Audit Report Global Standard Food Safety Issue 9

1. Audit Summary			
Company name	Bagnoli Group Srl	Site code	10008876
Site name	Bagnoli Group Srl		
Scope of audit	Mixing and packaging of spirits, liqueurs and other alcoholic beverages in glass bottles. Mixing and packaging of semi-finished fruit-based products packed in plastic containers. Mixing and packaging of syrups (for granitas) packaged in plastic and glass containers. Packaging of extra virgin olive oil in glass bottles.		
Exclusions from scope	Traded goods (can drinks)		
Justification for exclusion	Factored goods		
Audit start date	2024-02-01	Audit finish date	2024-02-02
Re-audit due date	2025-02-01	Head office	No

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Choose a module	Choose an item	N/A	N/A
Choose a module	Choose an item	N/A	N/A

2. Audit Results					
Audit result	Certificated	Audit grade	B	Audit programme	Announced
Previous audit grade	Choose an item		Previous audit date	Select a date	
Certificate issue date	2024-03-15		Certificate expiry date	2025-03-15	
Number of non-conformities			Fundamental	0	
			Critical	0	

2. Audit Results

	Major	0
	Minor	14

3. Company Details

Site address	Via Statale 16 n°4 - 35048 Stanghella PD		
Country	Italy	Site telephone number	042595395
Commercial representative name	Bagnoli Camillo	Email	camillo@distilleriebagnoli.it
Technical representative name	Paola Santi	Email	paola@distilleriebagnoli.it

4. Company Profile

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

Shift pattern	one shift only (8.00-12.00; 14.00-18.00)	
Seasonal site	No	
Seasonal opening times (Start/end date)	Click or tap to enter a date.	Click or tap to enter a date.
Other certificates held	None	
Outsourced processes	No	
Outsourced process description	Non-applicable	

4. Company Profile	
Regions exported to	Europe Choose a region Choose a region Choose a region Choose a region Choose a region
Company registration number	050ND03340
Major changes since last BRCGS audit	compartmentalization of the processing and packaging area; carried out separations with the installation of two automatic doors

Company Description

The company is privately owned.

Covered area: 2000 sq, of which production area 600 sq and storage area 1400 sq; no external storage; there are no other significant non-operational areas (e.g. there are no redundant production areas)

Combined audits with IFS food vers. 8

Company activities are involved only one single site with related logistics activities; there are no other logistics sites

History, age of company: the site was born in 1977.

Outline the type of specialist equipment or processes onsite: storage silos (also external for basic raw materials, alcohol) mixing and packaging

Production line: an automatic bottling line for both alcoholic and non-alcoholic beverages and a manual one for extra virgin olive oil

Volume of production: turnover 2023 about 12 mil.

Confirm number of staff: 13 people full time, of which 7 in production area; one shift only (8.00-12.00; 14.00-18.00)

Summary of product and customer types: alcoholic beverages (e.g. vodka, sambuca, gin, spirit drinks for aperitifs) packaged in bottles for both retailers, wholesalers and Ho.Re.ca; other semi-finished products for drinks: sugar-based syrups and semi-finished fruit-based drinks packaged in 5-litre bottles and cans for bars, restaurants, cloisters, etc.

Alcoholic beverages are intended above all for final consumption, including retailers, above all under the company brand (only one case of retailer brand). The market is mainly Italian and to a small extent in Europe

No interruption in the activities longer than a week

5. Product Characteristics					
Product categories	12 - Beverages 13 - Alcoholic drinks and fermented/brewed products 18 - Oils and fats Category Category Category Category Category				
Finished product safety rationale	Alcoholic beverages; sugar-based syrups and fruit-based products with brix > 65%.				
High care	No	High risk	No	Ambient high care	No
Justification for area	Enclosed products. As to Appendix 2 of the Standard and Guideline “Understanding production risk zones”; Alcoholic beverages; sugar-based syrups and fruit-based products with brix > 65%.				
Allergens handled on site	Sulphur dioxide and Sulphites Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen				
Product claims made e.g. IP, organic	None				
Product recalls in last 12 months	No				
Products in production at the time of the audit	Mixing and packaging of APE’ (liqueurs) in glass bottles 100 cl, lot L03224. Packaging of extra virgin olive oil in glass bottles lot 02624 500 ml. Filtration of Gin lot 02/24				

6. Audit Duration Details			
Total audit duration	20 man hours	Duration of production facility inspection	10 man hours
Reasons for deviation from typical or expected audit duration	Non-applicable		
Combined audits	IFS		
Next audit type selected	Announced		

Present at audit					
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)					
Name	Job title	Opening meeting	Site inspection	Procedure review	Closing meeting
Bagnoli Camillo	General Manager	X			X
Borella Santino	Production Manger	X	X	X	X
Simone Boretto	(Quality and HACCP manager),	X	X	X	X
Agelika Brandalese	Quality quality and supplier	X		X	X
Maria Contrini	External Consultant	X	X	X	X
Enrico Bellini	External Consultant	X	X	X	X

GFSI Post Farm Gate Audit History			
Date	Scheme/Standard	Announced/Unannounced	Pass/Fail

Document control				
CB Report number	ALI 02258			
Template name	F908 Food Safety Audit Report Template			
Standard issue	9	*Template issue date*	2022-12-16	
Directory allocation	Food	*Version*	1.1	

Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements			
Clause	Detail	Critical or Major	Re-audit date

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
2.3.2	L'elenco delle normative non è ben dettagliato in merito alle normative specifiche del settore. The list of regulations is not well detailed regarding industry-specific regulations	The list of standards in the HACCP plan has been updated (Attached document, *Sezione 23-Normative di riferimento)*	During the HACCP periodic review, planned for May 2024, the completeness of the list and timeliness of the standards included will be checked	During audit and HACCP review, the list of standards was not properly monitored	2024-02-29	Ok Vincenzo D'Annunzio
2.5.1	Nel diagramma di flusso non è prevista la eventuale rilavorazione (che è gestita a livello operativo). 2.5.1 The flow diagram does not foresee any rework (which is managed at an operational level)	Reworking has been included in the alcohol product flow diagram (Attached DOCBAG 07 REV. 01)	During the flow periodic review, planned for July 2024, the completeness of the list and timeliness of the standards included will be checked	It was not included in the flowcharts because it is not part of the ordinary procedure.	2024-02-29	Ok Vincenzo D'Annunzio
2.12.1	La validazione delle misure di controllo non è adeguatamente documentato. The validation of control measures is not adequately documented	A validation test of pre-operational control on filtering was conducted on 01.2.2024. attach MODBAG 14 R00 Validazione controlli preoperativi	For each pre-operational check, validation tests will be conducted and documented. Will be verified during the audit program.	Validation tests carried out by the production manager over the years were not properly documented	2024-02-29	Ok Vincenzo D'Annunzio
2.12.3	Il riesame dell'HACCP non è adeguatamente documentato. The HACCP review is not adequately documented	The management review has been updated by adding the haccp review section. See attach DOCBAG 06	it has been planned that a full review of HACCP will be carried out in December 2024 under review	The HACCP review had not been fomalized	2024-02-29	Ok Vincenzo D'Annunzio

Minor						
3.8.1	La procedura di gestione delle NC non riporta in maniera dettagliata la gestione dei prodotti non conformi e dei resi. Non-conforming products and returns are not covered under procedure of NCs.	A special procedure has been introduced for the disposal of non-compliant products (PROBAG10)	Will be carried out information and training on the need to manage non-compliant products. Will be verified during the audit program.	Management of non-compliant products was not properly documented	2024-02-29	Ok Vincenzo D'Annunzio
3.9.3	Prova di rintracciabilità da materia prima a prodotto finito non è stata documentata (il software gestionale è comunque in grado di offrire il bilancio di massa delle materie prime in poco tempo). Traceability test from raw material to finished product has not been documented (the management software is however able to offer the mass balance of raw materials in a short time)	A raw material to product traceability test has been carried out. See attach REGBAG 7.18-13	Every year, during the verification of the support area, traceability tests will be carried out both from finished product to raw material and vice versa (October 2024). Will be verified during the audit program.	The traceability tests were wrongly conducted only in one direction	2024-02-29	Ok Vincenzo D'Annunzio
3.11.4	Non aggiornata procedura di gestione delle incidenti/recall per comunicazioni all'organismo di certificazione. Not updated incident/recall	the operating instruction ISTBAG 8.9-8 REV 01 is been review	Will be carried out information and training on the need to manage incident/recall. Will be verified during the audit program.	Was not made explicit what was required by the standard	2024-02-29	Ok Vincenzo D'Annunzio

Minor						
	management procedure for communications to the certification					
4.6.3	Non documentata procedura per garantire in base alla valutazione del rischio la sicurezza ed integrità degli alimenti durante l'installazione di nuova attrezzatura presso il sito. Risk-based commissioning procedure are not in place to ensure that food safety and integrity is maintained during the installation of new equipment to site	the preoperative control carried out on the filtering has been validated. Seen attach procedure	A report to document the validation of pre-operational checks was unavoidable. Will be verified during the audit program.	No validation tests were documented	2024-02-29	Ok Vincenzo D'Annunzio
4.11.2	Controlli (esempio di start up) per verifica stato della pulizia non documentati. Check (e.g. start-up checks) to verify cleaning status not documented	the register, REGBAG 20 R 00 CONTROLLI PRE-OPERATIVI E OPERATIVI, has been revised	Will be inserted as a pfreoperative control, for all products, the control of the cleaning carried out. Will be verified during the audit program.	The cleaning check was carried out only after the cleaning was done and not at the beginning of the activity	2024-02-29	Ok Vincenzo D'Annunzio
4.14.10	Non disponibile valutazione approfondita del pest management. In-depth evaluation of pest management not available	The evidence related to the monitoring carried out by the external company in order to confirm the goodness of the service. See attach survey.	For the year 2024 will be drawn up a report to analyze the pest management service. Will be verified during the audit program.	It had not drawn up an overall report but only verified the reports provided by the supplier	2024-02-29	Ok Vincenzo D'Annunzio
4.14.4	Esche rodenticide esterne non adeguatamente fissate. External	additional intervention was requested to the service speaker to fix the perimeter baits. Seen photos	During the verification of the infastructs will also observe the fixing of the baits	Correct training on the correct monitoring of the plant of disinfestation	2024-02-29	Ok Vincenzo D'Annunzio

Minor						
	rodenticide baits not adequately fixed					
4.16.6	Non presente capitolato con la società di trasporto “Barone” . There are no specifications with the "Barone" transport company	The transport company was asked to countersign a hygienic specification. Seen attach of contract with “Barone”	All transport providers will be required to sign a hygienic specification together with the service contract	In view of the supplier’s historical background, it was not necessary to supplement the document	2024-02-29	Ok Vincenzo D’Annunzio

5.1.4	Non adeguatamente definito un programma shelf life per le valutazioni sensoriali. A shelf life program for sensory evaluations is not adequately defined	an operational instruction for the verification of sensory tests has been added. Seen attach ISTBAG 15 REV 00	sensory tests will be carried out for all products and the need for more in-depth tests will be defined. Will be verified during the audit program.	The deadline had been evaluated according to what the read said about the product	2024-02-29	Ok Vincenzo D’Annunzio
5.3.4	Non identificato chiaramente (es. coding colour) l’attrezzatura (paletta) per impiego di solfiti (metabisolfito di potassio)	Special tools for allergen management have been purchased. Seen photos	For each product containing an allergen will be purchased special containers and spatulas. Will be verified during the audit program.	Serum not correctly assessed the risk of allergen portioning	2024-02-29	Ok Vincenzo D’Annunzio

Comments on non-conformities
The non-conformities are not able to affect the safety and legality of the product

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Audit team

Lead auditor		
Auditor number	**First name**	**Second name**
21499	VINCENZO	D'ANNUNZIO

Audit team				Attendance (YYYY/MM/DD, 24hr: MM)			Presence	
First name	Second name	Auditor number	Role	Audit Date	Start time	End time	Remote or physical	Professional recognition number
Vincenzo	D'Annunzio	21499	Lead Auditor	2024/02/01	08:00	19:00	physical	
Vincenzo	D'Annunzio	21499	Lead Auditor	2024/02/02	08:00	19:00	physical	

1. Senior management commitment

Product safety and quality culture plan

The level of the culture at the site is identified through interviews for employees.

Activites undertaken relating culture plan “Piano per la cultura della sicurezza alimentare- DOG BAG 02” rev 0 of 1.7.2023, updated on 9.1.2024 involving all sections of the site. The success of the plan is measured through specific performance indicators (both training and results in the field in terms of reduction of NC causes and complaints). Senior management were available to discuss the plan during the audit. The plan is ongoing. The review is quarterly. Date of the last review: 27.5.2023

Food safety and legality objectives

Date of the corporate policy approval documented on DO BAG01 rev 00 of 22.12.2022

Date of the specific objectives: 9.1.2024 Identified several goals associated with food safety and quality with targets: number of complaints, product and system Non-Conformities, etc. The frequency of monitoring the objectives is quarterly carried out by the Quality Manager. Key findings (complaints, actually no compliant in the last year) or significant trends confirm that the company is performing well against its goals.

Management review

The management review is held annually, with the last management review meeting dated: 9.1.2023

Usually the Management, Quality Service and Managers participate in the meeting. The minutes are recorded with appropriate documentation and the actions are communicated to the competent personnel of the individual areas directly by the Management.

Senior management were available to discuss the plan during the audit

Regular meetings

Meetings are held monthly and issues routinely covered are related to food safety, authenticity, legality and quality. Seen meeting dated: 11.11.2023 and 9.1.2024

The meetings are recorded using special forms and the results communicated to the staff through special training.

Previous non-conformities

The non-conformities raised at last year’s audit have been resolved and there was evidence that root cause has been identified and actions instigated to prevent recurrence.

Organisational structure, responsibilities, and management authority

The company's management structure is documented in the “Company organization chart (name and function), rev 3 updated 18/9/2023"; defined responsibilities by function, company area, indication of the name of the person in charge of the role are identified and the substitutes for function are also identified,

identified by name: Bangnoli Camillo (General manager), Quality office (Brandalese Angelica), Simone Boretto (Quality and HACCP manager), Borella Santino (Production manager)

The Company has identified adequate human resources to maintain and continuously improve the IFS Standard.
Employees are aware of their responsibilities for advertising the organization chart advertised on the company
bulletin board.
The descriptions of duties, roles, skills and responsibilities are documented: having regard to the document "Company Job description" for every roles documented on form DOCBAG03, seen eg HACCP Manager dated 4.10.2023.
The roles of the quality manager and the quality control service, and the relative deputies, represent key elements for the safety, authenticity, legality and quality of the product. The current structure and reports are up to date and documents reflect the current structure.

The company receives updates from internal sources (quality area) and other sources (consultant- Studio RSPP for HACCP and FRRR for quality system) regarding the legislative update; in addition, the company uses lawyers for the legal evaluation of the labels.

The site uses external external knowledge, e.g. consultant relating HACCP team, Food Defense, Food Fraud and also in the development or maintenance of food safety systems, but there is an internal an internal member responsible for the day-today management of the food safety system

Present List of updated laws and regulations dated: section 12 of HACCM manual rev 6 of December 2023

The quality manager directly takes care of updating the main company contacts (including purchasing office and management of purchase specifications). Training for key figures such as: production manager, raw material reception managers. Management ensures that all relevant information is made available to all responsible staff through also with monthly meetings.

Reporting food safety issues

A confidential reporting system is in place for staff to report food safety risks, concerns or problems related to non-compliant products; a procedure is in place to manage such reports.

Visit of the authorities

Name of the authorities: ULSS n° 6 Euganea

Date and time of last visit: 6.2.2023

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

2. The Food Safety Plan – HACCP

The scope of the study includes the following key process steps: mixing and packaging, including receipt and handling, processing, storage and despatch and covers all the products produced at the site.

It is systematic, comprehensive and fully implemented and maintained. There flow process diagram/s relating every product matrix, currently at version 27.5.2023 and last verified by the team on 4.10.2023.

The process flow diagram/s cover/s the process steps, which are: ambient storage and refrigerated storage, mixing, filtering, intermediate storage, packaging, secondary packaging, storage and despatch.
The flow diagram accurately reflects the production processes.
Product descriptions are defined and also intended use is documented.
There is no sub contracting of any part of the process.

There are 2 HACCP study/ies (one for for alcoholic beverages, syrups and semi-finished fruit-based products and one for oil), currently at revision 06 and dated December 2023
Description for each product or group of products
The scope of HACCP study and HACCP plan accurately reflects all products on site
The company's food safety plan is based on Codex Alimentarius HACCP principles.

The HACCP team is led by Simone Boretto who is trained by "Studio RSPP" on 22.11.2023 (3 hours of HACCP and method) and experienced within the industry. The HACCP team includes representatives from production (Borella Santino, Mititelu Josef), Verlic Luca and Adriano (storage) , quality and despatch and all are trained on 31.05.2023, external consultant (specialist of HACCP) Enrico bellini.

A comprehensive pre-requisite programme is in place covering: personal hygiene, transport, allergens, pest control, foreign body controls, site/waste management, supplier approval/monitoring, hygiene and housekeeping.
References to legislation have been made within the study relating to the beverage and drinks industry.

The hazards considered specific to each stage of the process: physical (especially glass - bottling), chemical (heavy metals and pesticides, microbiological and allergen hazards have been considered within the study (eg types of micro-organism: toxin-producing molds (e.g. patulin). Allergens handled on site are sulphites.

Hazard analysis and CCP identification has been based on a likelihood and severity basis. No CCPs have been identified but only 2 Op. PRP:

- Filtration after mixing (one or two filtration passes) 5 types of filter Cardboard between 3,5 mm fino a 920 micron; monitoring carried out every assembly and mixing and recorded on working sheet (seen monitoring of 18.12.2023 relating product Bitter 25 ° Lot 318/23)
- rinsing pressure (verification at start of bottling),limit bar < 2, monitoring at start of botttling and recorded REG BAG 20 (seen record of 1.2.2024 durint the packaging of alcoholic drink "APE" lot 032/24

A corrective action procedure is in place. Responsibilities for monitoring the critical limits and for corrective action are defined. Provide examples of corrective actions in event of failure of a Op. PRP

Validation of HACCP plan including OPRP, control measures and PRPs specific for controlling food safety hazards has been based on industry standards, product microbiological results and shelf life testing.

Verification is carried out during internal audits and the daily verification checks performed. Verification reviews are carried out on 9.1.2024 (with annually frequency)
The HACCP plan is reviewed at least annually (last reviewed on 9.1.2024).

NC minor:
L'elenco delle normative non è ben dettagliato in merito alle normative specifiche del settore. The list of regulations is not well detailed regarding industry-specific regulations.
Nel diagramma di flusso non è prevista la eventuale rilavorazione (che è gestita a livello operativo). The flow diagram does not foresee any rework (which is managed at an operational level)
La validazione delle misure di controllo non è adeguatamente documentato. The validation of control measures is not adequately documented
Il riesame dell'HACCP non è adeguatamente documentato. The HACCP review is not adequately documented

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

3. Food safety and quality management system

3.1 Food safety and quality manual, 3.2 Document control, 3.3 Record completion and maintenance

The Quality Manual BRCGS Food -IFS food rev 00 of 1.2.2023 has been written to meet the requirements of the Standard and contains policies, procedures, work instructions and record forms. It is controlled electronically by the Quality Manager.

In place a procedure relating documental control and record keeping: "PRO BAG 02 Gestione documentazione SGC e Documenti di Registrazione" rev 0 of 23.6.2022

Controlled documents are listed on REGBAG 3 updated on 11.11.2023 and control is managed by quality manager (P.S) responsible for authorisation, changes/amendments and replacement of existing documents.

Department specific work instructions are available at key locations and all documents are in Italian language.

Records are partly manually and party electronically and are stored as hard copy/electronically and backed up with daily frequency (internal and external)

Records reviewed during the audit were seen to be legible and genuine and were easily retrieved.

Records are retained for 6 years (longest shelf life of product 5 years).

3.4 Internal audits

In place procedure documented on Quality manual section 8.1 rev 00 of 1.2.2023.
IN place audit program rev 00 of 27.5.2023, based on risk assessment (critical area identified: HACCP area, with 2 audit each year).
There is one trained internal auditors (Maria Contrini) based on site who are responsible for the site internal audits (seen certificate of auditor “Auditor interno” dated 5.7.2022 by AreaISO srl certificate n° ISO2022-07-05-06. The auditors on site cross audit departments to ensure independence from direct responsibility.

The internal audit schedule is documented and covers all of the documentation and food safety and quality management system on site.

Each area is audited with the frequency determined by risk assessment at least annually. Internal audits are carried out throughout the year, at least on 4 different dates.

Internal audit records reviewed were comprehensive recording evidence of both conformity and non-conformity. Corrective actions and their timescales had been agreed and completion had been verified by Angelica Brandalese (quality office)

During the audit seen the following audit report:
- dated 4.11.2023 of HACCP and commercial area; no NC are detected;
-7.8.2023 on senior management, on site production (structure and equipment), hygiene and rules, Quality control; detected 3 observation, 6 NCs (all closed based on root analysi, and follow up)

Monthly hygiene/fabrication and GMP inspections are carried out, based on risk assessment relating inspections for factory environment and processing equipment
Reports reviewed: of 7.8.2023 documented on “Verifica dello stato delgi ambienti di lavoro e dellell infrastrutture” MODBAG rev 8.2-10 of 27.5.2023 related hygiene/fabrication/GMP inspection reports).
3 NCs are detected and are managed as per the procedure (which provides for correction, management of corrective actions and verification - follow up).

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

A risk assessment of raw materials has been carried out, with products assessed for allergen, foreign body, chemical, microbiological and substitution/fraud risks documented on REGBAG 11 updated 27.5.2023 (approved on management review of 9.1.2024); example for (patulin on apple juice medium risk).

Suppliers of products are approved and monitored by Quality Manager using procedure of supplier approval of raw material “Processo di valutazione fornitori materia prime rev 1 of 7.7.2023” and assessment of suppliers is based on risk, quality and historical compliance. Last assessment of supplier carried out dated: 27.5.2023 (annually approved on management review of 9.1.2024)

An approved supplier list is in place dated 27.5.2023

Suppliers are approved by Quality Manager on the basis for risk assessment, deciding whether approval requires an audit, 3rd party certification (eg BRC) and/or a questionnaire. Only suppliers assessed as “low risk” are approved via a questionnaire alone.

Based on the risk assessment, no high-risk suppliers were found

Supplier questionnaires are issued (at least at the start of the qualification and every three years) and suppliers are required to notify the site of any significant changes in the meantime.
Seen following questionnaire:
- RADER (broker relating sugar) seen questionnaire sent of 24.1.2024 (produced Nordzucker FSSC certificated)
- Blowpack, supplier of plastic container, not GFSI certificated, seen questionnaire 13.10.2022

Following BRCGS certificates were checked during the audit via the BRCGS database and found to be genuine and valid:
- SIlcompa Spa supplier of ethyl alcohol, FSSC 22000 ceriticcated expiry date 23.6.2025,
- Enrico Giotti supplier offlavourings, colorings and preservatives, and clear juices, IFS (Coid 25288) and BRCGS certificated (BRC site code 1904280)
- Verallia Italia (supplier of glass bottles, FSSC 22000 certifcated expiry dated 23-9-2026)

If Suppliers is not audited or certificated, receive a traceability tested on first approval and then at least every three years. Suppliers' traceability procedures have been assessed by Quality Manager at least annually: seen last of supplier of plastic container dated 24.1.2024

Agents and brokers are used. Information to enable the approval of the manufacturer/packer/consolidator has been requested/received; agent/broker is not certificated GFSI.

Ongoing monitoring of supplier performance is via the non-conforming product system, at least annually. Exceptions are covered under procedure of supplier approval and are subject to more stringent quality checking. The suppliers approval procedure appears suitable and effective.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

In place procedure "Approvvigionamento" PROBAG 7.4. Raw materials are checked on intake for compliance with purchase orders and certificates of analysis/compliance are received.

- seen control on arrival of raw material documented on "Modulo controllo merci in ingresso" MODBAG 7.4-7 of 27.5.2023 (seen control of 21-7-2023 related glass bottle supplier Verallia Italia)

- seen control on arrival of raw material documented on "Modulo controllo merci in ingresso" MODBAG 7.4-7 of 27.5.2023 (seen control of 2.10.2023 related alcohol supplier Silcompa Spa: rinsing cleaning of tank, presence of seals (6), alcoholic level

3.5.3 Management of suppliers of services

Service suppliers are approved and monitored by Supplier manager (A.B) using "Processo di valutazione rischio fornitori di servizio" rev 0 of 7.7.2023 procedure and have appropriate contracts. These were reviewed for suppliers of pest control, laundry, calibration, lab. analysis.
Service providers are qualified according to the following parameters: punctuality, quality of service, compliance with contractual requirements.

During the audit assessed e.g. the following service provider documented on REGBAG 11 rev 0 of 27.5.2023 (seen assessment of RIPA Disinfestazioni srl dated 27.5.2023, score rating 12.5 (max of level).

3.5.4 Management of Outsourced processing

N/A – No outsourcing process

3.6 Specifications

Procedure for approval and review of raw material specifications: "Processo di valutazione fornitori materia prime rev 1 of 7.7.2023

Supplier's specifications are updated in the event of a change of supplier or raw material and at the latest every 3 years.

Copies of suppliers' specifications are held for all raw materials and packaging; they are kept in electronic or online
Specifications includes limits for relevant attributes (relevant chemical, microbiological, physical and allergens standards).

During the audit checked the following raw material specification:

- specific view of granulated sugar supplier Raded (broker), manufacturer Nordzucker (always specified on the big bag) dated 23.5.2022

- ascorbic acid from the supplier Giotti rev 3 of 28.9.2022

- Blue Pantent V 92 (colorant) from the supplier Giotti rev 4 dated 21.22.2022

- neutral ethyl alcohol from molasses from the supplier Silcompa rev 2 of 18.7.2023

- "Midori" aroma lot L22060-864 (Italian Aromi supplier) dated 2.3.2023 (also seen related allergen declaration dated 2.3.2023

- Tartrazine E 102 dye supplier "S.I.P.O srl lot 1020K specific view dated January 2021, E133 Brilliant Blue dye S.I.P.O srl lot 13302FR, technical data sheet view dated January 2021 (still valid)

Intermediate in-house specification products (work in process) are not developed based on risk assessment (no impact on food safety, authenticity and legality and quality).

Specifications for packaging materials

- Glass bottles: specific view of the "Anfora" type bottle supplier Verallia, dated 12.12.2022 and related declaration of conformity dated 5.5.2023; Verallia FSSC 22000, approved Packaging materials information questionnaire rev 0 dl 4.6.2021 completed and signed by the supplier on 7.2.2023

- Glass bottle of the Bagnoli Omnia 700 ml bottle from the supplier Covim dated 5.11.2021 and related declaration of conformity dated 27.2.2023

- Alplast cap specific sheet code 38.05 in aluminum liner Epe sent 3.11.2021, seen related decalration of conformity dated 3.11.2021

- cap for glass bottle Starlight line 29x15/19.5 supplier Tapi dated 16.6.2021 and related declaration of conformity dated 16.6.2020; Tapì is not GFSI certified, seen questionnaire "Information questionnaire for packaging materials rev 0 dl 4.6.2021 completed and signed by the supplier on 8.6.2021

- 5 liter “BP5” HDPE supplier Blowpack specification rev 3 of 2019 sent dated 26.4.2023, seen declaration of conformity dated 24.01.2024 based on migration tests report n 16/00170992 by Chelab srl, seen questionnaire sent on 10.10.2022

Manufacturing instructions/specifications are available at workstations and confirm compliance with finished goods specifications (updated in the event of a change of supplier or raw material and at the latest every 3 years).

DURING THE AUDIT ARE CHECKED THE FOLLOWING FINISHED PRODUCT SPECIFICATIONS:

Spirits (vodka, grappa, rum), liqueurs with or without herbal infusions and other alcoholic beverages

- Iceberg Vodka & Strawberry 21st in glass bottle 0.70 rev. 4 of 20.11.2023, (ingredients: water, sugar, strawberry juice, lemon juice, flavoring and coloring E124

- Cocktail drink “L'Apè aperitif liqueur 11° li 1 in glass bottle rev 4 of 28/7/2023 (sugar, alcohol 11°, infusions of vegetal substances, flavorings (including quinine, colorants E110 and E124, contains allergens (SO2 which does not contain gluten - there is no claim on the label but only in specification)

- “L'Ape spritz time 15th aperitif liqueur, the only product also under the customer's brand, glass bottle 1 liter rev 03 of 13.2.2023 (reports microbiological characteristics, TBC, mold and bacteria), allergens; customer accepts company specifications (there are no customer specifications)

- LIQUEUR Saruri Green Melon rev 4 of 20 November 2023

Flavored sugar-based syrups

- Syrup “The desire for Peppermint 1 liter, HDPE plastic bottle, dated 20.11.2023 (sugar, water, alcohol, mint essential oil, mint flavour, mint green colour)

- “The desire for Strawberry” 1 liter, HDPE plastic bottle, dated 20.11.2023 (sugar, water, citric acid, strawberry flavour)

Products based on fruit juices and purees:

- “La Frutteria Maracuja 1 liter, HDPE plastic bottle, dated 20.11.2023 (granulated sugar, passion fruit, apple puree, orange preparation, water, citric acid, thickener pectin, preservative: benzoate acid – sodium metabisulphite; coloring E 110

- “La Frutteria Cocco” 1.33 kg / 1 liter, HDPE plastic bottle, dated 20.11.2023 (refined sugar, coconut milk spray, potassium sorbate, citric acid (if any), preservative: benzoate acid.

- EVO oil 0.50 cl company brand “Novio” dated 20.11.2023

No PL/retail brands) has agreed upon with the customers: at the moment there are no longer any product customer branded; the last one was carried out in 2023 (currently contract not renewed)Finished product specifications are generated by the company and are supplied to customers on the company’s format or customer format.

The specifications are agreed with the customers through specific contracts (commercial agreements) which report the products covered by the contract

In reference to the customer's branded product (only an alcoholic product, last production of 2023) having regard to the contract with the customer H... B.. srl dated 6.5.2014 for the product l'Apè brand “Venezia” 15°, 1 liters (which establishes that for product specifications are accepted those of Bagnoli Group srl; the contract with H... B.. srl also includes two other Bagnoli brand products "Butterfly special dry gin 38° and an infusion-based liqueur l'Apè

The following specifications were reviewed: alcohol level from internal laboratory analysis ; the specification reviewed are found to be compliant to requirement agreed with customers.

3.7 Corrective and preventive actions

Corrective action procedure is in place PROBAG 07 rev 0 of 27.5.2023 (corrective action and complaints)

Non conformities that result in a risk to product safety, legality or quality are investigated and recorded in line with clause requirements. This includes the assessment of the consequences of the non conformity by quality manager according to the manager department, verification of corrective action by quality office (QC and quality manager), root cause analysis and the implementation of further corrective action to address the root cause, where this is necessary.

In the last year (last 12 months detected 15 NCs, of which 1 complaint)
14 NC with related corrective action
During the audit reviewed following corrective action:
- NC 2 of 7.8.2023 due to the lack of compartmentalization of the processing and packaging area; seen corrective action (carried out separations with the installation of two automatic doors); closed with follow up
- of 4.11.2023 lack of planimetry of finished product flows; floor plan implemented; verified during the audit program with follow up

Corrective actions taken are recorded and discussed during the monthly meeting held.
The corrective action management process appears suitable and effective.

3.8 Control of non-conforming product

In place procedure PROBAG 07 rev 0 of 27.5.2023
Non-conforming products are identified by specify non-conforming product area, and held in non-conforming product area. The Technical department is informed and are responsible for the holding and release of products.

According to procedure, all incidents of non-conforming product are recorded.

The procedure not document management of product returns which are managed as non-compliant products

During the audit observed example of challenge undertaken of product identified as non-compliant (old products that had problems (e.g. rum due to a defect identified post-production)) and managed appropriately.

The procedure also provides for the management of product returns.

Records are in place to demonstrate the investigation, analysis and cause of any non-conforming product. Defined responsibility and actions/timescales are documented.

There have been no major trends identified in the past 12 months.

NC minor: La procedura di gestione delle NC non riporta in maniera dettagliata la gestione dei prodotti non conformi e dei resi. Non-conforming products and returns are not covered under procedure of NCs.

3.9 Traceability

A recording system is in place with all raw materials, in process materials, packaging and finished product coded to allow for full traceability through the system and capable of meet to legal requirements in the country of sale or intended use
In place a procedure of traceability section 7.18 of Quality manual rev. 00 of 1.2.2023.
The traceability system is it is partly paper and partly computerized (ARC) and operates on a batch system with a unique batch code assigned. The batch code is recorded on finished goods labelling.

The company carry out an annual traceability challenge including mass balance and this was undertaken on 18.10.2023 on product Eau D'Orange lot L26523 (from finished product to raw material).

Vertical audit: a traceability challenge and mass balance was undertaken during the audit on "alcoholic drink named "Iceberg Vodka e Pesca" 21 °, company brand, shipped on 30.11.2023 with delivery note n° 3532 of 30.11.2023, quantity: 5x6=30 bottles, lot 29223
Seen related documentation:
- date of production 17.10.2023 and packed on 19.10.2023
- seen list of customer and related quantities;
- seen production sheet of 17.10.2023 n° 267/23, 5000 lt, with related control: alcoholic level, filtration verification, verification of colour (brightness)
- bottling date : 19.10.2023 (4241 lt) lot L29223 and 20.10.2023 (750lt) lot L29323
- seen labelling control of 19.10.2023
- seen receipt and related lot of raw material used: e.g caster sugar lot L070……1 (supplier Rader Spa), Alcool lot 2425-23 (supplier Silcompa Spa), clear apple and peach juices (lot 2023-10016- lot 2023-100 115), lot of bottles L 646…169, cap lot 29856 and fiter lot 321701
- seen control on arrival of raw material documented on "Modulo controllo merci in ingresso" MODBAG 7.4-7 of 27.5.2023 (seen control of 21-7-2023 related glass bottle supplier Verallia Italia)

- seen control on arrival of raw material documented on "Modulo controllo merci in ingresso" MODBAG 7.4-7 of 27.5.2023 (seen control of 2.10.2023 related alcohol supplier Silcompa Spa: rinsing cleaning of tank, presence of seals (6), alcoholic level

The exercise was completed in 2 hours, with positive result and and positive mass balance.

Rework is limited to residual of preview production and recorded by Quality and HACCP Manger and traceability is maintained by excel file (DOC BAG 20), seen record during the audit on site of 1.2.2024.

NC minor : Prova di rintracciabilità da materia prima a prodotto finito non è stata documentata (il software gestionale è comunque in grado di offrire il bilancio di massa delle materie prime in poco tempo).
Traceability test from raw material to finished product has not been documented (the management software is however able to offer the mass balance of raw materials in a short time)

3.10 Complaint-handling

A system of complaint handling is implemented via complaint procedure PROBAG 07 rev 0 of 27.5.2023.
All complaints are logged and investigated by the quality manager with full details kept of all actions taken.

Complaints are trended by department/product/type and discussed monthly.
Analysis of complaints viewed for the past 12 months indicate that the level of complaints is running below the target objective.

Indicator of complaints raised by consumers, retailers and authorities separately. Only retailer complaints raised in the last year.

Complaint target is set at max 5, with the current level at 1.
Main reasons for complaints from consumers/retailers are: lack of a bottle in the carton box
No complaints from foreign materials/bodies.

During the audit reviewed following complaints:

- only one complaint (dated 11.20.2023) from the customer "C..G.." for lack of a product inside the carton

3.11 Management of incidents, product withdrawal and product recall

In place a procedure of incidents and recalls: in place operative instruction ISTBAG 8.9-8 rev 0 of 27.5.2023 (includes “Nota Ministeriale of 2016”)

Procedure is adequate for the type of business and in sufficient detail.
There have been no recalls, incidents or withdrawals since the previous audit.

The company has comprehensive procedures and an out of hours contact list for all key members of staff, customers and organisations (NC at the moment not included communication to Certification Body). The requirement to notify the Certification Body within three days of the decision to issue a recall is included.

An annual challenge is undertaken by the company with the customer involved in the mock recall. The last challenge was undertaken on 10.20.2023 (APE’ 11 ° lot L28523) complete and effective test (concluded within 4 hours)

Nc minor : Non aggiornata procedura di gestione delle incidenti/recall per comunicazioni all’organismo di certificazione. Not updated incident/recall management procedure for communications to the certification

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.4	No Outsourcing

4. Site standards

4.1 External standards

The site occupies approximately 2000 metres square and production and storage buildings occupy 600 metres square

The approximate age of the buildings: born on 1977

Location of the site is rural area

There are no particular problems related to the location of the production site that may have an impact on the integrity of the products: no impact on product safety and quality due to the factory environment The outdoor areas are kept in good order and clean condition. The maintenance status of the building is adequate.

There are no rivers and train lines

External grounds is in good condition (traffic routes and planted areas have no impact).

Types of site security used: CCTV, internal alarm system (intrusion) at night and on weekends, use of security gates.

In place procedure relating access control for employees, contractors and visitors to ensure that unauthorised access is not permitted.

In place external storage and control measures to prevent contamination are in place. In place security systems for external storage, including external tanks or intake pipes (3 silos of alcohol)

4.2 Site security and food defence

Team of food defense (relating threat assessments and food defence plans development) is adequately competent.

There is no legal requirement for the site to be registered. There is no legal requirement for training (e.g. training in food defense awareness) but individuals assigned to work at actionable process steps they have received training. Food defense plan is suitable and effective. No improvements since the last audit

The site is enclosed with secure fencing with 24hr CCTV and a manned gatehouse. Entry doors to production are fitted with key code/fob systems.

A documented security assessment has been carried out.
Procedure of food defense plan dated: PROBAG 08 rev 0 of 4.9.2023
In place assessment of food defense Piano Food defensee" MOD BAG 01 rev 01 of 27.5.2023

A food defense review was carried out with annually frequency and the necessary controls are implemented with reporting to site for all visitors and contractors, last review: 27.5.2023

Test of food defense is carried out every year; date of the last test:

Training and signs are in place to remind staff to identify and report any unauthorised personnel and signs of tampering was carried out on: Training on signs of tampering was carried out on: 4.9.2023

Threats considered: unwanted access, control of areas with unsealed liquid products, mixing areas, secondary ingredients area; control measures in place: training to block any unauthorized person, peer monitoring.

4.3 Layout, product flow and segregation

The layout and flows are planned and suitable to minimize food safety risk.

The company has implemented effective measures to minimize cross-contamination from raw materials, semi-finished and finished products at the different process step.

The site is classified as low risk and these areas are defined on the site plan updated on 4.11.2023
Contractors and visitors, including drivers are informed of the requirements for the areas they are visiting by sharing internal procedures at the time of registration for access to the site.

The plan shows delineation, segregation, access routes for personnel, staff facilities, production process flow and waste removal.

There were no temporary structures noted.

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

Internal fabrication is well maintained with wall/ceiling cladding to all production areas, doors in good condition, sufficient and suitable windows and lighting. Floors are coated non slip concrete and drains are located throughout with traps to collect product debris. No water pooling was noted.
A drains plan is in place for all area where flushing water is used or drainage is required
There are no suspended ceilings or roof voids.
External windows are screened against insects.

Internal windows are plastic and all lights are covered and protected.

There are extraction systems in place and no evidence of excessive dust and/or condensation was noted.

External doors are either key pad secured, alarmed (fire exits) or kept closed/screened except when in use for material movements.

The standard of construction and condition of the property is good.
There are no elevated walkways, access steps or mezzanines adjacent to or above the open product

Plastic strip curtains were found to be suitable and in good condition.

4.5 Utilities – water, ice, air and other gases

Water is the only utility used on site and is potable from main municipal supply as ingredients and cleaning
An analysis plan is in place " Sampling Plan", and provides for analysis for water once a year for microbiological and chemical (routine); examples of analysis seen:
There is a water analysis plan in place "Water sampling plan" re v00 dated 19.1.2023, which provides for an analysis every 2 years, the last one carried out on 6.10.2022.
- View of analysis on post osmosis microbiological parameters carried out at Eptanord (0282L) report 22LA0121663 dated 10.19.2022 for the research Microorganisms 22 °C, Coliform bacteria, E. Coli, Enterococci, Clostridium perfrigens.

- View of analysis on chemical parameters after osmosis treatment carried out at Eptanord (0282L) report 22LA0121664 of 10.19.2022 for the search for pH, sensory parameters, chlorides, ammonium ion, hardness, nitrate and nitrite, iron, aluminium,

There is a plan of the water distribution system dated January 2023 which identifies sampling points.
Ice and steam is not used

The hazard analysis for the use of compressed air and gases has been completed: on December 2023
Do not use compressed air or gas in contact with product or primary packaging. Compressed air is used for machinery operation only
Other gases are not used.

4.6 Equipment

Equipment on site consists of industry standard beverage industry (eg mixers, tanks, filtering machine bottling line) Equipment are suitable and designed for the food industry

All machinery is well maintained and constructed of food grade stainless steel (SS316) and equipment can be stripped down for manual cleaning.

A new equipment risk assessment and validation system is in place with engineering, technical and hygiene assessment prior to purchase.

The machines have a good hygienic design in order to avoid possible contamination of the product
Equipment in direct contact with food is provided with an appropriate declaration of conformity, sample checked during the audit:
- connecting plastic pipes "Metalflex pipe from the manufacturer FITT with declaration of conformity reg 10/2011 of June 2018
- filtration materials (cardboard filters) manufacturer Industrial Filtro srl code A25 with declaration of conformity reg 1935/2004 dated 1.4.2023

A new equipment risk assessment and validation system is in place (documented on properly procedure) with engineering, technical and hygiene assessment prior to purchase.

Equipment not in use is suitable and segregated in special rooms
Mobile equipment and battery recharging equipment are in special dedicated areas in order to prevent potential risks for the product.

NC minor : Non documentata procedura per garantire in base alla valutazione del rischio la sicurezza ed integrità degli alimenti durante l'installazione di nuova attrezzatura presso il sito. Risk-based commissioning procedure are not in place to ensure that food safety and integrity is maintained during the installation of new equipment to site

4.7 Maintenance

In place procedure of maintenance In place REGBAG 14 maintenance plan is inserted inside each piece of equipment, for example M7.16.x example M7.16.1 "Maintenance and intervention program for the "AVE" bottling machine rev 00 of 28.7.2022 (contains weekly and monthly maintenance instructions) seen last maintenance dated 10.13.2023 (lubrication and greasing).

The engineering workshop is located well placed to avoid cross contamination.

In place a maintenance plan for all equipment (this covers all plant, processing equipment and mobile equipment). Defined frequency of main checks, carried out both internal or external contractors.

The on-site engineering team are responsible for day to day servicing and maintenance of equipment and plant.
Preventive maintenance or condition-based monitoring programmes are reviewed only after major breakups. There have been no major breakups in the recent past. The schedule for maintenance is based on risk, historical information and manufacturers' recommendations.

A purchasing brief available for new equipment includes a section for completion by maintenance.

There are individual maintenance logs for each piece of equipment which record all repairs and scheduled maintenance. There is a daily hygiene/integrity check of all equipment, including conveyor belt condition 8 even if there is no contact with the food).

Maintenance checks are completed following intrusive maintenance which includes sign off by engineering and production.

Contractors are supervised on site and have separate signing in procedures which include references to prevention of foreign body contamination.

All chemicals/lubricant used are suitable for food contact where applicable.

No temporary repairs were noted. Temporary repairs are subject to recording on maintenance request logs.

Monthly hygiene/fabrication and GMP inspections are carried out, based on risk assessment relating inspections for factory environment and processing equipment
Reports reviewed: of 7.8.2023 documented on "Verifica dello stato delgi ambienti di lavoro e dellell infrastrutture" MODBAG rev 8.2-10 of 27.5.2023 related hygiene/fabrication/GMP inspection reports).
3 NCs are detected and are managed as per the procedure (which provides for correction, management of corrective actions and verification - follow up).

4.8 Staff facilities

There two one main changing/locker room (one for man and one for woman), linearly located for personnel flow and access to production areas.
There are no high risk/high care facilities (no sensitive area).
The correct method of hand washing is clearly visible in all hand washing sinks and toilet areas; Hand washing is done every time people enter to production area, in the production area and in the toilet.
Washing basins are intended exclusively for hand washing. Hand washing facilities are provited with appropriate equipment for hand drying, liquid and disinfectant.

The production area is accessed with hands free hand washing facilities and suitable toilet facilities are provided, both of which meet clause requirements.
Staff facilities are sufficient and maintained in good and clean condition.
Outer wear/personal items and workwear are stored in in a special section at the top of the lockers and locked.

No catering canteen facilities.

Staff facilities of the premises are adapted to the type of production. In particular, the changing rooms are clean and proportionate to the number of staff (carefully inspected during the audit); appropriate break rooms canteens available, view the instructions in the refreshment areas on how to consume meals and snacks to prevent potential microbiological and allergen contamination hazards
Clean toilets and not directly related to the processing areas

An external smoking shelter is provided and staff must remove their protective clothing prior to using. Entrance back into production is via the changing and handwashing facilities.

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

4.9.1 Chemical control

Chemicals are risk assessed and managed.
Cleaning products are stored in dedicate, separate and locked room. Legal storage are in line with local legal requirements. Cleaning chemicals are identified and clearly labelled. In place properly procedure of chemical spillage controls, and chemical waste disposal procedure.

Examples of what chemicals are used and related Safety Data Sheet checked:
- Sanitec Igienc Orchidea (cleaning of floor) SDS of 11.3.2021
- Suma Inox Classic D7 seen specification and SDS of 25.1.2018

Strongly scented/taint-forming materials are not used.

4.9.2 Metal control

There is a sharps policy in place with a registration system for equipment. Only cutter available to cut pallets of bottles and caps and minor ingredients.
Monthly check during the inspection of cutter.
Staples, pins etc are not used in open product areas or packaging.

4.9.3 Glass, brittle plastic, ceramics and similar materials

An appropriate glass breakage procedure is in place: IST BAG “Istruzione in caso di rottura vetro rev 0 del 27.5.2023.

In place map (dated 4.11.2023) of identification of item.

Monthly glass and brittle plastic audits are carried out by the QC documented on MODBAG 10 rev 00 of 27.5.2023 (seen check of 4.9.2023)

Breakage incidents have been recorded for the last 3 months (only on bottling phase).

The window panes are protected (anti-fragmentation system also suitable for safety in the workplace)

4.9.4 Products packed into glass or other brittle containers

The products are packed in glass container: IST BAG “Istruzione in caso di rottura vetro rev 0 del 27.5.2023 (during the bottling phase (removal of glass with special identified and coded equipment, specific container, clean the line).

Glass breakages are dealt with procedure of management in the event of breakage on line
Records reviewed: breakages are recorded in each packaging on excel file REG BAG 20 (1 breakage was seen on 1.2.2024 during the audit, recorded, correctly recorded with post-breakage conditions restored). there is a statistical trend reported on an Excel sheet (currently set at 0.05%).

Storage of glass container is separated and isolated from other storage, in pallets with plastic film

4.9.5 Wood

Wood is restricted to finished product pallets.
Wood is not used for food contact purposes.

4.9.6 Other physical contaminants

Debagging is not in place; no physical contaminants relating of packaging
All portable handheld equipment used in open product areas (notoriously only pens) are blue colored and detectable.
There are no potential foreign-body or physical contamination from other types of contamination different of then section 4.9

4.10 Foreign-body detection and removal equipment

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

Following a documented assessment and documented on the HACCP study, the following types of foreign object detection/removal equipment are used: filter in cellulose and PA resin always after mixing (at least one filtering).

Following HACCP study, it has been concluded that Metal detection equipment is not necessary.

In place controls in place to minimise contamination from rigid containers (rinsing of glass bottles of alcoholic products and syrups in glass; visual checks and inversion relating semi-finished fruit-based products packed in plastic containers and EVO Oil in glass bottles).

the sensitivity of the control measures are appropriate; no recent foreign bodies detection

4.10.2 Filters and sieves

Based on risk analysis the company determined filter aperture size and the controls in place
Filters are used and are checked/inspected for integrity, checked each production

Filtration after mixing (one or two filtration passes) 5 types of filter Cardboard between 3,5 mm to 920 micron; monitoring carried out every assembly and mixing and recorded on working sheet (seen monitoring of 18.12.2023 relating product Bitter 25 ° Lot 318/23).

4.10.3 Metal detectors and X-ray equipment

No metal detector are in place; based on risk assessment justification is documented to establish that the equipment is not required. A risk assessment for metal contamination dated December 2023 has been carried out and it has been concluded that metal detection would not improve the protection of final products from metal contamination because in place filtering phase. This justification is documented in MHACCP, dated December 2023. Metal detection is not required by customers.

4.10.4 Magnets
N/A No magnets is required.
4.10.5 Optical sorting equipment
N/A No Optical sorting is required.
4.10.6 Container cleanliness – glass jars, cans and other rigid containers
In place controls in place to minimise contamination from rigid containers (rinsing of glass bottles of alcoholic products and syrups in glass; visual checks and inversion relating semi-finished fruit-based products packed in plastic containers and EVO Oil in glass bottles). Rinsing (verification at start of bottling), limit bar < 2, monitoring at start of botttling and recorded REG BAG 20 (seen record of 1.2.2024 durint the packaging of alcoholic drink "APE" lot 032/24
4.10.7 Other foreign-body detection and removal equipment
N/A No other foreign-body detection and removal equipment are implemented
4.11 Housekeeping and hygiene
IN place procedure of cleaning “PRO BAG 14 rev 00 of 7.10.2022” The site and equipment were seen to be maintained in a clean and hygienic condition. Full and detailed cleaning procedures are in place for all areas and equipment. Cleaning is carried out every day at the end of shift with full machine strip down and surface washing by operatives (in-house). There are no CIP systems in place. Tank of storage cleaning recycling pump using "Voldar" product The bottling system is washed only with osmotic water at each product change. Record of cleaning recorded on MODBAG 7.10-8 (seen cleaning of 22.1.2024) For effective cleaning, carry out quick swabs "ALI TEST P Rapido" Start up hygiene checks are documented for all key processes and equipment. Full validation records are available to show that cleaning regimes are effective. Cleaning procedures and frequency have been validated with historical evaluation of the results of the swabs Limits of acceptable and unacceptable cleaning are defined by quality manager. During the audit, the level of cleanliness and hygiene of premises and equipment appeared to be good. Operational cleaning activities were observed during the audit (as required by the procedure). Cleaning methods appear adequate.

NC minor: Controlli (esempio di start up) per verifica stato della pulizia non documentati. Check (e.g. start-up checks) to verify cleaning status not documented

4.11.7 Cleaning in place (CIP)

N/A There are no CIP systems in place.

4.11.8 Environmental monitoring

Despite the nature of the products and the analysis of the risks on the internal environment that cannot have negative effects on the safety of the products (the product does not support the development of pathogens or spoilage organisms, the areas are easy to clean, there are no literature specific problems in this sector, there were no areas or equipment previously tested positive), In place environmental monitoring programme for the production and packaging areas.
Last process and work environment validation conducted on 9.1.2024

Frequency of testing is risk-based and includes the organisms hygiene indicators using rapid tests with monthly frequency.

In place procedures for out of specification results (i.e. failure to meet a control limit or an upward trend towards a control or action limit) within its environmental monitoring programme.

The environmental monitoring appears suitable; annually review of the programme.

4.12 Waste and waste disposal

In place procedure “Gestione smaltimento rifiuti” rev 0 of 27.5.2023
All waste is cleared regularly from the processing areas and stored in suitable and identified containers.

Waste is collected from site by licensed contractors: e. g glass (municipal company S.E.S.A); paper and elastic by company Futura Recuperi.

There are collections for recycled waste, cardboard and plastics and for general waste.

Unsafe products/trademarked waste would be disposed of by specialist contractor and a disposal/condemnation note and evidence obtained.

The waste from the areas with open product is removed at the end of processing by means of a flow defined on a specific plan (the containers are suitable for the waste, identified and closed in the areas with exposed product).

No by-products/wastes are supplied as animal feed

4.13 Management of surplus food and products for animal feed

No surplus customer branded products in the last years. In case they should occur, authorization by customer is required.

No staff shop/charity arrangements etc.

No by-products/wastes are supplied as animal feed.

4.14 Pest management

Pest control is not undertaken in-house but is covered by external company; contract with RIPA Disinfestazioni dated 12.12.20211 consists of 8 routine visits (for rodents, crawling and flying insects) and inspections. Full records of pest control are maintained including site plan (dated 18.1.2012), data sheets, operative training records, records of inspections and treatments.
The frequency of routine inspection and expert survey is determined by an assessment carried out by the external company at the start of the activity (by reconnaissance of experts, evaluation of the external areas of the site, presence of possible sources of pest control); this assessment is confirmed every year; the pest control plan appears suitable and actions are completed.

The last visit to site was carried out on 16.1.2024, no issues identified.

All baits are secured. All recommendations are completed by the company in a timely manner.

External staff is trained and competent.
Annual trend of pest control trend: last seen of 30.12.2023

In-depth surveillance by expert field biologist carried not available

No evidence of infestation was found or has been identified during visits. No issues highlighted through trending reports.

NC minor:

Non disponibile valutazione approfondita del pest management. In-depth evaluation of pest management not available

Esche rodenticide esterne non adeguatamente fissate. External rodenticide baits not adequately fixed

4.15 Storage facilities

The steps and control measures of the receipt and storage of goods are following: order control, vehicle cleanliness control, vehicle integrity control and temperature control (only for chilled and / or frozen raw materials).
Refrigerated and storage is kept under control with temperature records. Temperature controlled storage areas are recorded ono REGBAG 29 (seen monitoring of 2.2.2024 with 3.5 °C)
FIFO systems are used throughout the site to ensure the products are used/despatched in correct order.
There are not electronic warehouse management system.
The raw materials are stored in a dedicated and separate area; packaging materials is stored in warehouse in good condition. Adequate flow and adequate storage plan do not allow cross contamination.

There is no controlled atmosphere or outside storage.

4.16 Dispatch and transport

Only approved third party company. In place contract with transport service provider (the most important transport service provider is Barone, 99% of transport)
Traceability is maintained during transportation (products and pallets are all identified with product name, lot, etc)
No temperature management required

Hygiene checks are in place: seen control at shipment carried out on 1.2.2024 and documented on "Vehicle preload control module" MODBAG 7.15-9, shipment of customer Vizzi Group srl 86 carton-box (1 pallet): integrity of packaging, hygiene of trailer, no pest.

NC minor 4.16.6: Non presente capitolato con la società di trasporto "Barone" . There are no specifications with the "Barone" transport company

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.10.3	Based on the risk analysis, there is no Metal detector
4.10.4	Based on the risk analysis, there are no magnets
4.10.5	Based on the risk analysis, there is no equipment for optical classification
4.13.2	Customer branded products not sold to staff or given to charities or other organizations
4.13.3	No by-products for animal feed
4.15.4	There is no controlled atmosphere storage

5. Product control

5.1 Product design/development

There are limited new product variations other than change of pack size.

Guidelines are in place which detail the following restriction(s) to the scope of any NPD: PRO BAG 7.3-4 rev 0 0 of 27.5.2023 (includes assessment fo allergens).

An procedure of new products is in place (including changes to exisiting product, packaging and manufacturing processes) with HACCP a key part of the development procedure; HACCP team will be involved and if applicable specific customer requirements will be taken into account..

HACCP team is involved: full development systems are in place based on a development checklist which needs to be followed prior to launch and includes a HACCP sign off.

Documented recipe development and production trials are undertaken.

A production test is carried out (small scale) and shelf life is determined and validated through lab analysis testing.
Seen following shelf life analysis:

- Tamarindo syrup lot 13523 analysis carried out at Eptanord (0282L) report 23LA0149709 dated 25.1.2024 for the research ph, Aw (0.768) SO2 (< 10), Gluten (not present) TBC 30 °C, yeasts and molds (also valid as initial shelf life test – step 1)

- Strawberry fruit lot 21323 analysis carried out at Eptard (0282L) report 23LA0149711 dated 25.1.2024 for the search for pH, Aw (0.778) SO2 (< 10), Gluten (not present) TBC 30 °C, yeasts and molds (also valid as initial shelf life test – step 1)

NC minor 5.1.4: Non adeguatamente definito un programma shelf life per le valutazioni sensoriali. A shelf life program for sensory evaluations is not adequately defined

5.2 Product labelling

In place procedure for artwork approval and sign-off including the procedure to verify ingredient and allergen information. Ingredient and allergen labelling information is verified by quality manager.

No claims are made.

No specific consumer claims are made.

All labelling information, including ingredient and allergen labelling reviewed during the audit was noted to meet legal requirements.
Following labels are checked during the audit, eg:
- APE' 11 % Vol 100 cl brand Bagnoli packed in glass bottle
- Sciroppo "Granatina" 1,33 kg 100 cl 66% brix packed in plastic container
- oil EVO 0.50 cl company brand "Novio".

No cooking instruction.

5.3 Management of allergens

In place procedure
There are no specific geographical legislative requirements for the raw materials, the country of production and/or the country of destination

The following allergens are handled on site: only sulphites.

Sulphites present (in caramel, concentrated lemon juice, potassium metabisulphite as an additive in certain recipes). the presence of sulphites is reported in alcoholic products. On other products (fruit base and syrups) sulphites are not listed on the label based on the risk assessment

An allergen policy, procedure and allergen matrix is in place. All raw materials, products and the process have been risk assessed. Supplier declarations are obtained for raw materials. Risk assessment carried out, dated: 9.1.2024
Last allergen verification dated: 9.1.2024

Separate areas are dedicated for allergen use with co
lour coded equipment and protective clothing.

All allergens are identified with labels and stored in a dedicated area of the warehouse.

Visitor questionnaires include questions relating to allergens.

Rework is limited to residual of preview production and recorded by Quality and HACCP Manger and traceability is maintained by excel file (DOC BAG 20), seen record during the audit on site of 1.2.2024.

Allergen warnings are not considered necessary because of the controls in place.

Allergen cleaning methods have been validated annually by accredited lab analysis and are routinely verified by cleaning plan (and verified with lab analysys).

No “free from” claims are made. No changeover during the audit.

NC minor 5.3.4: Non identificato chiaramente (es. coding colour) l’attrezzatura (paletta) per impiego di solfiti (metabisolfito di potassio)

5.4 Product authenticity, claims and chain of custody

The vulnerability assessment covers all mandatory requirements in section 5.4.
A risk assessment of raw materials has been carried out, with products assessed for allergen, foreign body, chemical, microbiological and substitution/fraud risks documented on REGBAG 11 updated 27.5.2023 (approved on management review of 9.1.2024); example for (patulin on apple juice medium risk).

The individuals and team completing vulnerability assessments have the appropriate knowledge; in particular, all the staff of the quality department and raw material acceptance are trained and above all informed about vulnerability.

Criteria used to evaluate the level of risk: History of product fraud incidents, Economic factors, Ease of fraudulent activity, Supply chain complexity
Raw material vulnerable to food fraud: EVO Oil (false Extra virgin olive oil)

Based on the risk assessment, a mitigation plan is implemented: only in case of purchase of EVO oil (if it happens; from the company's declaration probably no further bottling will take place) The food fraud team has validated risk assessment. Date of the last food fraud vulnerability assessment review: 9.1.2024.

No claim.

5.5 Product packaging

Based on the evaluation process during supplier qualification and systematically request by quality office relating specification and declaration of conformity, the control measures are able to guarantee the suitability of the packaging materials, in particular for suitability for food contact

Specifications for packaging materials (glass bottles and plastic containers (bottles and cans).

- Glass bottles: specific view of the “Anfora” type bottle supplier Verallia, dated 12.12.2022 and related declaration of conformity dated 5.5.2023; Verallia FSSC 22000, approved Packaging materials information questionnaire rev 0 dl 4.6.2021 completed and signed by the supplier on 7.2.2023

- Glass bottle of the Bagnoli Omnia 700 ml bottle from the supplier Covim dated 5.11.2021 and related declaration of conformity dated 27.2.2023

- Alplast cap specific sheet code 38.05 in aluminum liner Epe sent 3.11.2021, seen related decalration of conformity dated 3.11.2021

- cap for glass bottle Starlight line 29x15/19.5 supplier Tapi dated 16.6.2021 and related declaration of conformity dated 16.6.2020; Tapì is not GFSI certified, seen questionnaire "Information questionnaire for packaging materials rev 0 dl 4.6.2021 completed and signed by the supplier on 8.6.2021

- 5 liter “BP5” HDPE supplier Blowpack specification rev 3 of 2019 sent dated 26.4.2023, seen declaration of conformity dated 24.01.2024 based on migration tests report n 16/00170992 by Chelab srl, seen questionnaire sent on 10.10.2022.

5.6 Product inspection, on-site product testing and laboratory analysis

All analytical results are verified by the quality service and at least by the competent HACCP member for the type of analysis requested; to this end it can be considered that the procedures in place are suitable for guaranteeing the reliability of the laboratory results

In place internal lab only to analyse alcohol strength. In place control procedures to prevent product contamination

Analysis plan in place "Analysis plan for finished products rev 27.5.2023"
5 finished product analyzes have been budgeted for the last year considering the risk analysis (matrix, quantity, validation of organoleptic parameters).
Seen following test reports:
- Iceberg Vodka & Cinnamon 22% vol. lot 08723 analysis carried out at Eptanord (0282L) report 23LA0149705 dated 31.1.2024 for the search for acolometric strength (22.8% - max tolerance 0.3), SO2 (< 10 ppm), brix (33.30), gluten
- APE' 11% vol. lot 10923 analysis carried out at Eptanord (0282L) report 23LA0053596 dated 9.5.2023 for the search for gluten and SO2 (absent)
- Tamarindo syrup lot 13523 analysis carried out at Eptanord (0282L) report 23LA0149709 dated 25.1.2024 for the research ph, Aw (0.768) SO2 (< 10), Gluten (not present) TBC 30 °C, yeasts and molds (also valid as initial shelf life test)
- Strawberry fruit lot 21323 analysis carried out at Eptard (0282L) report 23LA0149711 dated 25.1.2024 for the search for pH, Aw (0.778) SO2 (< 10), Gluten (not present) TBC 30 °C, yeasts and molds (also valid as initial shelf life test)

There is a water analysis plan in place "Water sampling plan" re v00 dated 19.1.2023, which provides for an analysis every 2 years, the last one carried out on 6.10.2022.
- View of analysis on post osmosis microbiological parameters carried out at Eptanord (0282L) report 22LA0121663 dated 10.19.2022 for the research Microorganisms 22 °C, Coliform bacteria, E. Coli, Enterococci, Clostridium perfrigens.
- View of analysis on chemical parameters after osmosis treatment carried out at Eptanord (0282L) report 22LA0121664 dated 10.19.2022 for the search for pH, sensory parameters, chlorides, ammonium ion, hardness, nitrate and nitrite, iron, aluminium,

For the raw material, the strength of the alcohol on ethyl alcohol is carried out on a sample basis (unstructured frequency).
- Seen report on Ethyl alcohol molasses 96.5 % volume lot 2425/23 report at Eptanord (0282L) n° 23LA0149719 dated 31.1.2024 for the search for alcohol content, SO2, optical residue, gluten, heavy metals.
For effective cleaning, carry out quick swabs "ALI TEST P Rapido"
Checking for fraud is expected in the case of the purchase of Evo oil

5.7 Product release

The release procedure reported in the Food quality manual is in place; provides that if there are no blocks or non-compliant products identified during the production process, the product is released and shipped to the customer.

5.8 Pet food and animal feed

N/A No pet food

5.9 Animal primary conversion

N/A No animal convertion

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
5.8	No pet food products
5.9	No animal primary conversion

6. Process control

6.1 Control of operations

Process settings are documented and monitored according to the following procedures: IST BAG 9 rev 00 of 4.10.2023 Istruzione operative controllo operative e preoperative.

There are procedures and instructions in place in the packaging areas to ensure that consistent product is produced and packaged

There are no products outside the scope of the audit, except for the marketed products which are received already packed and inside packages and on pallets in the finished products warehouse

6.2 Labelling and pack control

According to procedure of packaging control, during a product changeover all previous labels and films are removed and a start-up check is carried out. No changeover during the audit (the company carried out packaging only one type a day).
The control for the correctness of the label is carried out at the beginning of bottling, during and at the end of bottling; the evidence of the control is reported behind the production sheet where the label of the product being packaged is applied (seen control of 1.2.2024 during the

Labels are already printed (only lot and expiry date printed online). In place reconciliation of label for those already printed with legal information (by unloading the batch from the initial warehouse load, at each production).

At the moment no customer labels used

6.3 Quantity, weight, volume and number control

Alcoholic products (in bottles) all have the "e" on the packaging. The control for these products is carried out using a scale approved according to law with a control unit according to law 690; the statistical control is carried out directly by the scale which archives the data for a month inside the device and is downloaded every month to the computer for archive purposes. Other products packaged in 5 liter cans (without "e") are in any case controlled by the HACCP and Quality manager during the production phase with an approved scale dedicated to the weight control of manually packaged products. During the audit, the statistical control of APE lot L03224 was viewed with a nominal volume of 1000 ml and an average value of 1074.31 ml.

6.4 Calibration and control of measuring and monitoring devices

In place list of instruments and devise “Database Strumenti di misura REGBAG 7.17-18 rev 00 of 27.5.2023:

- scale (2 production, 1 of ingredients and 1 for weigh control
- Densimeter (Enopiave srl mod ALM 155 calculating alcohol strength) new of June 2022

Seen following record:

- seen calibraion (homologation according to law) and calibration of the scale for end-of-line statistical weight serial number 34931298 od 8.11.2023
- calibration of scale dated 21.10.2022, serial number B163 (mixing area) expiry date october 2025

- calibration of scale of w 21.10.2022 for weight control of plastic container of 5 liter (manual packaging).

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
6.2.4	There are no automatic label control systems

7. Personnel

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

Based on the results of the inspection program, the training is defined and reviewed. Competences are reviewed in case of legal changes or new internal needs.
The level of competence demonstrated through interviews with staff during the audit (e.g. for activities relating to control measures) appeared sufficient.

Seen training 31.5.2023 and 22.11.2023 relating operator of storage and production and packaging area (HACCP and rules of hygiene, preoperative control, O PRP (there are not CCPs), allergen control, (carried out by Enrico Bellini external consultant included on HACCP team), methods of communication of food-borne diseases, recognition of signs of infestation(carried out by Enrico Bellini external consultant included on HACCP team), recognition of signs of infestation
Seen training on food defense on 9.1.2024 all operators regarding: food defense, confidential reports, packaging control,

Seen training of 22.11.2023 training of new HACCP team leader (Simone Boaretto) carried out by Studio RSPP (Dr Acquasanta Antonio accredited to provide training for food workers (includes 3 of HACCP)

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

Personal hygiene standards, which meet clause requirements, are documented and covered during induction training and basic food hygiene training (carried out in house).

Site hygiene policy dated IST BAG 6.1-1 rev 1 of 11.12.2023 documents the site rules and policies.

In place procedures of hand cleaning including plaster control. The correct method of hand washing is clearly displayed; hand washing are available at the entrance to the production areas (including changing room and toilet).

The use and storage of personal medicines is controlled by QC during the inspection programme

There were no issues regarding compliance to the documented hygiene policies.

Based on risk analysis blue plaster metal detectable not preset.

7.3 Medical screening
Medical control for all people each year with correct information; before entering production areas, packaging and storage visitors confirm that they are not suffering from any symptoms which could put at risk the safety of products; defined documented procedures for employees and visitors with regard the actions to be taken in cases of infection Employees are made aware of the symptoms of infection, disease or conditions which would prevent them from working with open food via training (e.g seen training of 31.5.2023 and 22.11.2023) Procedure is in place to enable staff, including temporary staff, to notify the site of any relevant symptoms, infection, disease or condition which they may have been in contact with or be suffering from. A visitor health questionnaire is in place with a verification check by the company host. Return to work interviews are carried out following absence/illness and this is detailed in the company handbook/rules issued to all staff members.
7.4 Protective clothing: employees or visitors to production areas
Protective clothing (provided by company of all employees - including agency and temporary personnel - are: sweatshirt, trousers, security footwear and for visitor and other contractor there is a single use protective clothes. Documented procedures are in place for the wearing of protective clothing. Protective clothing is changed (frequency at least 2 times a week), based on risk. Gloves are not systematically foreseen; define the rules for possible use. The washing is entrusted to the operators against defined procedures (Norme igieniche personale IST BAG 6.1-1 rev 1 del 11.12.2023) and training (washing at least 60 °C with sanitizer for clothes) and it is confirmed that this protective clothing is worn only in a low risk area or in a closed product area and is worn to protect the employee from handled products.

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

8. Production risk zones – high risk, high care and ambient high care production risk zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
Not applicable
8.2 Building fabric in high-risk and high-care zones
Not applicable
8.3 Equipment and maintenance in high-risk and high-care zones
Not applicable
8.4 Staff facilities for high-risk and high-care zones
Not applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not applicable
8.7 Protective clothing in the high-risk high-care zones
Not applicable

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

9. Requirements for traded products
9.1 The food safety plan - HACCP
Not applicable
9.2 Approval and performance monitoring of manufacturers/packers of traded food products
Not applicable
9.3 Specifications
Not applicable
9.4 Product inspection and laboratory testing
Not applicable
9.5 Product legality
Not applicable
9.6 Traceability
Not applicable

Module 11: Meat Supply Chain Assurance	
Scope	Click or tap here to enter text.
11.1 Traceability	
Click or tap here to enter text.	
11.2 Approval of meat supply chain	
Click or tap here to enter text.	

11.3 Raw material receipt and inspection
Click or tap here to enter text.
11.4 Management of cross-contamination between species
Click or tap here to enter text.
11.5 Product testing
Click or tap here to enter text.
11.6 Training
Click or tap here to enter text.

Module 13: Meeting FSMA Requirements for Food – July 2022
Preventive Controls for Human Food: 21 CFR Part 117 (Clauses 13.1.1 – 13.1.33)
Click or tap here to enter text.
Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1)
Click or tap here to enter text.
Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11)
Click or tap here to enter text.
Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9)
Click or tap here to enter text.
Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18)
Click or tap here to enter text.

14.1 Additional Specifier Requirements
14.1 Traceability
Click or tap here to enter text.
14.2 Environmental Monitoring
Click or tap here to enter text.
14.3 Product inspection and laboratory testing
Click or tap here to enter text.
14.4 Protective clothing: Employees or visitors to production areas
Click or tap here to enter text.