

### Audit Report Global Standard Food Safety Issue 9

1. Audit Summary			
Company name	ARBI DARIO S.p.A.	Site code	3723797
Site name	ARBI DARIO S.p.A.		
Scope of audit	Production (mixing, eventually cooking, freezing) of raw frozen fishery products and ready to cook fishery preparations with vegetable, packaged in vacuum pack, skin pack or sealed polybag. Production (mixing, battering or breading, frying or cooking, freezing) of ready to cook pre-fried and oven cooked fishery products packaged in plastic bags, plastic trays and carton box; Production (thawing) of chilled fish preparation packaged in skin pack. Trading of Frozen fish, crustaceans and molluscs packaged in plastic bags, plastic trays and carton box		
Exclusions from scope	None		
Justification for exclusion	None		
Audit start date	2024-01-22	Audit finish date	2024-01-24
Re-audit due date	2025-03-23	Head office	No

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

2. Audit Results					
Audit result	Certificated	Audit grade	AA+	Audit programme	Unannounced - Voluntary
Previous audit grade	AA+		Previous audit date	2022-12-12	
Certificate issue date	2024-03-05		Certificate expiry date	2025-05-04	

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2. Audit Results		
Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	3

3. Company Details			
Site address	Via Dott. Salvatore Giovannoli, 131/135, 51015 Monsummano Terme (PT)		
Country	ITALY	Site telephone number	+390572957830
Commercial representative name	Maurizio ARBI	Email	maurizio@arbi.it
Technical representative name	Benedetta MARIOTTI	Email	qualita@arbi.it

4. Company Profile					
Plant size (metres square)	10-25K sq.m	No. of employees	1-50	No. of HACCP plans	1-3
Shift pattern	2 shifts, 6-2pm, 2-10pm				
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	IFS FOOD v7, ISO 9001, MSC, ASC Chain of Custody, SMETA				
Outsourced processes	No				

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4. Company Profile	
Outsourced process description	None
Regions exported to	Asia Europe North America South America Choose a region Choose a region
Company registration number	IT 2402 CE
Major changes since last BRCGS audit	Enlargement and renewal of depuration plants; new packaging and cartooning machines at the end of lines; renewal of line B with change of weight control and metal detector

Company Description
<p>The Company was set up in 1958 by DARIO ARBI, to produce frozen food and afterwards specialized in the production of frozen fish supplies for the retail market. Company turnover is about 53.000.000€. The facilities in MONSUMMANO TERME have been planned and built in 2002 and was enlarged in 2012. It covers a surface of 13000 sqm, work n. 50 FTE on 2 shifts for 6 day a week and has a production capacity of around 8.000 tons. On site was installed n. 6 production lines: n. 1 skin-packing line (50/60 pieces /minute), n. 1 IQF Polybag line (50/80 pieces/minute), n. 1 vacuum-packing line (50/60 pieces/minute) n. 1 Shrink-wrapping line (20/25 pieces/minute). The Internal Laboratory was made by qualified personnel who carry out microbiological, organoleptic analysis on raw materials and finished products. Raw materials are purchased from selected, qualified suppliers all over the world. Storage and transport is outsourced to external company EUROTRADE and other companies. Trade goods on are present. FDA number 12302631402. Finished products are 91% with own brand plus 9% of private label; 90% for Domestic Market. Neither withdrawal, nor recall to date in the last year. A mock recall test is regularly carried out by the Company. Emergency contact Mr. Arbi Alessandro, Phone +390572957830 Mail: arbi@arbi.it.</p>

5. Product Characteristics	
Product categories	03 - Raw prepared products (meat and vegetarian) 04 - Raw fish products & preparations Category Category Category Category Category Category
Finished product safety rationale	Products to be cooked before eating at about 70-80°C for Minimum 6 minutes; stored at <-18°C; chilled product after defrosting 4°C

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5. Product Characteristics					
High care	No	High risk	No	Ambient high care	No
Justification for area		According to BRCGS decision tree. All product requires full cooking before eating			
Allergens handled on site		Cereals containing gluten Crustaceans Molluscs Fish Milk 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			
Product claims made e.g. IP, organic		MSC products; without gluten			
Product recalls in last 12 months		No			
Products in production at the time of the audit		Shellfish sauce with scampi, prawns and lobster meat 300g FiorFiore Coop batch 220124 BB 07/25; "Mare e Orto" brand Arbi mix of molluscs, crustaceans and broth with vegetables 300g 230124 07/25; "Misto Scoglio" Arbi brand, mix of molluscs and crustaceans with fish broth 230124 07/25; "Condiscoglio" with tomato sauce brand Arbi 450g 240124 07/25			

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	Extra time for combined IFS audit		
Combined audits	IFS		
Next audit type selected	Unannounced - Voluntary		



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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
Benedetta Mariotti	QAM	X	X	X	X
Fiammetta Fedi	Incoming QC		X	X	
Caterina Giuntini	QC PROD.		X	X	
Andrea Gori	QC		X	X	
Alessandro Arbi	CEO and Production Manager	X	X	X	X
Maurizio Arbi	Sales		X	X	X
Gabriele Guerri	Purchase		X	X	
Tiziano Magrini	Supply Chain		X	X	
Fabrizio Pisaneschi	Maintenance		X		
Bernard Allko	Operator		X		
Sergio Vela	Operator		X		
Musayen Rustam	Operator		X		

GFSI Post Farm Gate Audit History			
Date	Scheme/Standard	Announced/Unannounced	Pass/Fail
2022-02-01	BRCGS	Unannounced	Pass
2022-12-12	BRCGS	Unannounced	Pass
2024-01-22	BRCGS	Unannounced	Pass

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Document control			
CB Report number	IT/TO.20130050		
Template name	F908 Food Safety Audit Report Template		
Standard issue	9	Template issue date	2022-12-16
Directory allocation	Food	Version	1.1

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**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

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Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
3.5.3.1	The audit carried out in the last 12 months at Eurotrade S.r.l. (warehouse of raw materials and finished products), is not formalised nor that at Volfrigo (raw materials storage warehouse).	The audits carried out have been formalised	We have included the checklist formalisation of audits in our internal inspection visits plan; training will be carried out	Quality Assurance failure	2024-02-15	Alfredo Stefani
3.6.1	The technical specification of the tray purchased from the supplier Cerreti S.r.l. of R-PET for food, is in rev. 4 of 03/03/2020.	The updated technical data sheet has been sent by the supplier	Scheduled the automatic expire date alerts (3 years) of the technical sheets in Ayama quality software	Quality Assurance failure	2024-02-15	Alfredo Stefani
4.11.1	In the kitchen area, a clean stainless steel tub is overturned and placed on the floor.	The overturned clean stainless steel tub has been placed on Plastic pallets	We will always use plastic pallets to support the clean stainless steel tub. Training to the production operator on the corrected methods.	The production operator made a mistake and did not follow the indicated rules	2024-02-15	Alfredo Stefani

**Comments on non-conformities**

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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

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Lead auditor		
Auditor number	First name	Second name
20407	Alfredo	Stefani

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
Alfredo	Stefani	20407	Lead Auditor	2024/01/22	09:00	18:30	Physical	
Alfredo	Stefani	20407	Lead Auditor	2024/01/23	09:00	18:30	Physical	
Alfredo	Stefani	20407	Lead Auditor	2024/01/24	09:00	15:30	Physical	

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## Detailed Audit Report

### 1. Senior management commitment

There is an integrated Company policy: Quality, environment and food safety issue 6, dated 18/01/2024 which is signed by the Company President Mr STEFANO ARBI is displayed both at the site entrance and other points of the factory, furthermore, presented at all levels during training. Main pillars are as following MISSION, VISION, VALUES.

The site has a copy of the latest standard available.

Specific objective date 25.01.2023 defined during yearly management review in which also food defence, authenticity and food and quality culture plan were examined. The next management review will be carried out the next days.

Objectives for the year 2023: clear targets are set on document enclosed to management review: increase in export sales new products, in Food Service products, increase in production line. Review includes effectiveness of HACCP Plan, Food Defence Plan, authenticity. 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. 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.

Authenticity, 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.

The objectives on Authenticity, Quality, legality and food safety are analysed during monthly meeting e.g. quality and management meeting 17.01.2024

The objectives are analysed at least quarterly, for e.g. quarterly meeting report of 17.01.2024 and 03.01.2024, e.g. complaints CPM 5,44 vs 4-6 CPM target, CLUSTER QUALITY raw material, CLUSTER FOREIGN BODIES 20% Plastic, NO RECALL WITHDRAWAL, Status on PATHOGEN analysis, turnover, OEE, NCs internal.

Approach FOOD SAFETY CULTURE namely in internal document CULTURA DELLA SICUREZZA ALIMENTARE initial data 10/06/2019, updated and confirmed annually during managed review on date 25.01.2023. Setup base on 5 pillars. VISION and MISSION, (Management review, periodical meeting, output KPI on awareness of company policy); PEOPLE (training, KPI result of monitoring, on site verification; COHERENCE (awareness NC review, behaviour) ADEQUALITY (meeting, monitoring food safety, crisis management); AWARENESS (food safety CCP, recall). MATRIX with definition destination, responsible (owner) target KPI %, YTD 2022 commented. Set up (2021) a new tool in order to collect qualitative and quantitative information as point for measure awareness level. In 2022 based on results new approach on training was implemented. Survey for all employees managed by HR completed in November 2023, results are under evaluation, report scheduled for Feb 2024.

Senior Management are available to discuss the plan during the audit.

Also employee feedback mechanism and whistleblowing system is in place There is a confidential reporting system to enable staff to report concerns relating to product safety, integrity, quality and legality: a red box is in place at the entrance of staff facility.

The company properly uses BRCGS logo.

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.



Source of information MERIEUX based on safety alert, RASSF, fraud alert, monthly basis communication to the company. EURO FISH MARKET, ASSOITTICA consortium catering

NC and corrective action plan from last audit implemented.

Family company where there are strategic, production and commercial synergies. ARBI DARIO SPA is a one site company, Representative of the family are part of management active in the company and holds the role of General Manager and Commercial Management.

Overview of Management Structure verified. Organization chart dated 22.07.2022, in place for all managers and supervisors and responsibilities. Appropriate documented arrangements are in place to cover for the absence of key staff. Operators are sensitized and aware of their own skills and responsibilities, all staff have access to relevant procedures. Presence Job description ad deputies for many functions. MANSIONARIO REQUISITI MINIMI 03/01/2022

Example FOOD SAFETY team - HACCP team Ms. Benedetta Mariotti team leader, DIR, PROD, MAN, IT; FOOD DEFENCE team with QA, SALES, LOG, MAN. QUALITY CONTROL structure consists of 5 members: Mr. Carlo Tofanelli; Mr. Massimiliano Perrone; Mr. Andrea Gori; Ms. Caterina Giuntini; Ms. Fedi Fiammetta.

Food safety risks, concerns or non-conforming product issues are reported by staff through direct communication to QAM and resolved within short time

Healthy Ministry authority AUT 1039 29/04/202, veterinary registration IT 2402, last document SUAP data 4 /11 /2015 COMPANY food safety responsible Mr. ALESSANDRO ARBI responsible for food. On average, the company receive 6 visit x year.

Last visit performed by local authority made in date 07.12.2023, overall result conforms, without deviation.

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

Clause/Section Ref	Justification
//	//

**2. The Food Safety Plan – HACCP**

HACCP Study and Manual PQ7 General last updates v.4 dated 18.01.2023.

Main document supporting HACCP study PQ 7.1.1 GENERAL MANUALE

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.

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.  
Source of information CODEX ALIMENTARIUS, CAMPDEN BRI

The multi-disciplinary team formed by members from the following departments: HACCP Team leader by ARBI MAURIZIO GM who has experienced with HACCP experience in the food sector for many years and supported by QM MARIOTTI BENEDETTA Biologist graduate. The multi-disciplinary team comprises members from the following DIR, PROD, MAN, IT. HACCP methodology training performed in date 22/03/2019 PCQI, SEAFOOD HACCP ALLIANCE data 6/12/2019; 26/05/2021 HACCP training course; participants Ms. Benedetta Mariotti

#### **HACCP FAMILY**

PQ 7.1.2 PRODOTTI AL NATURALE (natural products) v.2 of 18.01.2023, ALLERGENS: molluscs, crustaceans, fish sodium metabisulfite,

PQ 7.1.3 CONDIMENTI (sauces and condiments v.7 of 18.01.2023, ALLERGENS molluscs, crustaceans, fish, sodium metabisulfite,

PQ 7.1.4 PREFRITTI (battered and breaded, pre-fried) v.2 of 3.3.2022 ALLERGENS molluscs, crustaceans, fish sodium metabisulfite, gluten, trace Soya; Milk protein

PQ 7.1.5 PRECOTTI IN FORNO (precooked) v.2 of 6.4.22 ALLERGENS fish, gluten, trace Soya, molluscs, crustaceans

PQ 7.1.6 CHILLED v.3 of 7.4.22 ALLERGENS fish, molluscs, crustaceans, gluten, trace Soya, sulphites

A full description product is developed and documented in the HACCP Manual, which includes all relevant information on food safety. Main products category

**RAW FROZEN FISH** e.g Cleaned octopus, shrimps, Hake fillets, cuttlefish, shrimps, Mussel meat, squid, Mixed natural frozen fish (pH 6.68 and aw 0.87); Final storage temperature -18°C or 4°C

**READY MEALS TO BE COOKED.** Ready-made scampi and seafood sauce, Ready-made soup, Cod in the Island, Cod fish, tomato and basil, Cod fish, potatoes, and rosemary. Crustaceans, XXL Argentine prawns, Medium prawns, Argentine prawns. Mixed frozen fish with broth (pH 7.8 and aw 0.99); Final storage temperature -18°C or 4°C

**BATTERED/BREADED TO BE COOKED** with tuna, smoked salmon, Bocconcini di mare, Fillets of Anchovies, Mixed fried Italian, Mixed for appetizers and first courses, Sea and vegetable garden, Mixed rock, Mixed risotto and spaghetti, Pre-fried product (cooking 180°C ); 6- Precooked in oven (temperature (180°C); Final storage temperature -18°C or 4°C

**SEAFOOD READY-MADE SAUCES TO BE COOKED,** Mixed well-being, Lightness, clam, scampi, fish and tomato sauce, ready-made lobster sauce, anchovy sauce Puttanesca, shellfish sauce, natural fish. Final storage temperature -18°C or 4°C

**PREPARATION FISH BASED CHILLED from FROZEN.** Starting from Frozen storage temperature -18 ° C to finished product 4 ° C upon departure, Do not refreeze, Skin pack tray with clusters, Ingredients fish, crustaceans, molluscs, breading, predust flour, vegetable oil (sunflower seeds), FROZEN 18 months, TMC 13 days, not exceeding TMC Frozen, Do not refreeze,

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 " except for people who are allergic to the ingredients contained in the product.

As quoted in the back label "To be eaten only after cooking and to be conserved at temperature < - 18°C. TMC 18 months; 4°C, 13 days only for one product family



**MAIN PROCESS**

On site was installed n. 6 production lines: n. 1 skin-packing line (50/60 pieces /minute), n. 1 IQF Polybag line (50/80 pieces/minute), n. 1 vacuum-packing line (50/60 pieces/minute) n. 1 Shrink-wrapping line (20/25 pieces/minute), n. 1 carton box packaging line. steps: Freezing- defrosting; water treatment (chlorination; reverse osmosis filtration;), Packing MAP, Packing under vacuum; Processes to prevent product contamination; Frying in oil, Cooking in oven, Manipulation, packaging

**FLOW DIAGRAMS**

- PQ 7.1.2 PRODOTTI AL NATURALE (natural products), ALLERGENS: molluscs, crustaceans, fish sodium metabisulfite,
- PQ 7.1.3 CONDIMENTI (sauces and condiments), ALLERGENS molluscs, crustaceans, fish, sodium metabisulfite,
- PQ 7.1.4 PREFRITTI (battered and breaded, pre-fried), ALLERGENS molluscs, crustaceans, fish sodium metabisulfite, gluten, trace Soya, Mustard; Milk protein
- PQ 7.1.5 PRECOTTI IN FORNO (precooked), ALLERGENS fish, gluten, trace Soya mustard, molluscs, crustaceans
- PQ 7.1.6 CHILLED, ALLERGENS fish, molluscs, crustaceans, gluten, trace Soya Mustard, sulphites

For all FLOW DIAGRAMS on site verification 18.01.2024.

**HAZARD ANALYSIS**

The team have used a 4 steps decision tree. Last hazard analysis dated 25.10.2023. 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 have been identified as: Microbial hazards are Listeria, Salmonella, Staphylococci, Coliforms, Escherichia Coli, Vibrio C., yeast and moulds; Chemical like residues of veterinary drugs, histamine, bio-toxin, mycotoxin, heavy metals, radiological, preservatives; migration of primary packaging; foreign bodies specifically plastic, wood, glass and metal.

HACCP is generally developed and comprehensive with Codex principles applied in sequenced chapters.

CCPs identified are as follow with relative critical limits:

- CCP1: During storage of raw material and frozen finished products. Microbial risk. CA: Temperature control. Critical Limit: >-18 °C.
- CCP2: During freezing tunnel, microbial risk. CA: Temperature control. Critical Limit: >-18 °C.
- CCP3: Metal detector monitored at the start every hour, at the end by QC, records provided and signed. CA in case of loss of check: rejection of the batch. Critical limits 2,5 mm Fe; 2,5 mm ss, 3.0 mm no Fe

Critical limits had been agreed and signed off by team. All CCPs are validated considering legislation (where applicable), validation studies, industry best practice and commissioning studies. The company's HACCP plan is based on following updated and comprehensive information:

- scientific literature and known hazards associated with frozen products production
- complaints and customer requirements
- food-safety European legislation
- codes of practice of packing process (Manual of good practices).

Monitoring procedure defined as follows:

CCP1: Temperature monitored in continuous, alarm on site and sms message in case of loss of control, plus QC check correct functioning every 30 minutes, records provided and signed. CA in case of loss of check: rejection of the batch. Seen records on checked records 23.01.2024; signed by Quality Control



operator.

CCP2: Temperature monitored in continuous, alarm on site and sms message in case of loss of control, plus QC check correct functioning every 60 minutes, records provided and signed. CA in case of loss of check: rejection of the batch. Seen records on 23.01.2024; signed by Quality Control operator.

CCP3: Metal detector monitored at start and end of production and every hour by QC, records provided and signed. CA in case of loss of check: rejection of the batch. Seen records on checked records 23.01.2023 signed by Quality Control operator.

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. Seen process records 23.01.2024 signed by Quality Control operator.

Presence control measure

PRPO: cooking temperature according to recipe; PRPO: chilling according to recipe; PRPO: The temperature in the loading Critical limit (T< -18 °C); PRPO: XRAY detector 2mm Stone. X-ray: 2,5mm Fe, 3mm NFe, 2,5mm, SS, 2mm Glass monitoring hourly; PRPO: Polarity <25%; PRPO: Oven cooked 160°C - 200°C monitoring hourly; PRPO: verifies labelling and legibility, hourly; PRPO: defrosting temperature (<0 °C) via radio frequency measurement on the product for every batch, cycle

Procedures of verification are established to confirm that the HACCP plan, including CCPs are effective. HACCP plan is reviewed every year during Management Review and/or in case of a production change in ingredients or technology.

Last HACCP review dated 18.01.2024

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

Clause/Section Ref	Justification
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**3. Food safety and quality management system**

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

Different document level: QUALITY MANUAL v.1 date 16/07/2020; procedure PQ7.5 "Informazioni Documentate" rev 5 of 15.01.2021; LIST OF DOCUMENTS /INSTRUCTION in on going validity.

The company has implemented a Quality Management System documented in the Quality Management System with department specific work instruction manuals available on the company intranet. 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.

Collection, review, maintenance, storage, and retrieval of all records relating to product safety, legality and

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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.

Documentation and Registrations Management: "PQ7.5 "Informazioni Documentate" rev 5 of 15.01.2021. Records retained for a time consistent with the shelf life of products as indicated on technical sheets: Maximum Shelf-life Products: 2 years. The retention period for records is defined: 42 months. IT department has the responsibility to maintain security on achieve and cyber. Electronic records are automatically backed up every month to an external server to prevent loss and are held securely with a password protection

### 3.4 Internal audits

Procedure PQ 9.2 "VERIFICHE ISPETTIVE INTERNE" rev 3 of 18.01.2018 was available and implemented. There is a program of internal audits of the quality systems carried out by the QA Team on refer procedure QMS Manual.

The company has identified the storage of raw materials, primary packaging and finished products, processing and packaging areas, mechanical plant and cleanliness as critical for food safety and product specifications. Audit are performed by internal personnel and external consultant.

Internal audit plan, on risk assessment, documented into mod 8.2.2/3 (scheduling), in 2023 26 audits carried out.

Internal audits are scheduled throughout the year and carried out at least quarterly, for e.g.:

- 18.12.2023 on the whole production process and CCPs: no NC's.
- 27.09.2023 on purchasing and raw material handling and acceptance: 13 NC raised: all properly closed.
- 16.06.2023 on internal lab: no NC's.
- 07.02.2023 on Pest control: no NC's.

QAM is in charge for CA's with proper closing and timescale, seen records.

In case of NC's raised, section managers are in charge for relative CA's implementation, timescale and actions.

FACTORY INSPECTION. Inspection of the manufacturing site to verify the structure and management of cleaning on a monthly basis (seen report of 18.12.2023, 27.11.2023 and 16.10.2023 all conforming). Daily preoperative checks in all production areas. Non-conformities are reported to the section manager and reviewed at monthly management meetings. Create a level with points and photography support

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

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

Procedure PQ 8.4.1 Purchase materials rev. 14 of 09.02.2022 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 suppliers risk assessment.

Risk assessment Tool AYAMA risk assessment of raw materials date 29.09.22, Allergens, microbiology, chemical, counterfeiting fraud (history, economic factors, ingredient typology, detectability, EC contamination, emerging risks, GMO risk. Performed on single raw material. Ongoing update.

For every cluster there is an evaluation (PxG) based on: Risk of contamination by allergen. This take into account allergens present in supplier plant, their management (i.e. segregation, dedicated production lines, cleaning validation) and any non-conformity raised up to the supplier; Risk of contamination by Foreign Bodies. This take into account kind of raw material, risk management in place (i.e. electronical sorting devices, any other food safety device) and any non-conformity raised up to the supplier; Risk of





contamination by Microbial agents; Risk of contamination by Chemical agents; Risk of substitution or food fraud.

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. Questionnaire is carried out to evaluate suppliers, in such questionnaire there are questions about Quality system presence, analysis carried out, GFSI certification, process control, risk assessment and layout of processes.

Randomly checked following suppliers from VERTICAL AUDIT

**INGREDIENT SUPPLIERS:**

- Shrimp, supplier "A.T.", valid IFS certificate and ISO 22000 certificate
- Mussels, supplier "B.B.S.P.", BRCGS certificate exp. 23.11.24, MSC Certificate
- TOMATO CUBE frozen, supplier "O.C.", IFS certificate exp. 27.11.24
- Clams, Supplier "T.H.F.", certificate BRCGS exp 28.4.23, IFS certificate exp. 13.5.24
- Extra virgin olive oil, supplier "M.A.", BRCGS certificate exp. 27.10.23, IFS certificate exp. 11.01.24
- Totani, supplier "C.C.", IFS certificate exp 12.05.2024
- Frozen Parsley, supplier "F." BRCGS certificate exp 26.11.24
- Yeast extract, supplier "Q.srl" BRCGS certificate, IFS certificate exp 15.08.24
- WHITE WINE, supplier "S.V.EV.", certificate BRCGS, expire 2024.05.14,
- Frozen garlic, supplier "S.P.A, certificate BRCGS exp.24.07.2024
- SUNFLOWER SEED OIL, supplier "A.C., IFS Certification expire date 4.3.2024.

**PACKAGING MATERIAL SUPPLIER:**

- BOTTOM & TOP, Supplier "S.A. srl, BRCGS 1979997 certification expire date 26.11.2024;
- FILM, reels TH300; Supplier "S.A. srl, BRCGS 1979997 certification expire date 26.11.2024;
- Plastic Tray, supplier Cerrett spa, BRCGS 1830037 certificate exp 31.05.2024.

One Broker used PESCIRO SLU from Spain for frozen fish: IFS BROKER certified COID 72433 exp on 28.07.2024. Traceability is maintained.

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

IO 8.4\_33 "Controlli qualità materia prima\_imballaggio primario\_in arrivo\_prodotto finito in uscita" rev9 of 20.04.2022, is followed for raw and packaging incoming check and finish products' release. Raw materials are assessed on receipt. One dedicated operator for acceptance control. Acceptance control verified: product sampling and testing; visual inspection on receipt; certificates of analysis – specific to the consignment; certificates of conformance.

For each hazard identified for every raw material (e.g. Presence of pesticide and heavy metal, residual radiological contaminants, contamination of packaging) has been made a risk analysis. Preventive measures are defined for each hazard. Specific control plans on incoming materials are provided, considering the typical hazard sources and risks and are conducted by external accredited laboratory. All materials are inspected on arrival at the site and are given of traceability coding. The HACCP plan governs the acceptance of raw materials, defining which parameters are inspected before goods are accepted onto stock. Raw material acceptance and its release for use are based on visual inspection on receipt / certificates of conformance - specific to each consignment / certificate of analysis / product sampling and testing. Are provided: visual checks (conditions of supply and means of transport) and analysis of samples.

RANDOMLY CHECKED FOLLOWING ACCEPTANCE CONTROL from VERTICAL AUDIT

- 16.01.2024 on supplier L. for clams 500g: all conforming;
- 18.10.2023 on EVO oil Montalbano analysis certificate checked with multiresidues conforming;
- 25.10.2023 on unshelled prawn from Argentina: check CoA on SO2 with conforming values
- 31.07.2023 on frozen diced tomato seen check of CoA on TVC, Coliform, E Coli, Salmonella and Listeria



all conforming.
<b>3.5.3 Management of suppliers of services</b>
<p>SERVICE (e.g. external consultant, laundry, pest management, laboratory) Procedure PQ 8.4._5 Acquisito servizi rev. 1 date 09.20.07.2021; STORAGE, TRANSPORT Procedure PQ 8.4.4 Acquisito servizio deposito e distribuzione v. 5 data 04/01/2021</p> <p>Checked during the audit: ALSCO certificate UNI EN ISO 14065:2016, bio contamination 09/06/2024, SVAT transport service, IFS LOG certification, COID 12530, expire date 25/11/2024, in addition presence Good distribution practice document.</p> <p>Service suppliers are managed through audit or questionnaire. Questionnaires are updated every three years, seen last compiled questionnaires sent by suppliers (seen questionnaire of MareAlto S.r.l. storage service of 20.01.2022).</p> <p><b>MINOR CAR 3.5.3.1 raised: The audit carried out in the last 12 months at Eurotrade S.r.l. (warehouse of raw materials and finished products), is not formalised nor that at Volfrigo (raw materials storage warehouse).</b></p>
<b>3.5.4 Management of Outsourced processing</b>
Not applicable.
<b>3.6 Specifications</b>
<p>The product specifications show the article code and EAN, the name of the product, the indication of the product category, the list of ingredients, the microbiological, chemical and organoleptic characteristics, the nutritional table, weight indications, storage methods, TMC, any claims, the packaging characteristics and the allergen list. Contracts with customer were present. Specifications were authorised and controlled and revised at least every three years.</p> <p>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 through software AYAMA:</p> <p><b>INGREDIENTS:</b></p> <ul style="list-style-type: none"> <li>- 10853 Argentinian shrimps unshelled issue 3 dated 01.08.2023;</li> <li>- Sunflower oil by A. issue 14 dated 12.10.2021;</li> <li>- Pepper Spices by A. issue 1 dated 12.03.2021;</li> <li>- Tomato sauce issue 9 dated 0.06.2021;</li> <li>- White wine by S. issue 3 dated 18.10.2023.</li> </ul> <p><b>PACKAGING MATERIAL SUPPLIER:</b></p> <ul style="list-style-type: none"> <li>• BOTTOM &amp; TOP, Supplier "S.A. srl, supplier techn. Spec rev 9 of 2020, reconfirmed 2023, DoC of 9.10.2022, declaration of migration limit, temperature and contact time</li> <li>• FILM, reels TH300; Supplier "S.A. srl, supplier techn. Spec rev 9 of 2020, reconfirmed 2023, DoC of 9.10.2022, declaration of migration limit, temperature and contact time</li> <li>• Carton Tray, supplier S.I.S. spa, supplier techn. Spec of 10.2021, Doc of 18.11.2021.</li> </ul> <p>Finished product of Company brand:</p> <ul style="list-style-type: none"> <li>- Sautè di Mare 400g dated 22.08.2023;</li> <li>- Condiscoglio with tomato 450g issue 9 dated 24.03.2022.</li> </ul>

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Seen specification for finished products for client brand which are formally agreed with clients: CRUSTACEAN SAUCE, customer COOP, 450g date 25.01.2023, approved by customer the 25.01.2023, Product description, shelf life 540 days, ingredient list, Allergens list, GMO status, Technical data, Logistics data Microbial characteristics, Organoleptic characteristics, Transport temperature, storage temperature.

Seen contract with major retailer client COOP and CArefoundedated 2023 with formulas, recipe and technological requirements defined and agreed; such parameters are the same as for the own brand product of the Company.

**MINOR CAR 3.6.1 raised: The technical specification of the tray purchased from the supplier Cerreti S.r.l. of R-PET for food, is in rev. 4 of 03/03/2020.**

### 3.7 Corrective and preventive actions

Procedure "PQ 10.2 – Tenuta sotto controllo non conformità e reclami e AC", issue 5 of 16.02.2018 is available. There is a documented procedure for handling non-conformances identified within the scope of this Standard. 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.

#### Example

March 2023 following NC for missing sanitization of floor. CA: restoring sanitization and training of line operators the same day. Verified training effectiveness after 1 month of observation.

### 3.8 Control of non-conforming product

Procedure "PQ 10.2 – Tenuta sotto controllo non conformità e reclami e AC", issue 5 of 16.02.2018 and IO10-3 GESTIONE PRODOTTO NC issue 1 dated 16.04.2023 were available and in place and well implemented when required. NC managed by software and pc. Clear process 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.

2022 NC 441 in total. In place criteria for statistical data analysis  
2023 NC 252 in total. In place criteria for statistical data analysis

316 from supplier (damage nonconformity, foreign bodies, ingredient labelling, allergens in incoming steps) and 117 from site production (GMP inspection).

### 3.9 Traceability

Traceability Systems is defined in the dedicated procedure PQ 8.5.2 PRODUCT TRACEABILITY SYSTEM issue 4 dated 16.02.2018 and "PQ 8.5.2\_1 – IDENTIFICAZIONE, TRACCIABILITÀ E CONSEGNA", rev.3 07.04.2021 was available and implemented for raw materials, finished products and packaging materials. "PROGRAMMA DI TRACCIABILITÀ, issue 1 is present. The responsibilities were determined. No rework was carried out in site. Upstream traceability tested regularly done, mass balance product to customer.

#### VERTICAL AUDIT

Product chosen by the auditor from sample area. FiorFiore with crustaceans code 944 produced on 13.09.2023, batch 130723 BB 03.01.2025, delivered to client C.  
Seen recipe and hake broth base (batch SE120923).



Checked all production-process and traceability records, ingredients and finished product specifications, customer agreement, laboratory analysis and line/equipment maintenance, calibration, sanitation as well as operators training records. Accurate results including mass balance check: produced 19.440 pieces, sold 13.752 pieces and in warehouse 5.688 pieces.  
Test successfully completed within 1 h.

**INTERNAL TRACEABILITY TEST** 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 from raw material to finished products and viceversa on 04.11.2023 finish product to raw material: Lobster sauce for client L. produced on 04.10.2023 batch 041023 exp on 27.03.2025. Seen ingredient and production checks. Mass balance: produced and sold 20168 pieces. Time 60 min

### 3.10 Complaint-handling

Operative Instruction “PQ 10.2 – NON CONFORMITÀ E RECLAMI” issue 5 16/02/2018 is in place and well implemented when required. The procedure for the management of the complaint handling was defined. The responsibility was determined.

**Considering year 2022** 5,20 CPMU (85) complaints raised from retailers (35) and consumers (50): Mainly RAW MATERIAL (organoleptic), 20 for FOREIGN BODIES (9 natural crustacea shell, 1 shell, 3 hairs, 1 fly, 1 insect, 2 sands, 1 wood, 2 soft plastic). No form authorities

**Considering year 2023** 5,44 CPMU (74) raised from retailers (21) and consumers (56): of which 21 foreign bodies (9 natural crustacea shell, 1 shell, 3 hairs, 1 cigarette butt, 1 piece of nail, 5 soft plastic) No complaint from authorities.

Main reasons of complaint: organoleptic, foreign bodies and packaging.

Seen quality complain date November 2023 for the presence of not identified mollusc with shell. Seen root cause analysis: mollusc was not identified. Treatment/correction, communication to clams supplier and client.

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

IO 8.7.2 PIANO DI EMERGENZA”, issue 12, 10/10/2019 was available and implemented for the management of product withdrawal and product recall.

Crisis team defined including BENEDETTA MARIOTTI (QAM), ARBI MAURIZIO (Dir). The responsibilities were determined and the team have the appropriate Knowledge for issue the risk assessment. 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.

Presence of lay out of activity with included responsibility, including external support, step for decision of action to be done. Considered labelling, microbiological and chemical factors, gluten/allergens, foreign bodies, MSC chain of custody,

The procedure indicates, to call the certification body in 3 working days in case of real recall.

Present document PIANO CONTINUITA’ OPERATIVA” (business continuity), IO8.7\_1 of 11/01/2021 issue 6. Factors considered, Food alert, Electricity, Environmental, well contamination, Fire, Headquarter, Internal /external Strike, Human resource, Intentional actions, Cyber security, Pandemic situation.

Business continuity incorporating crisis management, contamination protocol, impact of pre-requirement.

Withdrawal test performed date 13.04.2023 on code 10464 Cod filet breaded batch 3012. Mock recall cause and Scenario: wrong MSC ASC certification of raw material. Client Conad Nord Ovest, delivered the 12.01.2023 30 pieces (3.900kg) with mass balance: in warehouse 14.245kg and produced 18.145kg.



Verified customers contact list and in collaboration with customer mail. Time < 4 hs.

No real cases of product withdrawal/recall since previous audit.

Details of non-applicable clauses with justification	
Clause/Section Ref	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
3.5.4.5	No outsourced processing and packing
3.5.4.6	No outsourced processing and packing
3.9.4	No rework used or reworking operations carried out

#### 4. Site standards

##### 4.1 External standards

Located in a large, light industrial estate in MONSUMMANO TERME with green fields around the plant. The external area is in good repair and well maintained. The site is located in an industrial area and consists of 1 building, constructed in concrete, one with the staff offices, production and packaging area, the shipping area and a laboratory, one, connected with the first by means of a covered walkway, with a mixing room, a storage area for raw material and the warehouse of primary packaging, and the last for storage of secondary packaging. Construction and design were suitable to prevent product contamination. No local activities that would risk product contamination. No additional buildings on site. Security system is in place. Measures were in place to maintain site security and to ensure only authorised personnel could access production. Key-card entry was required for key areas. CCTV on site: video surveillance, use of security gates; security staff. No external storage. Controlled access for all external people by approval only. Plant area is surrounded by fence.

##### 4.2 Site security and food defence

FDA number 12302631402

PQ 7.3.1\_1 "Food Defence", issue 6 of 13.12.2022.



Identification of critical area. with daily and annual activities. Element considered : IT system, Cleaning systems, controlled temperature cell, storage of raw materials, silos and spices, storage of Chemical products, storage of laboratory products, personnel, plant, ingredients dosage, manual dosing, heat treatment, finished product storage, loading and shipping, product handling NC, processing scraps, waste, external perimeter, entry into the plant, management of services reception, receipt of raw materials and ingredients, packaging receipt, return receipt, utilities.

Analyse such as threat, preventive action, responsible frequency, and corrective action. Enclosed site with 24-hour security; one alarm system was installed. ITAL SICURITALIA h 24.

CCTV on site: video surveillance, use of security gates; security staff. No external storage. Controlled access for all external people by approval only. Plant area is surrounded by fence.

Last risk assessment dated 18.01.2024.

Last test date 10.10.2023: awareness/ reaction test with introduction scenario

Last training dated 02.10.2023 including verification of implementation status of system.

Responsible for Food Defence is Alessandro Arbi who has appropriate knowledge.

#### 4.3 Layout, product flow and segregation

Plan updated 2018: 1- Personal flow; 2- flow of raw materials; 3- finished product flow; 4- Waste flows; 5- Drainage and water flow. No refurbishment works or temporary structures that may affect product safety

MICROBIOLOGICAL APPROACH FOR MICROBIAL Mitigation: Layout documented and process flow of one-way type. Raw material intake separates from finished product delivery. Internal movement external yard routes clearly indicated. Different levels of risk areas have been correctly identified. Plan of site designates areas as enclosed products areas for the storage areas and low risk areas for the production zone. Raw products to be cooked before eating at about 70-80°C for Minimum 6 minutes; Raw materials and Finish products stored at <-18°C/ 4°C

There was a plan of the site which designates areas:

- Microbial high-risk areas (cooked product ready to eat) – not present
- Microbial high-care areas (cooked and not cooked product ready to eat) – not present
- Microbial ambient high-care areas – not present
- Microbial low-risk areas (product to be cooked) – production and packaging area.
- enclosed product areas – receiving, RM and finished product storage warehouse
- non-product areas – administration office, staff facilities, maintenance area.

ALLERGEN APPROACH FOR CROSS CONTAMINATION mitigation: Separated storage of allergens, intermediate cleaning after allergen products, allergens taken into consideration during production planning, verification test done of allergen traces from following product not containing allergen. Cross contamination well managed by dedicated area for identification, equipment, and staff. For product containing GLUTEN has been dedicated a PROCESSING AREA physically separate from the other, maintained in under pressure compared with confined area, using specific entry point by operator and protective clothing identified in yellow color wearing and removed in dedicate staff facility. Where no possible potential contamination is present in the label with may contain in addition to ingredient present in ingredient list

PHYSICAL APPROACH. Presence difference between wooden pallets and plastic pallets. Plastic pallets are present in warehouse and before entry in processing area ingredients and packaging are moved on plastic pallets. Only plastic pallets are present in processing area. The wooden pallets are present then at the end of secondary packaging.



Contractors and visitors including drivers are informed through signs, trainings and bulletin boards.  
No temporary works.

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

The fabrication of the site buildings and facilities are suitable. Floors are constructed of coated concrete and whilst some areas show minor wear which is maintained through the maintenance programme, generally in good repair. Floors are in satisfactory condition, being of impervious resin finish and able to meet demands of the process. Drainage is of satisfactory design and is maintained to minimise risk of product contamination. Ceilings are constructed in concrete. They are all well finished and maintained and facilitated good hygiene, and no mould growth or condensation was noted. There are no suspended ceilings on site. Externally opening windows in production and storage areas are screened against pest ingress. Walls are designed, constructed, finished and maintained in good order. Walls are designed, constructed, finished and maintained in good order. Glass windows are covered with plastic laminate. External doors are in good condition and designed for easy cleaning. All lights and EFK tubes are suitably protected against breakage. The presence of glass is not considered a risk for the product, but it may damage the bag before packaging. So, the lights in the production area are covered with fine mesh and inspected daily. Ventilation and extraction throughout the site are satisfactory. There is a dust extraction system installed in the dry powder handling area (fried products department).

No elevated walkways on site or suspended ceiling.

No plastic strip curtains.

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

Procedure IO 71.1 “Servizi, Acqua, Aria e Luce” issue 9 dated 04.10.2023 for water management in HACCP manual. Potable water in use available from well (POZZO NORD - POZZO SUD). Water used for cleaning and ingredient. A schematic plan of water is available dated 03.01.2024. Relevant records are maintained. Plumbing system map detailing all sampling points was available. Water test criteria evaluation considering well water. Create matrix, based on quantity used 155/ m3. Yearly basis, with chemical and microbial analysis, verification parameters chemical (arsenic, pesticide, IPA) consideration point at the use cleaning, nebulization, QAT, monthly basis for nebulization. Routine monthly LINE A, H, L microbiology, potability.

YEARLY Analysis are carried out by external accredited lab MERIEUX (Accredia 0051) for microbiological (including TMC, E. coli, Coliforms and Enterococcus) and chemical (including heavy metals) parameters with reference to D. Lgs. 18/2023.

Example Data Laboratory Merieux (Accredia 0051) sampling point 6 of 08.01.2024 chemical, pesticide, and microbial parameters QAT water analysis scheduled: Lab BLOKIM (Accredia 0968) point LINE A date 23.11.2023 nebulization with conforming values. Verification considering chemical and contaminant and microbiology CBT, E. Coli, pseudomonas, clostridium Perfringens.

Water process maintenance via software namely CARL SOURCE continued updated. Chlorinated water in use, verification every day measured online (e.g. 0,25 ppm data 23.11.2023). Parallel off-site verification made example result 0,3 ppm. Well, storage 20.000-litre, chlorination 2 ppm, macro filtering of water, carbon filter for deleting chlorine one part destined to osmotic and water destined to mix, then water destined to use point and verification residual chlorine.

Presence of 2 ultrafiltration and osmosis equipment. Line SUD Example QAT, TECNOCOM maintenance contract 4 inspection on yearly basis. Randomly checked maintenance plan for Osmosis water used only for steam production, assistance from TECNOCOM example Nov.2023



#### 4.6 Equipment

Equipment for preparation raw material and for mixing raw material and ingredients; On site was installed n. 6 production lines: n. 1 skin-packing line (50/60 pieces /minute), n. 1 IQF Polybag line (50/80 pieces/minute), n. 1 vacuum-packing line (50/60 pieces/minute) n. 1 Shrink-wrapping line (20/25 pieces/minute), n. 1 carton box packaging line. Main equipment was well maintained under routine maintenance systems. Equipment contacts surfaces all SS 316 but predate certification. New conveyor belts supplied with confirmation of approval for food use. Engineers aware of the requirement. Safe and clean storage of equipment and the positioning of fixed equipment for adequate cleaning. Seen DoC of conveyor belt HSABASIT AG polyurethane of 31.01.2020, with FDA, 21 CFR DoC also

Good level of cleanliness and equipment integrity was found during sites' inspection. Plant and machines all of updated technology and realized according to food industry best practice. Food contact suitability documents available for most recent plants and implements as food contact suitability declaration for screw of packing plant department released by the supplier.

Equipment contacts surfaces all SS 316. Maintenance operators are aware of the requirement.

In case of new equipment purchased there is a check on certificate for food use and on suitability to all the standards. Defined also the installation.

No mobile equipment.

#### 4.7 Maintenance

Maintenance Plan according with PQ 7.1.3 "Manutenzione Attrezzature e infrastrutture" rev 4 of 22.10.2019, scheduled via software namely CARL SOURCE. Yearly maintenance plan defined in December 2021 and continuous updating, is available and well implemented. 5 maintenance workers who operates computerised maintenance plan and procedure, with workshop area located in a dedicated area in the site which is maintained in good hygienic condition. Refrigeration equipment subcontracted to specialists on case of breakdowns equipment. Maintenance work is followed by a documented hygiene clearance procedure, which records that product contamination hazards have been removed from machinery and equipment. No allergens in food lubricants. Food Grade Oil: MULTIPLUS, NSFH1 dated 31.05.2017. In place procedure for clearance line after maintenance responsibility CQ.

Seen record of maintenance with cleaning dated 22.01.2024 on line L for a breakage in the pump of the sauce: substitution. Another maintenance on 22.01.2024 for substitution of a sensor on Line L and on 13.01.2024 on freezing plant for routine maintenance.

#### 4.8 Staff facilities

No sensitive area are present but only low-risk areas (the product must be cooked before eaten). Single large changing facility within main building for all personnel entering production, packing and storage areas maintained in clean condition by dedicated cleaning staff. Staff facilities are designed and operated to minimise the risk of product contamination. Separate lockers are provided to allow outdoor clothing and other personal items to be stored separately from work wear.

The toilets do not open directly into production areas. Adequate hand washing facilities are provided with warm water, soap, and paper towels. Hand washing facilities, provided with non-hand operated taps, suitable soap and towels are situated at the entrance to production and at various points within the area. sufficient number of foot-operated washbasins and lukewarm water, liquid soap and paper towel dispensers. It is accessed directly from the outside and is connected to the production premises. Washing basins dedicate.

Catering Facility was not present; lunch break takes place outside the Company. Only some vending machines are present in dedicated areas: sign for allergens are on site.





Smoking is not permitted inside the plant. Dedicate areas for smoking was identified on external perimeter of building.
4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas
4.9.1 Chemical control
IO 7.2-3 MANIPOLAZIONE SOSTANZE CHIMICHE issue 2 dated 28.08.2018 and IO 7.1.4-6 CORPI ESTRANEI E SOSTANZE CHIMICHE issue 1 dated 18.01.2023. 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 Safety Data Sheet checked during HYPOFOAM v.6 technical sheet of 2014, alkaline foam, MSDS rev 14.2 of 26.02.2019 CIPTON VC 11 technical sheet 25/01/2018 alkaline for CIP, MSDS rev.08 of 25.01.2018 Sodium hypochlorite for water treatment, DONAU CHEMIE, DoC EN 901 of 12.12.2019, msds rev 1.0.2 of 27.05.2015
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. Seen records dated 22, 23 and 24.01.2024.
4.9.3 Glass, brittle plastic, ceramics and similar materials
The procedure Schedule “MONITORAGGIO INTEGRITÀ VETRI E PLASTICHE DURE” 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. 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. Daily start up control and monthly glass and hard plastic audits, seen daily start up control record dated 21.01.2024 and monthly record dated 12.2023. During the audit, auditor has checked randomly windows and glasses present in the glass list: all conforming on 22, 23 and 24.01.2024.
4.9.4 Products packed into glass or other brittle containers
Not applicable. Not present packaging in glass containers
4.9.5 Wood
Instruction “IO 7.1.4_6 Corpi estranei e sostanze chimiche” rev1 of 18.01.2023. Control of wood properly managed. The presence of wood is allowed only at the end of the packaging line.
4.9.6 Other physical contaminants
Before entry to expose production, area there is change of pallet from wood to plastic. De-cartooning in general is done far from the production line (e.g. LINE L) The IQF ingredient are then placed on vibrating sieve in order to broken IQF pieced of ice. The ingredients are loading to dosage unit. Detectable pens

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adopted and under management criteria.
<b>4.10 Foreign-body detection and removal equipment</b>
<b>4.10.1 Selection and operation of foreign-body detection and removal equipment</b>
The procedure to prevent the risk of physical contamination of product was defined. In the final part of every production line a metal detector. The equipment to detect foreign materials are: - Filtration of EVO oil destined to Line. Oil filter 25 micron - Metal detector at the end of every production line (Fe 2,5mm, NonFe 3mm, SS 2,5mm). - Two X-ray Detector at the end of every production line (Metal 2,5 mm, Glass 2,5 mm, stone 10 mm).
<b>4.10.2 Filters and sieves</b>
Presence filtration of EVO oil destined to Line. Oil filter 25 micron Seen records for filters checked dated 22, 23 and 24.01.2024.
<b>4.10.3 Metal detectors and X-ray equipment</b>
Physical product contamination control is described on HACCP plan and it is properly managed. The storage of the containers is 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. The equipment to detect foreign materials are: - Metal detector at the end of every production line (Fe 2,5mm, Non-Fe 3mm, SS 2,5mm), managed as CCP. X-ray Detector at the end of every production line, managed as oPRP Critical Limits: metal detector and X rays. Critical limit: MD: 2,5mm Fe, 3,0mm NFe, 2,5mm SS; X-ray: 2,5mm Fe, 3,0mmNFe, 2,6 mm SS, 2mm Glass 2mm Stone. Operative Instruction "IO 8.5.1_1 "Gestione Metal Detector Rilevatore Raggi X Controllore di peso" rev5 , was available and well implemented During the audit witnessed Metal Detector control operation carried out during the audit of Shellfish sauce with scampi, prawns and lobster meat 300g FiorFiore Coop batch 220124 BB 07/25; "Mare e Orto" brand Arbi mix of molluscs, crustaceans and broth with vegetables 300g 230124 07/25; "Misto Scoglio" Arbi brand, mix of molluscs and crustaceans with fish broth 230124 07/25; "Condiscoglio" with tomato sauce brand Arbi 450g 240124 07/25; the reject system was effectiveness. The metal detector has an automatic rejection device, which diverts contaminated product to a closed unit accessible only to authorised personnel. Metal detection on each line of production. Staff working on Metal detectors and X-rays was interviewed and has demonstrated required competency level.
<b>4.10.4 Magnets</b>
Not applicable. Not necessary for the type of product and process. Risk based justification.
<b>4.10.5 Optical sorting equipment</b>
Not applicable. Not present.
<b>4.10.6 Container cleanliness – glass jars, cans and other rigid containers</b>
Not present packaging in glass containers
<b>4.10.7 Other foreign-body detection and removal equipment</b>
N/A

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4.11 Housekeeping and hygiene

Mainly manual washing of the systems performed by cleaning company staff no external company.  
 CIP in place for tank and kitchen pipe washing.  
 No third part service provider involved in cleaning activity.  
 Procedure SSOP IO7.1.4 \_2 SSOP GENERALE rev 2 date 01.03.2022  
 There are in place specific cleaning operation procedure for every line. Example LINE A IO 7.1.4 .2/1 v.0 25/01/2022  
 Procedure SSOP the cleaning procedures detail the following requirements. Cleaning is carried out every day and it includes cleaning of equipment (Sponges, dusters and microfibre cloths, glass polishing cloths, cleaning brushes, mop and bucket, dustpan and brush, Protective gloves), 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 by production manager. Procedure includes a list of all cleaning chemicals and their use, instructions, the frequency, responsibility for cleaning, item/area to be cleaned, frequency of cleaning, method of cleaning, including dismantling equipment for cleaning purposes where required, cleaning chemicals and concentrations, cleaning materials to be used, cleaning records and responsibility for verification, seen records of December 2023 and January 2024.

Cleaning partner DIVERSEY that provide detergent. Internal TEAM dedicated to cleaning operation. Data are collected and trends identified that has resulted in improvements to cleaning procedures. During the audit following equipment was observed at the pre-operative  
 Site's storing conditions: External building, internal perimeter, Ground floor, Correct storage, Locked down. Chemical correctly labelled.

Adequate cleaning level found in place at the audit time (e.g. equipment line L, processing area)  
 During the audit was checked the cleaning of the packaging line and kitchen correctly carried out by operators. Good hygienic status observed apart from what is defined in the following Non-conformity

**MINOR CAR 4.11.1 raised: In the kitchen area, a clean stainless steel tub is overturned and placed on the floor.**

4.11.7 Cleaning in place (CIP)

CIP in place for tank and kitchen pipe washing. Schematic diagram of the layout of the CIP system including process piping circuits shall be available. Dosing rates were controlled automatically for CIP sets. CIP caustic strength was checked daily on each set and at each use (as and when used). Water pH control at the end of the cycle with litmus paper or pH meter CIP. Program consists Rinse water 80°C, wastewater, detergent 80°C 28 micro siemens, time according to line, recycle, rinse with potable water T ambient, flow 13500 l/h, concentration 28 ms. (2%), set up rinse 7 ms. CIP. CIP VALIDATION. Third part service provider DIVERSEY. Last performed in data 5/12/2019 with some corrective action as output, second report date 01/2020

4.11.8 Environmental monitoring

Criteria of environmental monitoring are present inside SSOP. SSOP protocol in case of analytical test NC IO7.1.4 \_2 protocol SSOP REV.2 date 01.03.22 and IO 7,1/1 ACQUA, ARIA, LUCE issue 9 dated 04.10.2023.  
 Monitoring program dated 18.07.2023.

Made different consideration according to risk assessment with identification of area (contact and not contact surface, precooking, post cooking; sampling point, frequency)



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The following microbiological criteria are considered Yearly basis: CBT, total coliforms, E. Coli, Staphylococcus, salmonella. Sampling Internally performed using 30 x 30 sponge on contact surface at preoperational time. Also Yearly air analysis with count on slab for TVC at 30 °C, mould and yeast. Limits ("absence" limits for Salmonella spp. And Listeria spp., 30x30 CFU / cm2 for coliforms, 90000 CFU / cm2 for CBT).

Example LINE L of 18.07.2023: Coat, boots, gloves, trolley, wagon, ingredient dosing basket, spreaders DX, SX, collection well, tank TK 5,6,7, tunnel exit, oil dispenser SX, DX, conveyor belt, collection pan, floor, tool, grey container, scales loading openings, multi-head scales, tunnel entrance, vibrating table, ceiling, tunnel exit carter. Result conforms. The analysis of the trend is good.

4.12 Waste and waste disposal

The procedure Prerequisite SSOP IO 7.1.4\_1 Rifiuti issue 2 of 13.5.2022 for waste management is available and implemented. Waste is selected by nature in dedicated containers disposed by specialized service on contract. Every day the animal wastes are stored at <+4 °C of temperature. The specialised Company "PAPINI" is dedicated to the collection of CAT3 materials. The company have defined a procedure dedicated to the collection of laboratory waste.

4.13 Management of surplus food and products for animal feed

There is animal waste, which are disposed by licensed contractor ROMANO PAPAINI, disposed every 15 days. Food products intended to be supplied for animal feed are segregated from waste and managed in accordance with relevant legislative requirements. Certificates of destruction are available and properly recorded. Product processing waste thoroughly disposed as category 3 according to national legal requirements. Surplus of customer branded products is destroyed, seen IO 8.5.3/1 dated 28.08.2018 issue 0

4.14 Pest management

Pest management Responsible part of CQ team.  
 A specific procedure IO 7.1.4\_3 dated 09/08/2018 is clearly defined in HACCP Manual and in contract with external services company.  
 A contract with ANTICIMEX dated 01/2021 yearly renewed was in place with external provider to manage pest control on site 12 routine visits each year.  
 Schematic map of baits dated 28.12.2023 visual online.  
 Defined threshold present in clear on online system 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 is correctly sited and they are inspected on a regular basis (monthly basis).  
 Electrical lamps changed yearly 10 in total bulbs substituted.  
 Pheromone traps are present for food insects such as moths, bugs, beetles.  
 Last intervention dated 28.12.2023 and 24.11.2023 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, on risk assessment, by a pest control expert to review the pest control measures in place: last one carried out on 08.06.2023 documental check, inspection, trend analysis. (2022-2023)  
 Trend analytical half-year. Monthly inspection, according to the model, it has not identified the other catches.

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Employees understand the signs of pest activity and are aware of the need to report any evidence of pest activity to a designated manager. Last training dated 20.07.2023 (2h) to 22 operators.  
 Building constructed in order avoid bird refuge. New agreement with falconer Boncilini Fabio to deter the presence of birds, last intervention of January 2024.  
 No sign of infestation highlighted at the audit time

**4.15 Storage facilities**

Present a double warehouse management system with manual and computer system.  
 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 store.  
 During the acceptance phase, checks are carried out relating to the conformity of the accompanying documents, suitability, and cleanliness of the raw materials and, if necessary, of the relative packaging, adequacy, where applicable, of the transport temperatures.  
 Instruction "IO 7.5.3/2" IMMAGAZZINAMENTO STOCCAGGIO PRODOTTO FINITO" issue 2, is available and the process is well managed; the FIFO controls was documented monthly.  
 Refrigerated temperature required: storage temperature required < -18°C. Temperature's registrations were carried out every 30 minutes according with operative instruction "IO 8.3/3 "PIANO DI CONTINUITÀ OPERATIVA". The cold chain is assured by documents and registrations. No controlled atmosphere requested. During audit randomly checked days 22 and 23.01.2024.  
 Storage Facilities results adequate.  
 The finished products are stored at "EURO TRADE Srl" warehouse, an external Company under the ARBI'S Company property. Last audit by QA of ARBI DARIO Spa dated 06/2022  
 The storage temperatures of raw materials, semi-finished and finished products are kept under control by means of calibrated thermometric probes connected to continuous recording software, which in turn is connected to alarms. The alarm is present on the telephone of the production manager (T> -12 ° C frozen; T> 6 ° C fresh). There are also paper records. Checked monitoring Criteria for Mussels of 13.12.2023 frozen storage.  
 No electronic warehouse. FIFO principle in use.

**4.16 Dispatch and transport**

Procedure PQ 7.4/9 "ACQUISTO SERVIZI DI TRASPORTO", issue 1, Procedure PQ 7.4/7 "ACQUISTI SERVIZI DI DEPOSITO E DISTRIBUZIONE", issue 1. Operative Instruction "IO 7.5.3/3 "SPEDIZIONE PRODOTTO FINITO", issue 1 was available and well managed. "EUROTRADE Srl" Company manages the distribution of frozen finished products. The vehicles cleaning check in the loading are registered and monitored. Temperature control is in place. Documented maintenance and hygiene procedures maintained for equipment used for loading/unloading with truck photo.  
 Example SVAT transport service, IFS LOG certification, COID 12530, in addition presence good distribution practice document  
 During the audit verified DDT 24BD100-1000230 dated 19.01.2024 sent to Iceland Foods by transporter Bova Group. Result of control, conform

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

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4.3.6	No temporary structure
4.4.5	No suspended ceilings or roof voids present
4.6.7	No battery changing equipment stored in open food area
4.7.3	No temporary repairs
4.9.4.1	No products packed into glass or other brittle containers
4.9.4.2	No products packed into glass or other brittle containers
4.9.4.3	No products packed into glass or other brittle containers
4.10.4.1	No magnets in place
4.10.5.1	No optical sorting equipment in place
4.10.6.1	No products packed into glass jars, cans or other rigid containers
4.10.6.2	No products packed into glass jars, cans or other rigid containers
4.12.1	No Licensing contractors required
4.12.4	No Trademarked products are transferred to third parties for destruction
4.13.3	No products intended for animal feed
4.14.3	The site doesn't undertake its own pest management
4.15.4	No controlled atmosphere is required
4.15.5	No outside storage

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<b>5. Product control</b>
<b>5.1 Product design/development</b>
<p>New products submitted to specific R&amp;D procedure innovation process “Procedura creazione Progetto” rev0 7.09.22 and PQ 8.3 PROGETTAZIONE E SVILUPPO issue 5 dated 16.02.20218: identification and assessment of potential safety hazard, HACCP team must approve the new product after validation with legal office, identification of CCPs and validation of the product. Shelf life trials will be carried out in case of new products: analysis MB (low bacterial counts) and good taste. Labelling meets all legal requirements.</p> <p>At the audit time checked:          AYAMA software is used as support of PRODUCT DEVELOPMENT of Project AQUAMAR started on 18.07.2023 and closed on 16.01.22024: high pressure treated fished: first sample on 01.008.22023 and second on 10.10.2023: 20 days of shelf life.          If new materials or process/equipment change HACCP team evaluates impact.          HACCP team approves the new product after validation with legal office, identification of CCPs and validation of the product. Shelf life trials are carried out in case of new products.</p>
<b>5.2 Product labelling</b>
<p>Labelling is in line with legal requirements. Labelling information is reviewed whenever changes occur. There are in place different label typology. Label with ARBI DARIO as owner and label with retailer as owner. At the audit time randomly checked</p> <p>Example checked at audit time:          Shellfish sauce with scampi, prawns and lobster meat 300g FiorFiore Coop batch 220124 BB 07/25; "Mare e Orto" brand Arbi mix of molluscs, crustaceans and broth with vegetables 300g 230124 07/25; "Misto Scoglio" Arbi brand, mix of molluscs and crustaceans with fish broth 230124 07/25; "Condiscoglio" with tomato sauce brand Arbi 450g 240124 07/25          Gluten free claim present, seen analysis dated November 2023 with conforming results (no gluten detected).</p>
<b>5.3 Management of allergens</b>
<p>Protocol IO 8.51/7 ALLERGEN MANAGEMENT CONTROL date v.7 26.09.2023          Allergens list: Fish, molluscs (mussels, shellfish), crustaceans, Sulphur dioxide (SO<sub>2</sub>), Gluten, milk. Soya and Mustard are not present but communicated by supplier as cross contamination and considered by the company. Modification with impact of process in kitchen department</p> <p>AYAMA risk assessment of raw materials update, 01/2022, Allergens, microbiology, chemical, counterfeit fraud, EC contamination, emerging risks, GMO risk</p> <p>RISK ASSESSMENT On going update due to management via database: PQ 7.1.2 PRODOTTI AL NATURALE (natural products) v.2 of 18.01.2023, ALLERGEN: molluscs, crustaceans, fish sodium metabisulfite.          PQ 7.1.3 CONDIMENTI (sauces and condiments) v.7 of 18.01.2023, ALLERGEN molluscs, crustaceans, fish, sodium metabisulfite.          PQ 7.1.4 PREFRITTI (battered and breaded, pre-fried) v.2 03.03.2022 ALLERGENI molluscs, crustaceans, fish sodium metabisulfite, gluten, trace Soya, Mustard; Milk protein.          PQ 7.1.5 PRECOTTI IN FORNO (precooked) v.2 06.04.2022 ALLERGEN fish, gluten, trace Soya Mustard.</p>

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PQ 7.1.6 CHILLED v.3 07.04.2022 ALLERGENS fish, molluscs, crustaceans, gluten, trace Soya mustard, sulphites.

ALLERGEN APPROACH FOR CROSS CONTAMINATION mitigation: Separated storage of allergens, intermediate cleaning after allergen products, allergens taken into consideration during production planning, verification test done of allergen traces from following product not containing allergen. Cross contamination well managed by dedicated area for identification, equipment, and staff. For product containing GLUTEN has been dedicated a PROCESSING AREA physically separate from the other, maintained in under pressure compared with confined area, using specific entry point by operator and protective clothing identified in yellow color wearing and removed in dedicate staff facility. Where no possible potential contamination is present in the label with may contain in addition to ingredient present in ingredient list

**PROCESS SEQUENCE**

From minor to major ad number of allergens Example Day 23.01.2024, kitchen activities verified the correct sequence of process growing allergen criterion.

Cleaning methods are validated against cross contamination. Allergen policy on site communicated at induction – staff may not bring allergen containing products on site. ALLERGEN FREE Cooking area and industrial plant, Surface and water rinse example CIP T400, T300, allergens SO2, crustacea, sulfuric anidride, Third part laboratory test MERIEUX; CIP VALIDATION, Third part service provider DIVERSEY. COP CLEANING VALIDATION Washing procedure with UNIFORM 3% detergent + TEGO 51 disinfectant; Surface test conform, CBT, Coliforms, Enterobacteriaceae listeria, salmonella; 03/2021; CROSS CONTAMINATION GLUTEN FREE VALIDATION, Contact Surface test line H (area with gluten) after cleaning absence of gluten, laboratory MERIEUX data 02.11.2023. No changes since last test, Contact Surface test line L (area without gluten) after cleaning absence of gluten, laboratory MERIEUX data 02.11.2023.

Gluten Free Verification performed every 2-batch analysis for detection absence of gluten LINE L. Seen gluten free analysis dated 03.11.2023.

Allergens communicated in LABEL via ingredient list (intentionally present) and/or cross contamination. Example of label randomly checked at the audit time.

Training on allergens dated 18.07.2023 to 35 operators (1h).

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

Food fraud team is represented by HACCP team HACCP team made up of DG, RGQ, RP, SPED, MAN, ACQ. RGQ team leader, there are no significant shortcomings in the plan itself and in the specific training of the drafting functions. The teams have the appropriate Knowledge.

Performed on 2020 training course IZS LOMBARDIA EMILIA ROMAGNA on fish fraud with species recognition 14/09/2020 - 20/12/2020 e.g. Caterina Giuntin.

SAFETY HUD Source of information MERIEUX based on safety alert, RASSF, fraud alert, monthly basis communication to the company. EURO FISH MARKET, ASSOITTICA consortium catering.

FOOD FRAUD PREVENTION PQ 73.1/2 data 16/02/2018, confirmed for 2024 on 18.01.2025. AYAMA software with quantitative evaluation (risk definition quantitative risk level allergens, microbiology, chemical, fraud, foreign bodies, GMO, new potential hazard). Document PIANO ANTI FRODE (anti fraud plan).

Last vulnerability risk assessment carried out the 18.01.2024 on all food raw materials or groups of raw materials to assess the potential risk of adulteration or substitution. It was taken into account: historical



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evidence of substitution or adulteration, economic factors which may make adulteration or substitution more attractive, ease of access to raw materials through the supply chain, sophistication of routine testing to identify adulterants and the nature of the raw material such as episodes of counterfeiting over time (adulteration and economic convenience), available analyses, control plans in place also by authorities, characteristics of anti-counterfeiting tests, etc. For each assessment, the organization has foreseen a control action on the raw material, subsequently compared to the supplier from which it procures it and, for the same, it has assessed its criticality through historical data, knowledge and years of supply, certifications, samples provided.

Raw materials identified as being at particular risk of adulteration or substitution appropriate assurance is in place to reduce the risk: WHOLE FISH (acceptance checks); NOT WHOLE FISH FILLET / MINCED (Genetic recognition), VEGETABLE OILS (Mineral oils); FISH RAW MATERIAL (additives in acceptance checks); FISH RAW MATERIAL (glazing on acceptance checks); FINISHED PRODUCTS MARKETED (net weight in acceptance checks)

Example SUNFLOWER OIL yearly test for research of mineral oil Supplier C. n°22/000303646 by NEOTRON.

Following product authenticity:

- MSC CHAIN OF CUSTODY, MSC-C-52593 expiring on 26/12/2025.
- ASC-C-01644 expiring on 26/12/2025

Last Mass balance dated 02.11.2023.

### 5.5 Product packaging

Packaging material used: thermoformed film, plastic trays, vacuum packing film.

The suppliers are certified according to GFSI standard (e.g. BRCGS) or in alternative audit.

At the audit time randomly checked:

- BOTTOM & TOP, Supplier "S.A. srl, BRCGS 1979997 certification expire date 26.11.2024.
- FILM, reels TH300; Supplier "S.A. srl, BRCGS 1979997 certification expire date 26.11.2024.
- Plastic Tray, supplier Cerrett spa, BRCGS 1830037 certificate exp 31.05.2024.

Seen PET Food Declaration issue 4 dated 29.12.2021 and MSDS of film by Sealed Air Cryovac daed 12/2022 and declaration of conformity for food dated 01.08.2023.

Correct storage of all packaging and the practices in place to part used packaging is stored suitably and fit for purpose if it is to be used in production. Criteria for collecting evidence that confirm food contact suitability in place.

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.

Obsolete materials are properly identified and labelled as "Obsolete" and no longer used.

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

The company has a schedule of analysis, based upon risk assessment, that cover raw materials, final products and packaging. These schedules include chemicals and microbiological testing.

The external laboratory (NEOTRON Accredia 0026 and MERIEUX 0051) conduces microbiological analysis (CBT, Salmonella, Listeria, Escherichia Coli, Enterobacter, Bacillus C.), chemical analysis (pesticide, hard metal, nutrition facts radioactivity, species characterization).

External labs work to ISO standards. Internal lab is properly separated from the production area. 1 operator is part of laboratory staff. Staff is properly trained, competencies verified: seen training and degree.



The internal lab was used for all the analysis on acceptance of raw materials and finished product: Listeria and Salmonella. PCR, swab analysis listeria, CBT, coliform total, E. coli, staphylococcus aureus.

Ring test carried out with LGC on 15.06.2023 on Listeria: result conform, detected.

Test results and inspections are recorded and reviewed regularly to identify general trends. Lab results are acted upon and actions taken to address unsatisfactory results and trended; no evidence so far of non-conforming results in analysis.

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.

Seen analysis/inspection carried out with conforming results on:

- 18.04.2024 on Condiscoglio batch 180124 for Listeria Monocitogenes;
- 17.01.2024 on Condivongola batch 170124 on AR7007.
- 22.09.2023 on FiorFiore Coop for TVC, E. Coli, Salmonella, Listeria, Vibrio;
- 12.01.2024 on raw material Prawns for citric acid, added phosphates.

SHELF-LIFE VALIDATION. MERIEUX NUTRISCIENCE laboratory; used as input Bibliographic studies; Sensory and sensory evaluation performed after cooking, CBT, Perfringens, Enterobacteria, E. Coli, qualitative and quantitative listeria, fungi, peroxides, Salmonella Staphylococcus, Cooking tests. Considered Mandatory law, raw material, allergens, sampling plan, process flow, regulation, shelf life, qualification process, technical specification, cooking parameters in order to guaranty food safety 70 °C x 2 minutes in order to confirm cooking information in oven 200°C 12 min + 4 minutes. Seen Shelf Life on Condiscoglio dated April 2021: conforming after 24 months

#### 5.7 Product release

Release via software AYAMA  
IO 8.4. 33 CONTROLLO QUALITA' MATERIE PRIME PRODOTTO FINITO IN USCITA issue 10 dated 11.09.2023. The procedure for laboratory activity was definite in accordance at the QMS date and version Procedures are in place to ensure that release does not occur until all release criteria have been completed and release authorised. No products are held off site.

#### 5.8 Pet food and animal feed

N/A

#### 5.9 Animal primary conversion

N/A

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

Clause/Section Ref	Justification
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5.3.5	No rework used or reworking operations carried out
5.5.3	No obsolete packaging in use
5.8	No Pet food and animal feed
5.9	No animal primary conversion

<b>6. Process control</b>	
<b>6.1 Control of operations</b>	
<p>Process specifications resulted being in accordance with the finished product specification, verified Process monitoring checks conducted include receipt checks, process control, packaging control,</p> <p>Monitoring procedure defined as follows:          CCP1: Temperature monitored in continuous, alarm on site and sms message in case of loss of control, plus QC check correct functioning every 30 minutes, records provided and signed. CA in case of loss of check: rejection of the batch. Seen records on checked records 12/12/2022 signed by Quality Control operator.          CCP2: Temperature monitored in continuous, alarm on site and sms message in case of loss of control, plus QC check correct functioning every 60 minutes, records provided and signed. CA in case of loss of check: rejection of the batch. Seen records on 12/02/2022 signed by Quality Control operator.          CCP3: Metal detector monitored every hour by QC, records provided and signed. CA in case of loss of check: rejection of the batch. Seen records on checked records 1/02/2022 signed by Quality Control operator.          Dedicated records defined, available and checked during audit. CA are in place for deviation of standard parameters and procedure is in place in case of equipment failure. Equipment settings are completed by authorized trained personnel only.</p> <p>Presence of additional control measure not classified as CCP: PRPO: The temperature in the loading Critical limit (T&lt; -18°C); monitoring continues; PRPO: XRAY detector 2mm Stone. X-ray: 2,5mm Fe, 3,0 mm NFe, 2,5mm, SS, 2mm Glass monitoring hourly; PRPO: frying in oil 180°C monitoring hourly; PRPO: Oven cooked 160°C - 200°C monitoring hourly; PRPO verifies labeling and legibility; PRPO defrosting temperature (&lt;0 °C) via radio frequency measurement on the product for every batch, cycle</p> <p>At the audit time randomly checked the production management for Shellfish sauce with scampi, prawns and lobster meat 300g FiorFiore Coop batch 220124 BB 07/25; "Mare e Orto" brand Arbi mix of molluscs, crustaceans and broth with vegetables 300g 230124 07/25; "Misto Scoglio" Arbi brand, mix of molluscs and crustaceans with fish broth 230124 07/25; "Condiscoglio" with tomato sauce brand Arbi 450g 240124 07/25.</p> <p>VALIDATION.</p> <p><b>FISH SPECIES CHARACTERIZATION</b> Laboratory IMPRINT ANALYTICAL cleaning method PRC DNA to verify cleaning efficiency.  <b>METAL DETECTOR</b> Validation method of CCPs: example MD considering continue test and memory test</p>	

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PRO IO751 /19 METAL DETECTOR VALIDATION.

**INTERNAL LABORATORY PCR**, Ring test, 1 operator (Caterina Giuntini), Salmonella as target, , LGC circuits result conform, detected;

**ALLERGEN FREE** Cooking area and industrial plant, surface and water rinse, allergens SO2, crustacea, sulfuric anidride,

**CIP VALIDATION**, Third part service provider DIVERSEY.

**CONDENSATION LINE L**. line analysis with condensation situation that could be created between the upper floor and the underlying environment. Attention to operators and control by QC.

**COP CLEANING VALIDATION** Washing procedure with UNIFORM 3% detergent + TEGO 51 disinfectant; Surface test conform, CBT, Coliforms, Enterobacteriaceae listeria, salmonella.

**CROSS CONTAMINATION GLUTEN FREE VALIDATION**, Contact Surface test line H (area with gluten) after cleaning absence of gluten, laboratory MERIEUX.

**VALIDATION OF PARK PRODUCT IN ANTICELLE**. Considering the thermal increase of the product before loading with evaluation of the external temperature, anti-cell temperature, load compartment temperature. Tolerate time 1 h.

**DEEP FREEZING TUNNEL SETTING** worst case scenario product <-18 °C;

**OPRP XRAY DETECTOR VALIDATION**; acceptable limit for repeatability 1,5 mm fe, 2,0 mm ss., 2,5 mm no Fe glass.

**VALIDATION COOKING CHILLING**, Test performed considering the initial temperature of fish sauce 80°C and time to reach target temperature 4°C before product assembling. Time required 40 min.

**LENGTHENING OF POWDER INGREDIENTS SHELF LIFE HACCP MANUAL 8.3** shelf life extension for raw material to be cooked in process, microbiological and organoleptic control, 6 months lengthening.

## 6.2 Labelling and pack control

Procedure to managed label and pack control as in site, IO 8.4\_33 "Controlli qualità materia prima\_imballaggio primario\_in arrivo\_prodotto finito in uscita" rev9 of 20.04.2022. Adherence to packaging allocation procedure was observed during product changeover ensuring pack clearance before starting 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.

At the audit time randomly checked packaging and labelling operation for Shellfish sauce with scampi, prawns and lobster meat 300g FiorFiore Coop batch 220124 BB 07/25; "Mare e Orto" brand Arbi mix of molluscs, crustaceans and broth with vegetables 300g 230124 07/25; "Misto Scoglio" Arbi brand, mix of molluscs and crustaceans with fish broth 230124 07/25; "Condiscoglio" with tomato sauce brand Arbi 450g 240124 07/25

Seen product changeover from Shellfish sauce with scampi, prawns and lobster meat 300g FiorFiore Coop batch 220124 BB 07/25 to "Mare e Orto" brand Arbi mix of molluscs, crustaceans and broth with vegetables 300g 230124 07/25: verified label changed, checks on product name and batch of the first product produced after changeover, hygiene clearance verified. Staff was interviewed and was properly trained on changeover procedure.

## 6.3 Quantity, weight, volume and number control

IO.7.5.1/2 "SET UP LINEA" rev. 2. Frequency of checks: 100% weight check with automatic rejection system in place and concerning verification the frequency of quantity checking is respected on refer Italian legislative requirements DPR 690/78 and EU legislation. In case of BtB packaging the packaging and weight is done manually with target to reach the declared quantity. The company use "e" mark on packaging for retail units.



At the audit time randomly checked Shellfish sauce with scampi, prawns and lobster meat 300g FiorFiore Coop batch 220124 BB 07/25; "Mare e Orto" brand Arbi mix of molluscs, crustaceans and broth with vegetables 300g 230124 07/25.  
e-mark on packaging.

6.4 Calibration and control of measuring and monitoring devices

Procedure "IO 7.5.1/1 – ISTRUZIONE TARATURA E VERIFICA date 5/11/2018 is available and implemented. Software CARL with list of instruments to be verified.

The procedure for calibration activity, was definite in accordance at the QMS. 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. List of measurement instrumentation include processing and laboratory.

Example checked.

- Thermometer in production verified annually, last one on 15.12.2023;
- Thermometer in freezing tunnel calibrated annually, last one 16.10.2023;
- Metal Detector calibrated annually, last one dated 23.02.2023;
- Tank Probe Sm113 calibrated annually, last one 18.12.2023;
- Weight balance Skin line Combi Line A calibrated annually, last one dated 25.01.2023.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
6.3.2	No bulk quantities packed

7. Personnel

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

Training program year 2024 in place v.0 1/01/2024  
Main training: Food defence (all participants), Food safety culture (all participants), HACCP Training course, incoming good check, yearly mandatory GMP, certification traceability MSC  
The company ensures that all employees are adequately trained, instructed, and supervised commensurate with their activity and are demonstrably competent to carry out that activity. The procedure for training activity was definite in accordance at the QMS PQ 7.1.2 "RISORSE UMANE" v.4 19/12/2019 and the Prerequisite on HACCP plan. The procedure for training activity was definite in accordance at the QMS; the training program of assessment and refreshment are approved annually.

Trainings and monitoring records checked during audit:

- 19.09.2023 to 8 operators on cell management;
- 02.10.2023 on CCPs and GMP to 46 operators;
- 14.12.2023 on HACCP, hygiene, packaging and labelling procedures to 40 operators;



- 13.12.2023 on GMP and production operations to 4 operators.  
Test questionnaire, output, training, communication.

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

IO 7.2.1 rev. 5 “IGIENE DEL PERSONALE E BUONE PRASSI IGIENICHE”. Date 22/04/2021  
The Organization defined and documented the hygienic standards for the personnel of manufacturing department. These standards are formulated with due regard to risk of product contamination and are included in the company handbook issued to all staff. All staff were noted to be observing the rules and visitors, including the auditor, are briefed before entry to the factory is permitted. The jewellery policy is fully documented. Eating and drinking are only permitted in the social area. Smoking is only allowed in the external smoking area. Personal medicines are only allowed in personal lockers, unless authorised by management. Metal detectable plasters of distinctive colour are in use

7.3 Medical screening

Notification by employees regarding infections and similar is properly managed. Medical screening according to Italian law requirements. there is information about symptoms of infection and disease and there is a specific commitment to the staff to advice in case of disease. This document is a topic during the general training.

7.4 Protective clothing: employees or visitors to production areas

Low microbial risk areas (products to be cooked before eaten). Provided by Company 3 clothing sets, provided to all production staff. Disposable mob hats provided. Safety shoes also provided. Third part laundry supplier provider ALSCO.

Disposable visitor coats and hat provided. Protective clothing is removed on leaving the production areas. Seen Sheet Mod. 7.5.1/15 “AUTODICHIARAZIONE VISITATORI”. The frequency of Personal hygiene audits is adequate (schedule Mod 7.5.1/1 “MONITORAGGIO PREOPERATIVO”). Blue gloves used “no bare hand” policy, only disposable gloves changed at every batch change.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
//	//



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<b>8. Production risk zones – high risk, high care and ambient high care production risk zones</b>
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
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

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8	No high-risk / high-care areas defined
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**9. Requirements for traded products**

**9.1 The food safety plan - HACCP**

Traded products are approved according to procedure PQ 8.4\_1 Acquisti materiali rev. 15 of 23.12.2022, based on hygiene risk (definite on HACCP plan) and quality impact to the product with suppliers / materials: allergen contamination, foreign-bodies risk, micro/chemical contamination, substitution or fraud are taken into account in suppliers risk assessment.

Traded product supplier's approval is based on certificates in possess, questionnaires, documentation available, HACCP studies, eventual NC encountered, possible complaints received by the company for traded products. Products are realized on company brand; 1 private label products is involved.

- Cabomar (Producer: Nuestro Mar De Siempre), IFS COID 66524 EXP 10.02.2024 for Argentine shrimp 400 g
- Cabomar (Producer: SeisOitoFish), IFS COID 66757 exp 06.02.2024, sliced Verdesca 400 g, sliced swordfish 400 g
- Dalian Guofu,, BRCGS site code 6137187 exp 17/08/2024, IFS COID 52455 exp. 13/07/2024 for redfish fillet
- Gadre Marine, BRCGS site code 1057007 exp 04.04.2024, for breaded crab claws
- Heiploeg, BRCGS site code 1214329 exp 29/06/2024, IFS COID 2340 exp 02/03/2024 for shelled shrimps
- Hongqiao (Producer: Home Sea International) BRCGS site code 1161215 exp 19/11/2024 for Alaska Cod fillet
- Keshodwala Foods BRCGS site code 9244550 exp 16/04/2024 for squid
- Morubel BRCGS site code 2092118 exp 03.03.2024, IFS COID 1402 exp 27.03.24 for shelled shrimps
- Pesciro SL (Producer: Viet Truong), BRCGS site code 4173204 exp 30/06/2024 for clams
- Pesciro (Producer: Fujian Dongshan), BRCGS site code 1005753 exp 11/08/2024 for squid
- Seafrost, BRCGS site code 1655180 exp 04.01.2025 for squid rings
- Sonia Fisheries Pvt Ltd. BRCGS site code 1554641 exp 19/12/2024 for squid
- St. Andrews BRCGS site code 1620466 exp 21/02/2024, IFS site code 49789 exp 11/03/2024 for Mussels
- Thanh Hoa, Art. 9473, BRCGS site code 7068488 exp. 28.04.24, IFS certified COID 81742 exp 13.05.2024 for clams
- Trong Nhan Seafood BRCGS site code 6217777 exp. 08/02/2024 for tropical prawns
- VG Italy (Producer: UAB Plungės kooperatinė prekyba) BRCGS site code 1324532 exp 02.04.2024 IFS COID 7816 exp 16.06.2024 for crab fingers.

Risk assessment during supply chain is done on annual basis, last of 18/01/2024.

This includes also the risk assessment for substitution or fraud. No products at risk were identified.

Checked the traded products supply specifications shared and signed by both parties (company, outsourcing companies).

**9.2 Approval and performance monitoring of manufacturers/packers of traded food products**

All manufacturers and packers of traded products are certified:

Traded products are realized by GFSI certified:

- Cabomar (Producer: Nuestro Mar De Siempre), IFS COID 66524 EXP 10.02.2024 for Argentine shrimp 400 g
- Cabomar (Producer: SeisOitoFish), IFS COID 66757 exp 06.02.2024, sliced Verdesca 400 g, sliced

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swordfish 400 g

- Dalian Guofu., BRCGS site code 6137187 exp 17/08/2024, IFS COID 52455 exp. 13/07/2024 for redfish fillet
- Gadre Marine, BRCGS site code 1057007 exp 04.04.2024, for breaded crab claws
- Heiploeg, BRCGS site code 1214329 exp 29/06/2024, IFS COID 2340 exp 02/03/2024 for shelled shrimps
- Hongqiao (Producer: Home Sea International) BRCGS site code 1161215 exp 19/11/2024 for Alaska Cod fillet
- Keshodwala Foods BRCGS site code 9244550 exp 16/04/2024 for squid
- Morubel BRCGS site code 2092118 exp 03.03.2024, IFS COID 1402 exp 27.03.24 for shelled shrimps
- Pesciro SL (Producer: Viet Truong), BRCGS site code 4173204 exp 30/06/2024 for clams
- Pesciro (Producer: Fujian Dongshan), BRCGS site code 1005753 exp 11/08/2024 for squid
- Seafrost, BRCGS site code 1655180 exp 04.01.2025 for squid rings
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- Trong Nhan Seafood BRCGS site code 6217777 exp. 08/02/2024 for tropical prawns
- VG Italy (Producer: UAB Plungės kooperatinė prekyba) BRCGS site code 1324532 exp 02.04.2024 IFS COID 7816 exp 16.06.2024 for crab fingers.

### 9.3 Specifications

Technical data sheet including product parameters allergen-Gmo-mycotoxins statement are available for every traded product. Moreover, traded products suppliers are required to sign the supplier's specification every commercial agreement. There are 25 traded products at all, one produced by each supplier. All products are labelled by supplier.

Checked the specifications shared with sign by both parties and approved, eg:

- Pesciro SL (Producer: Viet Truong), IFS BROKER COID 72433 exp 28.07.2024, BRCGS site code 4173204 exp 30/06/2024 for clams, Techn. Spec "Vongola Guscio Brown 500g" rev 4 of 23.06.2023.

### 9.4 Product inspection and laboratory testing

The company has a schedule of analysis, based upon risk assessment, that cover raw materials, final products and packaging. These schedules include chemicals and microbiological testing. Last update of 13.10.2023.

For trade products analysis provided by supplier is commissioned according to risk assessment.

Seen analysis of the following products:

Lidl Vongola Guscio supplier T. (Vietnam) 24/10/2023, Lot KS2306301/A BB 15.06.2025.

### 9.5 Product legality

Labelling is in line with legal requirements. Labelling information is reviewed whenever changes occur. There are in place different label typology. At the audit time randomly checked: Frozen clams 500 g, art. 4010; see tech spec. "Vongole con guscio" 500g.

### 9.6 Traceability

Traceability Systems is defined in the dedicated procedure "PQ 8.5.2\_1 – IDENTIFICAZIONE, TRACCIABILITÀ E CONSEGNA", rev.3 07.04.2021 was available and implemented for raw materials, finished products and packaging materials. "PROGRAMMA DI TRACCIABILITÀ, issue 4 dated 16/02/2018 is present. The responsibilities were determined. Upstream traceability tested regularly done, mass balance product to customer, e.g.:

Art 4010 Vongola Guscio g.500, lot KS2310510, BB 06.10.2025, delivery of 14.12.2023, supplier T (Vietnam), sent to customer with 10 delivery from 18.12.2023 to 23/01/2024, eg: DDT n° 24BD100-1000256 in date



23/01/2024, customer A. (GDO).

**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)**

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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.

<b>14.1 Additional Specifier Requirements</b>
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.

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