.
The packaging materials are effectively protected after use.
The current specification details the safety use of the packaging material conforming to Reg. 1935/04.
Seen specification for Closure Gual for Glass with food contact conformity dated 02.11.2016.

## 5.6 Product inspection and laboratory testing

### 5.6.1 Product inspection and testing

Test results and inspections are recorded and reviewed regularly to identify general trends. The site has a continuous assessment system of the shelf-life. The system includes the risk assessment, as well as the microbiological and sensory analysis and the analysis of the relevant chemical factors. Proficiency tests with external Laboratories.
Seen analysis with confirming results carried out on:

- 15.01.2019 internal lab for microbiological results;
- 20.12.2018 with conforming values to the spring;
- 10.01.2019 by Arpam (accredia 0271) on sparkling mineral water for MB analysis;
- 12.12.2018 on shelf life of flavoured water lemon 500ml;
- 21.08.2018 Ring test carried out.

### 5.6.2 Laboratory testing

The external laboratories (PH TUV – Accredia 0069, Merieux Accredia 0051 and Arpam accredia 0271, Università di Camerino Accredia 0863) are in charge for chemical and microbiological determinations (TBC, P. aeruginosa, Coliforms, Streptococci and S. aureus, yeast and moulds) and sensorial analysis. External labs work to ISO standards.
Internal lab is properly separated from the production area. Staff is properly trained, competencies verified: seen training and degree of the 2 operators. The internal lab was used for: CBT (20°C and 37°C), Coli, staphylococci, Pseudomonas Aeruginosa, PH, nitrates, Chlorine, Bicarbonates, Calcium, Magnesium, sulphates. Internal lab also carries out analysis on raw material as fruit juice, acidifiers, flavours, mineral water for chemical (brix, acidity, heavy metals, conductivity, pH, dry extract and salt contents).

**MINOR CAR 5.6.2.4 RAISED.**

## 5.7 Product release

The procedure for laboratory activity was definite in accordance at the QMS
Procedures are in place to ensure that release does not occur until all release criteria have been completed and release authorised.

## Details of non-applicable clauses with justification

| Clause reference | Justification |
|---|---|
| 5.1.3 | Trials are not necessary for the product(s) produced |
| 5.3.5 | No rework used or reworking operations carried out |
| 5.3.6 | No allergen cross contamination risks |
| 5.3.7 | No claims made regarding suitability for allergy or food sensitivity sufferers |

## 6. Process control

### 6.1 Control of operations

Clear procedures to cover the specific kind of process are in place and well implemented.
PRO 7.2.03 “Programmazione della produzione e gestione ordini logistica” issue 2 on 31/01/11, PRO 7.5.00 “Gestione bottiglie” rev. 1 on03/04/09; PRO 7.5.01 VDM “Ciclo imbottigliamento acqua minerale Val di Meti in PET” issue 3 19/01/11, PRO 7.5.02 VDM “Ciclo imbottigliamento acqua minerale Val di Meti in vetro” issue 3 on 29/04/2011; PRO 7.5.03 VDM “Ciclo di produzione bevande analcoliche in PET” issue 4; PRO 7.5.04 VDM “Ciclo di produzione bevande analcoliche in vetro” issue 3updated on 26/01/12; PRO 7.5.05 VDM “Ciclo di produzione acqua aromatizzata in PET” issue 3; PRO 7.5.06 VDM “Ciclo di produzione acqua mineralizzata in vetro” ver. 8 updated on 16/5/11.
IST 07.05.00 B “Buone pratiche di lavorazione”; IST 7.5.02 “Controlli analitici sciacquatrice”; IST 7.5.30 “Istruzioni per gli operatori alla linea di imbottigliamento”,; TAB 7.5.6 “Piano dei controlli” issue 6.
Verified the daily process parameters checks carried out during flavoring preparation and filling process, as sanitizer presence for cleaning process, absence of sanitizer after final rinsing, pressure of water from nozzles for rinsing, CO2 pressure for carbonated products, filter integrity (50 micron), volume of filed bottle, presence and torque test for caps, blowing parameters for PET bottles, label control and coding parameters. All process control are well managed according to QMS and registered
Monitoring of CCPs available and recorded.
In the case of equipment failure or deviation of the process from specification, procedures are in place to establish the safety status and quality of the product to determine the action to be taken.

### 6.2 Labelling and pack control

Adherence to packaging allocation procedure was observed during product changeover ensuring pack clearance before start up and documented label and packaging checks.
The label is composed of batch, type and client name.
Documented procedures are in place to ensure that products are packed into the correct packaging and correctly labelled. Checks on batch, quantity, bar code etc.

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

Frequency of checks: every batch 80 samples are taken.
Statistical check: every batch.
The frequency of quantity checking are respected on refer Italian legislative requirements DPR 690/78.
The quantity checking was recorded systematically.
Verified the volume check on MOD 229 VDM, using graduated cylinder N LAC – 12B. Seen record of production date 23 and 24 Jan 2019.

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

The procedure for calibration activity, was definite in accordance at the QMS: 7.6.01 “Procedura per la gestione e la taratura delle apparecchiature” version 4 on 03806/08, in accordance to 7.6 ISO 9001 requirements. Controls are recorded on TAB 7.6.01 “Elenco strumenti di misura con frequenza tarature”, with Calibration Instrument List updated.
Thermometers and weighing scales are calibrated yearly by external authorised contractors.
Calibration was traceable to National standards, with supporting documentation where applicable.
Any issues with measuring and monitoring devices could be raised through non-conformance or corrective action systems.
Seen calibration of: thermometer dated 18.01.2019, balance dated 24.12.2018.

### Details of non-applicable clauses with justification

| Clause reference | Justification |
|---|---|
| 6.2.4 | No on-line vision equipment used to check product labels and printing |
| 6.3.2 | No bulk quantities packed |

## 7. Personnel

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

The procedure for training activity was definite in accordance at the QMS: PRO 6.2.01 “Criteri di addestramento e formazione del personale” version 3 on 26/05/08; training program registred on TAB 6.1.02 “Programma di formazione”.
The procedure for training activity was definite in accordance at the QMS; the training program of assessment and refreshment are approved annually.
Training carried out on :

- CCP and food defense training on 2018.12.10 to 17 operators (2h) by Matteo Spinozzi. Test verified.
- Training on 09.10.2018 on FDA (1h).

For all training effectiveness evaluation was present (test after training): seen test records of the previous mentioned training during audit.

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

Procedure IST 7.5.00 on 6/6/11 and communicated to the staff. Verified the procedures IST. 7.5.00 “Buone pratiche di igiene e buone pratiche di fabbricazione” and IST 7.5.00 A “Comportamento da tenere in stabilimento per gli appaltatori”. The Organization defined and documented the hygienic standards for the personnel of manufacturing department. No issues seen regarding compliance to documented hygiene policies. The use of personal medicines is well regulated and monitored to avoid the risk of contamination. First aid set in place including plaster control.

### 7.3 Medical screening

Notification by employees regarding infections and similar is properly managed. Medical screening according to Italian law requirements. The medicines handling policy is in place and properly applied by the operators: medicines are closed in a locked closet and access is monitored and registered. Used only in case of emergency.

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

Low risk areas is provided Company issued clothing 3 gowns sets, provided to all production staff. Disposable mob hats provided. Safety shoes also provided. Disposable visitor’s coats and hat provided
Protective clothing is removed on leaving the production areas.
Home laundry clothing is protected from home to site with special bags, moreover swabs are carried out in order to validate home laundry (seen swabs carried out on January 2019. No gloves used: seen swabs on clothes and hands dated December 2018 and January 2019 with conforming results.

### Details of non-applicable clauses with justification

| Clause | Justification |
|---|---|

| reference | |
|---|---|
| 7.2.4 | No metal detector in place |
| 7.4.4 | No high-risk / high-care areas defined |
| 7.4.6 | No gloves used |
| 7.4.7 | No items of personal protective clothing that are not suitable for laundering are provided. |

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# Food Safety Plan for Sparkling Mineral Water (PET L2)

Developed by the Quality Assurance department Date: 30/10/2019

Reviewed by PCQI Date: 30/10/2019

# Table of Contents

# Company Overview

The Val di Meti spring rises naturally and bubbles to the surface on the western side of Mount Nerone in the Appennine mountains of Italy at about 2,300 feet above sea level.
This is the heart of Italy where the regions of Marche, Tuscany and Umbria all come together. Mount Nerone, which rises nearly 5,000 feet above sea level and is snow-capped most of the year, dominates the surrounding region known as Montefeltro.
Val di Meti is guaranteed by Galvanina, the famous Ancient Roman Spring of Rimini. Great experience has been accumulated over more than 2000 years of history and more than 100 years of bottling. A brand prestigious throughout the world for never delivering less than its Quality promise.
The Val di Meti facility is one of the most modern PET bottling plants in Europe and is famous in Italy and the rest of the world for Mineral Water and Flavored Waters made with natural flavors.
The products are bottled in PET bottles and, since 2019, glass bottles with aluminum caps. Thanks to the latest technology, Val di Meti is able to guarantee the best preservation of the bottled product.
The work shifts are articulated in 5 days a week, with two 8-hour production shifts, followed by sanitation operations scheduled by Quality Control Manager.
There are 31 employees at the facility, divided as follows: 1 Plant Manager, 1 Production Manager, 3 office employees, 3 quality control employees, 23 production workers.
Cleaning and sanitizing of all processing equipment is conducted per a master sanitation schedule, which also includes cleaning and sanitizing between production runs. The spring water is used also for all cleaning operations. An integrated Pest Control Program is also in place.
Val di Meti does not produce any product containing Allergens. As an assurance of this statement, the raw materials chosen are without Allergens. The documentation stating the absence of Allergens in the raw materials purchased is reviewed by qualified internal staff. Furthermore, Val di Meti does not process products containing GMOs (Genetically Modified Organisms). In order to assure that no raw material purchased contains GMOs, qualified internal staff verify the documentation certifying the absence of GMOs inside the raw material.

# Food Safety Team

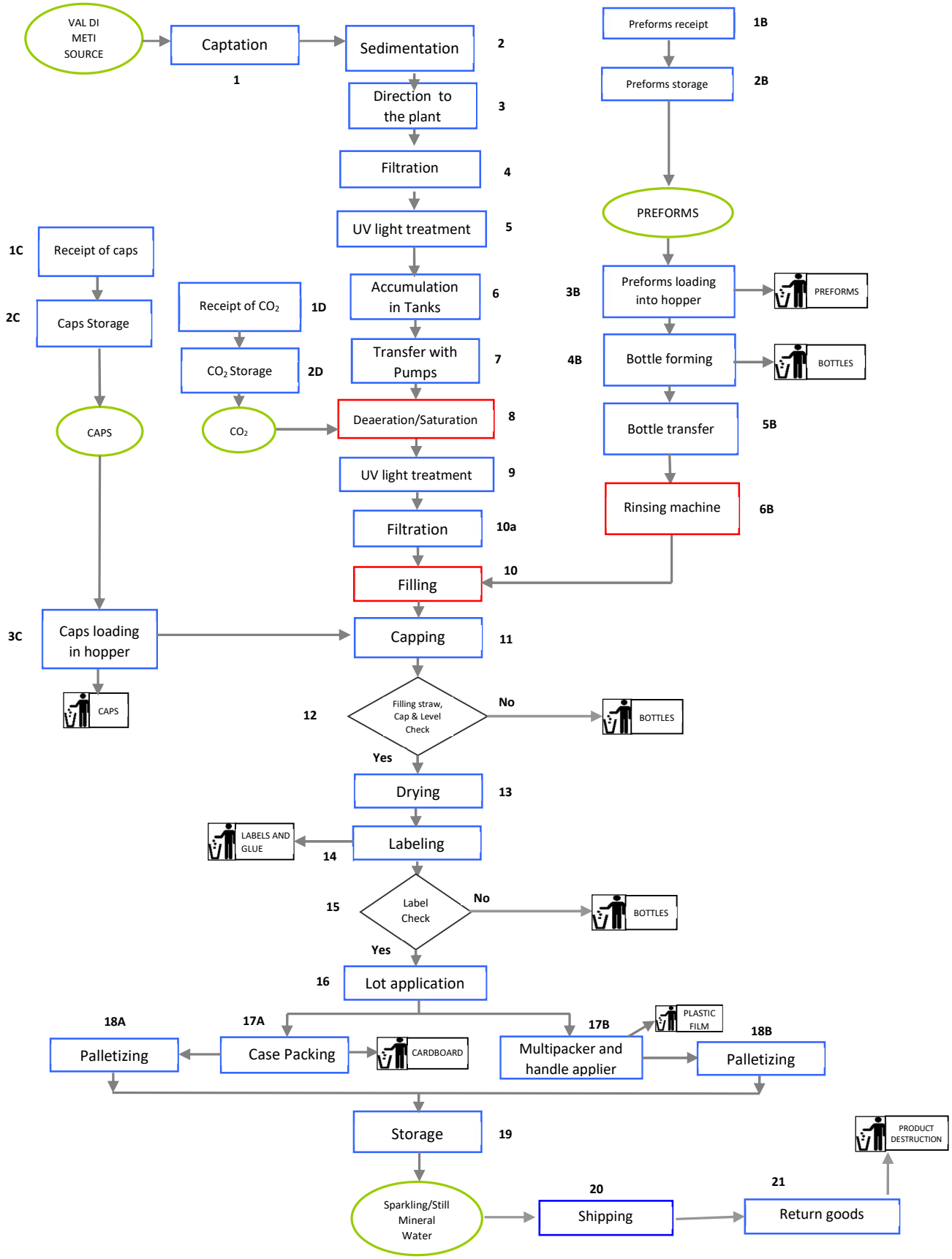
| Name | Title | Qualifications | Phone |
|---|---|---|---|
| Matteo Matassoni | Quality Control Manager | PCQI, GMP internet training course, MSc in Food science, 15 years of experience in the food industry | +39 0722 99757 |
| Matteo Biguzzi | R&D Manager | PCQI, MSc in Food science, 10 years of experience in the food industry | +39 0722 99757 |

| | | | |
|---|---|---|---|
| Lorenzo Valeriani | Quality Assurance Assistant | PCQI, MSc in Food science, experience with Food Safety and Quality Standards | +39 0722 99757 |

*This Food Safety Plan covers production of PET Sparkling Mineral Water.* Other products have separate Food Safety Plans.

| **Product Description Distribution, Consumers and Intended Use** | |
|---|---|
| **Product Name(s)** | Sparkling Mineral Water. |
| **Product Description, including Important Food Safety Characteristics** | Mineral Water with added carbonation in PET bottles with PET caps.<br><br>Room Temperature, ready to drink, carbonated with natural carbon dioxide.<br>pH 5.5 ± 0.5 (sparkling)<br>water activity ≥0.99<br>$CO_2$ ≤7.0 g/l (sparkling) |
| **Ingredients** | Mineral Water, natural carbon dioxide (for sparkling products). |
| **Packaging Used** | **Food contact packaging materials**: 33.8 fl.oz PET bottle with PET cap, 16.9 fl.oz PET bottle with PET cap.<br>**Non-Food contact packaging materials**: label, corrugated cardboard boxes, plastic wrap film. |
| **Intended Use** | The product is sold to an importer who then distributes is to various retailers.<br>Ready to drink, no further processing is required. |
| **Intended Consumers** | The product is intended for the general public. |
| **Shelf Life** | 9 months at ambient temperature. |
| **Labeling Instructions related to Safety** | Product name, volume, ingredients list, nutritional table, manufacturing company or distributor name, address and contact information, storage and handling instructions. |
| **Storage and Distribution** | Do not store in direct light and heat sources. Store in a cool, dry, odorless clean place. Do not freeze. Contents under pressure. |
| **Approved:**<br>PCQI | **Date**:<br>30/10/2019 |

# Flow Chart: Production Cycle for Sparkling Mineral Water (PET L2)






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

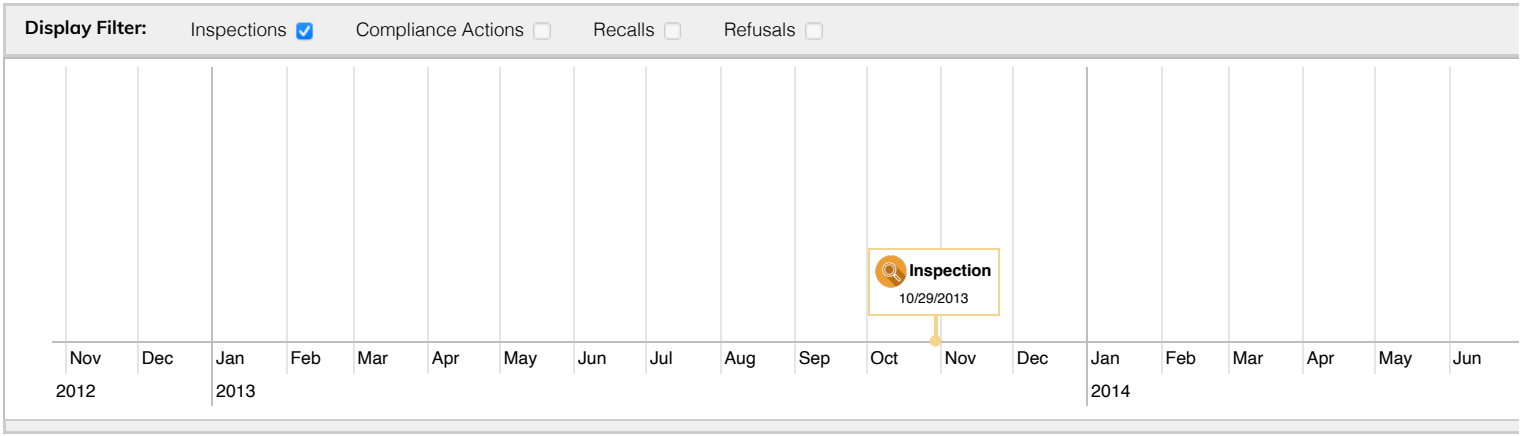
Claudio Innocenti

FEI Number
**3003097690**

Firm Name
**La Galvanina S.p.A.**

Firm Address
**Via della Torretta N.**
**Rimini, Rimini 4792**
**Italy**

## FDA Actions Timeline



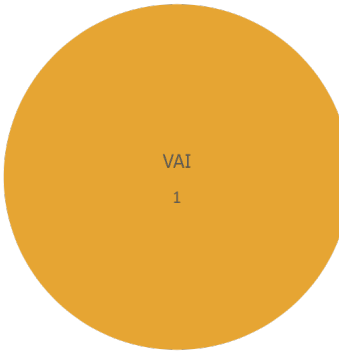

## 3003097690 – La Galvanina S.p.A.

### Inspections

| Inspections | Classifications |
|---|---|
| 1 | 1 |

**Inspection Classifications by Fiscal Year**
Fiscal Years: 2014 - 2014


**Inspection Classifications by**
Fiscal Years: 2014 - 2014




### Inspections Details

| Inspection ID | Inspection End Date | Project Area | Product Type | Classification |
|---|---|---|---|---|
| 853158 | 10/29/2013 | Foodborne Biological Hazards | Food/Cosmetics | VAI |

## 3003097690 – La Galvanina S.p.A.

**Inspections Citations Details**

No data found for the selected firm

## 3003097690 – La Galvanina S.p.A.

## Compliance Actions

| Warning Letters | Injunctions | Seizures |
|---|---|---|
| 0 | 0 | 0 |

**Actions by Percentage**

Fiscal Years: 2009 - 2022

No data found for the selected firm

**Compliance Actions Details**

No data found for the selected firm

## 3003097690 – La Galvanina S.p.A.

## Recalls

**Recalled Products by Classification**

Fiscal Years: 2012 - 2022

No data found for the selected firm

**F**

No d

**Recalls Details**

No data found for the selected firm

## 3003097690 – La Galvanina S.p.A.

## Import Refusals

**Refusals by Product Category**

Fiscal Years: 2002 - 2022

No data found for the selected firm

**Import Refusals Details**

No data found for the selected firm

## 3003097690 – La Galvanina S.p.A.

### Import Alerts

- Search results are not returned based on an exact match of the firm name. Users should review the search results to determine whether the firm appears in the Impo allowed into the country.
- Only current/active Import Alerts are displayed. For more information see Import Alerts.

No Import Alerts data found for the selected firm.

## 3003097690 – La Galvanina S.p.A.

### Warning Letters

- The search results below should be reviewed to determine whether the firm is directly or indirectly referenced in the Warning Letter.
- Only Warning Letters issued in the last 5 years are displayed. For more information see Warning Letters.

No Warning Letters data found for the selected firm.

## Caveats:

- Certain information in these datasets may not be presented or may have changed since the posting. The datasets are updated weekly and only include final actions. If you need to official purposes or have questions about obtaining other data, please contact the Division of Freedom of Information about what materials may be available in electronic reading r satisfy your needs.
- Compliance data provide information on a subset of the actions used by the FDA to bring firms into compliance, specifically data pertaining to Warning Letters, Seizures, and Injun only finalized and completed actions and are primarily used in the domestic arena.
- More than one establishment may be associated with one compliance action. The counts provided in this section reflect the number of establishments linked to the compliance acti
- For more information regarding the Center for Tobacco Products (CTP) issued warning letters click here.

**Search Results**

| FEI Number | Firm Name | Physical Address | Mailing Address |
|---|---|---|---|
| 3003097690 | La Galvanina S.p.A. | Via della Torretta N. 2, Rimini, Rimini, 47923, IT | Via della Torretta N. 2, Rimini, Rimini, 47923, IT |

# Sparkling mineral water production process

### *1. Captation*

Captation of water from the source "VAL DI METI" was realized by means of tunnels, which intercept water coming out from the bedrock, from which it flows. All plumbing components, ducts, gate valves etc. are made in stainless steel. Sanitization of these systems is carried out only when necessary (**IST. 7.5.01**).

Within the "Val Di Meti" mining resources extraction concession, the spring zones are areas subject to absolute protection, meaning that they are equipped with adequate ducts for the surface drainage of rainwater. To give an additional guarantee, to protect the zone against possible contamination, these areas are kept uncultivated or untreated, and are assigned exclusively to extraction activities.
The entire catchment area is kept under constant observation.

### *2. Sedimentation*

Water collected through the stratum flows in the sedimentation tanks in order to release naturally any residual sandy deposits, using the principle of sedimentation.

### *3. Conduction at the plant*

The mineral water is conducted through stainless steel ducts to the plant for bottling.
A tap is connected on this duct in order to enable sampling.
Collection of samples for chemical, chemico-physical and bacteriological analyses is carried out by technicians of the USL Marche (Local Health Authority) and QC of Galvanina (see **TAB. 7.5.06** "Control plan") or by an external authorized laboratory appointed by the DG of the company.
Every week, microbiological and physical/chemical analyses are done in order to monitor the source. The results of the analyses are recorded on a form **(MOD. 46).**

### *4. Filtration*

The Mineral Water undergoes a filtration process to retain eventual sand particles thanks to a metal sieve with 1mm meshes.

### *5. UV light treatment*

The Mineral Water passes through an UV light system to remove any microorganism and improve the cleanliness of the machines and pipes.
The Mineral Water is already pathogen free from the source (historically no pathogen has ever been found in the source) and it is frequently tested by the Quality Control department (**TAB. 7.5.06 VDM**).

### *6. Accumulation in tanks*

Water is stored in four accumulation tanks, each of 300 $m^3$ and made stainless steel. There are Specific cleaning and sanitizing treatments (**TAB. 7.5.05** "Cleaning and sanitizing Program") are applied to the tanks at determined time intervals (**IST. 7.5.01**) with relative registrations on **MOD. 12**.

### *7. Transfer with pumps*

The Mineral Water collected in the tanks is sent to the bottling plants through sanitary pumps. This equipment guarantees the healthiness of the mineral water and are verified with monthly checks like the storage tanks.

### *1.D $CO_2$ Receival*

$CO_2$ is delivered by means of a special tanker from a supplier. At the time of unloading, a lab worker verifies the integrity of the safety seal and the accompanying documentation (CoA), later reviewed and validated by the QCM. This verification is recorded in the **MOD. 36**.

### *2.D $CO_2$ Storage*

$CO_2$ is stored in two tanks and is carried to the filling department through a pipeline.

### *8. Deaeration / saturation*

A special "premix" machine is located in the bottling room; it mixes water with Carbon dioxide ($CO_2$).
Operators working on the filling line, program the machines to produce Sparkling Mineral Water with the established $CO_2$ concentration. This $CO_2$ concentration is determined in accordance with special techniques and setting operations are recorded in **MOD. 54 VDM PET**.
After mixing, Sparkling Mineral Water is automatically sent to the filling machine. At the end of the production, the "premix" / Filling PET line is sanitized by means of a CIP system, recording this operation in **MOD. 48 VDM CCP1-CCP2 P**.

### *9. UV light treatment*

The Mineral Water passes through an UV light system to remove any microorganism and improve the cleanliness of the machines and pipes.
The Mineral Water is already pathogen free from the source (historically no pathogen has ever been found in the source) and it is frequently tested by the Quality Control department (**TAB. 7.5.06 VDM**). The sedimentation tanks, storage tanks and pipes present prior to this step are periodically sanitized and checked by the Quality Control department (**IST. 7.5.01 VDM**).

### *10a. Filtration*

Sparkling Mineral Water undergoes a filtration process to retain any foreign bodies thanks to a metal sieve with 0.5mm meshes. Before the line sanitization operations, operators dismantle the sieve and check its compliance and presence of any foreign bodies. The intervention is recorded in **MOD. 48 VDM CCP1-CCP2 P**. The presence of foreign bodies caught by the sieve is reported to the QCM.

### *1.B Preforms receipt*

The warehouse keeper receives the goods and check the integrity of packaging, quantity and the delivery note filling in the **MOD. 36** "Check list controls in acceptance", if the product is non-compliant, it is not unloaded and immediately returned to the supplier.

### *2.B Preform storage*

Every preform batch delivery comes along with analytical proofs (CoA) in order to certify compliance to the technical specifications. Preform pallets are moved with attention to avoid any damage. For every typology of preform technical and safety sheets as well as compliances for food use are filed. For every product, a migration test is carried out every year and every time there is a supplier change.
Preforms are store in an exclusively dedicated storage area.

### *3.B Preforms loading into hopper*

The operator, after consulting the production order provided by the PM, takes the required preforms from the warehouse, recording the operation in **MOD. 54 VDM PET**; after the visual check of the packaging, opens package and carries out another visual check in order to ensure it is free of foreign bodies. In the event that foreign bodies are found, the worker will remove the box, set it aside and label the package with the Non-Conformity Card in order to warn the

PM about the anomaly (see **PRO 8.5.01** - "Non-conformity/Preventive Corrective Actions"). If, on the contrary, nothing is found, the operator transfers the performs into the hopper.
Preforms are introduced in the bottle blower through the hopper. An adequate blowing system eliminates any residual solid material. The hopper is completely isolated from the environment by being covered by a transparent plastic material.

### *4.B Bottle forming*

The bottle forming system is equipped with a pneumatic machinery which insufflates high-pressure air inside the previously heated up preforms and forms bottles in the mold. Preforms arrive vertically to the entrance of the machine, are linked to a system that plugs them and leads them to the furnace. An optical reader discards preforms with non-conforming shapes, with inclusions or containing foreign material. Preforms are heated up until they become shapeable at a temperature of about 105 ° C. After leaving the furnace, preforms pass in the insufflating molds; where filtered air is insufflated through filters of 0,2 μm with a pressure of 40 bar. The worker carries out a visual check of the blown bottles in order to verify the correct blowing and records the results in **MOD. 158 VDM,** and checks plastic material distribution following the procedure indicated in **IST.8.2.31 VDM,** recording the values obtained in **MOD. 339 VDM.**

### *5.B Bottle Transfer*

Once blown, the bottles are conveyed by air conveyor belts to the filler. This system guarantees the transport of empty PET containers in a hygienic and safe way. The air used for transport is previously filtered with anti-dust filters that guarantee the absence of any foreign bodies or particles in dispersion in the surrounding environment. The filters have a lifetime of 1500 hours, after which it is necessary to replace them.

### *6.B Rinsing Machine*

The bottles are turned over and sanitized with a solution of water and 2% peracetic acid and rinsed with mineral water. The operators record the presence / absence of the sanitizer in the **MOD. 53 B CCP3 VDM PET2** *"Addetto sterilizz_sciacquatr".* The machine is subject to a sanitizing and rinsing program, verified by the operator through the use of indicator strips that shows the presence or absence of the sanitizer. At the end of each phase, the operators record the controls on the module **MOD. 53 B CCP3 VDM PET2**. In the case of NC repeat the operation as shown in the **TAB. 7.5.06 VDM "Control plan".** These checks are carried out to prevent the risk of chemical contamination of the finished product.

### *10. Filling*

Prior to the filling phase, the operator checks the absence of residues of detergent or sanitizing products, used in the sanitizing procedures, with indicator strips, recording the operation on the **MOD.48 CCP1-CCP2 PET 2**. In the event of NC they repeat the operation as indicated in **TAB. 7.5.06 VDM** "Control Plan". These controls are carried out in order to prevent chemical contamination hazard of the finished product.
The formed bottles are introduced inside the filling machine, in which they are filled with Sparkling Mineral Water by means of volumetric valves.
During the production, operators take 10 bottles every hour, for a total of 80 bottles, weight the samples and record the measured values in **MOD. 229**. If values are below the declared volume, the production stops and the bottles are removed from the previous control until the NC is detected
Operators set the machine in order to bring it back to the correct value.
In addition to the filling volume, $CO_2$ is controlled every 30 minutes by recording in **MOD. 54 A VDM**.
The filler is also connected to the forming block, the tunnel is sealed with glass walls and positive pressure to avoid environmental contamination. The filling machine is not equipped with filling nozzles, therefore the risk of fall of any foreign material during the filling process is handled in a controlled environment.

### *1.C Cap Receival*

Every delivery is checked for conformity with the order, integrity and cleanliness of the delivered crates, and compliance with the shipping documents, these checks are registered in the **MOD. 36.** In the event of a NC with the goods, the delivery is rejected. All the crates are handled carefully by well-trained personnel to avoid damage.

### *2.C Cap Storage*

The caps are stored in an appropriate warehouse, separate from the rest of the production area. The warehouse workers carefully follow the GMPs for handling in order to avoid breakage of the protective packaging and consequent contamination of the caps. The QCM approves the attached CoA with a signature and archives it at the lab. The technical data sheets and the documents certifying the caps are suitable to come in contact with food or beverage, previously approved by the QCM/QAM, are filed at the quality assurance office.

### *3.C Loading caps into hopper*

The operator, after consulting the production order provided by the PM, takes the required caps from the warehouse, recording the operation in **MOD. 54 VDM PET**; after the visual check of the packaging, opens package and carries out another visual check in order to ensure it is free of foreign bodies. In the event that foreign bodies are found, the worker will remove the box, set it aside and label the package with the Non-Conformity Card in order to warn the PM about the anomaly (see **PRO 8.5.01** - "Non-conformity/Preventive Corrective Actions"). If, on the contrary, nothing is found, the operator transfers the requested caps into the hopper.

### *11. Capping*

The filled bottles move on directly to the capping machine installed on the filling machine. The operators for each production verify correct closure and record the result in the **MOD.47**.

### *12. Filling straw, cap and Level check*

After the capping machine the bottles are checked by a machine that checks the filling level and the presence of the cap. The operators set the machine at the beginning of production according to the bottle produced and an ejector will discard the non-compliant bottles. At this point there is also the detector of the filling straws that could possibly come off the filling heads. The detector is made up of two magnets which can detect the presence of any filling straws immediately interrupting the conveyor belts. The operation is guaranteed by the operator's control before the start of production and registered in **Mod. 54 VDM PET.**

### *13. Bottle drying*

The PET bottles filled and capped pass through an automatic drying system to avoid condensation in order to make the labeling process more efficient.

### *14. Labeling*

The dried bottles continue to slide to the labeling machine for labeling the products and the size labels.

The used glues are adequate for PET in accordance with the filed technical sheets.

The workers must check the production order. **MOD.78** and prepare the labels to be used accordingly with the "Product Sheets" **MOD.15**.

All the activities and checks of the labeling process are recorded on **MOD. 52 VDM** by the workers.

The operators must collect a sample of the finished product every 20 minutes from the beginning of the production. Those samples are needed for internal analysis as indicated in in the **Control plan TAB. 7.5.06 VDM.**

### *15. Label application check*
The labeled bottles pass through a machine that verifies the presence of the label, and discards the non-labelled bottles. The operator sets the machine according to the dimension of the bottle.

### *16. Lot Number and Best Before Date*
A laser machine prints the Lot Number and the Best Before Date on the labeled bottle according to the indications in the **MOD. 15.** The operator sets the machine for the Lot Number verifying the production order in **MOD. 78** recording the checks in **MOD. 52 VDM**.

### *17.A Case packing*
### *18.A Palletizing*
The bottles are packed in cartons with a cartoning machine which puts the identification information on the carton as indicated in **IST. 7.5.07** and "Product Sheet" **MOD.15.** The operator of the cartoning machine records the modality and the products used for cartoning in the form **MOD. 51 VDM** "Checks cartoning operator".
The crates are sent to the palletizer which automates the production of the pallet on which a plastic film is applied to ensure its stability. Every pallet is identified with a specific code, a machine applies the label with the requested indications. The operator sets the labeling machine with the necessary information.

### *17.B Multipacker handle applier*
### *18.B Palletizing*
Bottles are wrapped with a thermos-shrinking plastic material, adequate for food, in single or double packs according to the production order. The operator sets the machine in accordance with the format and loads the roll in its position. The package passes then to the handle applicator.
According to the production order, the packages pass to the palletizing machine which applies a plastic film to the pallet. Every pallet is identified by a code. The machine applies a label with the requested indications. The operator sets the labeling machine with the necessary information.

### *19. Storage*
The pallets are taken by the workers and stored in the warehouse. The Warehouse Manager decides on the goods storage areas and the layout of the lots by applying the principle first in first out.

### *20. Shipping*
Every container is inspected before shipment, following the seven points procedure described in the **IST. 7.5.08C**.

### *21. Return goods*
The product itself is never re-processed and, in case of a non-compliance, it is always destroyed.