

Audit Report **Global Standard Food Safety Issue 8**

1. Audit Summary			
Company name	RODOLFI MANSUETO SPA	Site Code	8506055
Site name	RODOLFI MANSUETO S.p.A.		
Scope of audit	Production (evaporation, acidification, mixing, pasteurization) of tomato products (pulp, puree, concentrate, sauce) in different kind of packaging (aseptic plastic bag or Bag in Box, can, tube, glass bottle or jar).		
Exclusions from scope	Production (dehydration) of dried, spray dried tomato powder/flake in plastic big bag or bag. Production (mixing, pasteurization) and packaging of pesto sauce in glass, in tube. Production (cutting, acidification, salting, mixing) and packing in bulk of chilled semi-processed basil products. Traded products: Tomato paste in single dose, tomatoes sauces in glass, in squeeze plastic units.		
Justification for exclusion	During the summer season, the company produce only from fresh tomatoes, furthermore an extension audit will be planned in October to verify production of dried, spray dried tomato powder/flake in plastic big bag or bag, and production and packaging of pesto sauce in glass jars, in tube and in June to verify production of chilled semi-processed basil product packed in bulk. Traded products are realized by another legal entities and excluded.		
Audit Start Date	2022-08-04	Audit Finish Date	2022-08-05
Re-audit due date	2023-08-25	Head Office	No

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

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit Programme	Announced
Previous audit grade	A		Previous audit date	2021-07-28	
Certificate issue date	2022-09-10		Certificate expiry date	2023-10-06	

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Auditor: Barbara Ellena



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2. Audit Results		
Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	6

3. Company Details			
Address	Via Mansueto Rodolfi 3, 43044 - Ozzano Taro - Collecchio (PR)		
Country	Italy	Site Telephone Number	+39 0521 333111
Commercial representative Name	Guido Montecchi	Email	guido.montecchi@rodolfimnsueto.com
Technical representative Name	Giovanni Mainardi	Email	giovanni.mainardi@rodolfimansueto.com

4. Company Profile					
Plant size (Metres square)	10-25K sq.m	No. of employees	51-500	No. of HACCP plans	4-6
Shift Pattern	3 shifts 6-2pm, 2-10pm, 10-6am				
Subcontracted processes	No				
Other certificates held	ISO 22005, ISO 14001, Organic, Kosher, Halal, SA8000, ISO 45001, QC according to Regional Disciplinary on tomato growing				
Regions exported to	Europe North America Asia Oceania South America Choose a region				

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4. Company Profile

Company registration number	1879 05/02/2016
Major changes since last BRCGS audit	None, current maintenance of equipment and infrastructure only.

Company founded in 1896 extending its activity through years and being specialized in tomato products as well as pesto processing.

The company has three plants, one in Ozzano Taro/ Collecchio (province Parma) object of current audit, one in Fontanini (province Parma) and the third in Castelguelfo (BO). Annual Group turnover 101 MIO €, annual group production of 99500 tons of finished products, Ozzano plant 48000 tons. f the plant: 1950/2014 Registration number of companies: FDA: 10461955508, local authorities: protocol. No. 1879 of 05/02/2016. Company specialized in processing of tomato and vegetable products. In 2021 no new investments for Ozzano plant, current maintenance of equipment and infrastructure only. Emergency contact data Name Aldo Rodolfi, phone: (+39)3392154786, email: aldo.rodolfi@rodolfimansueto.com. Product groups and products per group: pulp, puree, concentrate, tomato powder, semi processed basil product (basil content 65%). Traded products: excluded because produced by other legal entity. No. 305 of employees: own employees' full time: 86, part time: 1; temporary: full time 64; part time: 133; leased: 21; no. of shifts: 4 for 7 days a week during fresh tomato production (06-12/12-18/18-24/24-06), 3 shifts/5 days out of campaign. Seasonal breaks more than one week: during Easter, 2 a Christmas e 2 from end June and Beginning July. Outsourced processes: none. Ozzano plant produces the 60% of group turnover. the 96% of retail market is from PL.55% for export (80 countries, USA, EU, Australia) and 45% for Italian Market, Group turnover is about 1/3 as retail, 1/3 H.O.R.E.C.A. and 1/3 B2B, the 60% of retail market is from PL, Ozzano plant turnover is about 96% for retailer and 4% for HO.RE.C.A. Site area in square meters: production area incl. storage: 17.000 sqm, whole premises incl. outdoor area: 45.000 sqm, Use of BRCGS logo: no. Reasons for audit time reduction: N/A, Other certification: IFS, ISO 22005, ISO 14001, Organic, Kosher, Halal, SA8000, ISO45001, QC according to Regional Disciplinary on tomato growing, ISCC plus certification is ongoing. Exclusions: traded products. Audit performed by audit team.

5. Product Characteristics

Product categories	<p>11 - Low/high acid in cans/glass</p> <p>15 - Dried food and ingredients</p> <p>Category</p> <p>Category</p> <p>Category</p> <p>Category</p> <p>Category</p>
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5. Product Characteristics					
Finished product safety rationale		pH <4.6 from 4.3 to 4.6 aw >98, aw <98 ph<4,3 pasteurization thermal treatment equivalent F0> 0.7 (aseptic pulp, puree), F100> 10 (boxes), F85> 5 (tubes), Aw< 0,6 for dry.			
High care	No	High risk	No	Ambient high care	No
Justification for area		According to decision tree with hurdles technology intrinsic and extrinsic that does not support the grow of microbial pathogens.			
Allergens handled on site		Celery Milk Egg Nuts Choose an allergen Choose an allergen Choose an allergen			
Product claims made e.g. IP, organic		Organic, integrated supply chain according to ISO 22005, 100% Italian tomato, organic, Kosher			
Product recalls in last 12 Months		No			
Products in production at the time of the audit		Rich and tasty pulp in pieces Ortolina 400 g batch R1LF216 BB 12/2025. Tomato pulp cubes R6 206 kg lot R1F216 BB 04.08.2024. Pulp Ardita Super Pizza 2x5 kg lot R1LF216 BB 08/2024. Aseptic drums 235 Kg batch R1F216 BB 04.08.2024. Pureed Ortolina 690 kg lot lot R1LF216 BB 08/2025: Polpa Pizza Fine Alpina 4050 g lotto R1LF216 BB 06/2025. Double Concentrate Tomato Paste 130 g lotto R1LF216 BB 08/2025. Oro di Parma Tomaten Stuckig Bella Italia 400 g lotto R1LF216 BB 12/2025			

6. Audit Duration Details			
Total audit duration	28 man hours	Duration of production facility inspection	14 man hours
Reasons for deviation from typical or expected audit duration	Extra time added due to IFS combined audit		
Next audit type selected	Unannounced		

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Audit Duration per day			
Audit Day	Date	Start Time	Finish time
1	2022-08-04	08:30	18:00
2	2022-08-05	08:30	15:00

Audit Team	Auditor number	Name	Role
Lead Auditor	20142	Barbara Ellena	Lead Auditor
Second Auditor	21676	Flavio Munegato	Auditor

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
Gian Paolo Ghiretti HACCP team leader, Laboratory Manager	X	X	X	X
Manuela Biacchi Quality Control	X	X	X	X
F. Bonvini Factory Mgr	X	X	X	X
Daniele Burani External Consultant	X	X	X	X
Francesca Savani Laboratory	X	X	X	X
Alice Strazer Quality Assurance	X	X	X	X
Chiara Bellaghi Employee at raw Tomato acceptance area		X		
Chiara Mazzocchi Employee at cans labelling		X		
Giacomo Vernazza Head of shift at Bag in box area		X		
Domenico Ravo Warehouse		X	X	
Mr. A. Ceci Maintenance		X	X	

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GFSI Post Farm Gate Audit History		
Date	Scheme/Standard	Announced/Unannounced
2020-08-13	BRCGS	Announced
2021-07-28	BRCGS	Announced
2022-08-04	BRCGS	Announced

Document control			
CB Report number	ITTO.20120061B		
Template Name	F834 Food Safety Audit Report Template v11		
Standard Issue	8	Template issue date	2022-02-15
Directory allocation	Food	Version	1.0

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Non-Conformity Summary Sheet

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

Critical			
No.	Clause	Detail	Re-audit date

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

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Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	3.2.1	The form used for records of monitoring of water coloration is not identified as document of QS	Form has been codified in "Mod.9.1-23 Quaderno di registrazione tenore cloro, rev.0 of 08.08.2022"	Check for the presence of other non-coded modules	Pre-printed records deemed compliant.	2022-08-24	Barbara Ellena
2	3.6.1	Specification of Passata Pomodoro 8-9 Fusti e combi rev.10 del 26.4.2022 it is not specified the geographic origin of Citric acid requested	Updated technical sheet Passata Pomodoro 8-9 Fusti e combi with Citric Acid geographic origin	Extraordinary Internal audit on Chapter 3 with highlight on 3.6 requirement to check all customer requests and update internal process of material specifications approval.	Forget to update the information on the Data Sheet	2022-08-24	Barbara Ellena
3	4.5.1	Analysis plan of water is not supported by specific risk assessment	Water risk analysis has been prepared (ALL.PO.26) attached to PO.26.	Annual water risk check for updating the procedure and analysis plan	Risk assessment not explicit in the procedure	2022-08-24	Barbara Ellena
4	4.7.3	Presence of equipment not in use resulted not suitability protected in order to maintain hygienic condition	Equipment not in use has been removed	Check the absence of unsuitable equipment in "MOD.9.1-1 Controlli avvio linea" with QA coaching activity 1-2-1 to increase GMP- GHP awareness.	Delay in removing the equipment	2022-08-24	Barbara Ellena
5	5.4.2	Documented vulnerability assessment does not consider all required aspects (e.g. detectability)	Documented vulnerability assessment has been revised	Annual fraud risk assessment under management review Extraordinary Internal audit on Chapter 5 to guarantee	Although the documented vulnerability assessment did not consider some aspect such as the	2022-08-24	Barbara Ellena

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Minor							
				compliance on standard requirement	analysis, tests, or specific checks, that are needed, however they were indicated on specific documents of internal quality system		
6	7.2.1	Unlike the hygiene rules, one operator of external cleaning provider operators was not wearing a beard cover. At that step products is not open	Training for the operators of the external company carried out.	Specified control in MOD.PG.10.4 Ispezione igienica GMP_GHP_ozzano_rev.2 by the Shift Manager with QA coaching activity 1-2-1 to increase GMP-GHP awareness.	Operator error	2022-08-24	Barbara Ellena

Comments on non-conformities

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Critical			
No	Clause	Detail	Re-audit date

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

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

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Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Integrated Group / Site POLICY reviewed on 6.7.22 in rev. 7, signed by GM Aldo Rodolfi, update with ISSC plus requirements, containing also main objectives Company policy is affixed in staff dashboards and handed to all operators.

Target objectives defined in MOD.PG 12-1 for macro areas and for each group owned plant R1/2/3 and food safety, environment, safety on work, certification maintenance, customer satisfaction, training program.

Examples of target reached: Customer complaints / tons of sold product: target <10/113.327-tons, result 2021 10/100000 tons; Analysis non - conformity / finished product total analysis x 100, target <1%, result <1%; Staff training program completion: 100% completion, Structural improvements: investments realized. Since previous audit 1 AUSL audit on 17.03.2022, no NC or observation raised. Since last audit 1 remote audit by customer "A" the 06.07.2022 and "S.U" the 20.08.2021, no NCs raised.

The Management Review is performed with annual frequency (last performed on 07/07/2022) and is aimed to elaborate an improvement plan shared by the different company functions. Tons of tomatoes processed 113327 in OZZANO TARO Plant, Annual Group turnover 101 MIO €, annual group production of 99500 tons of finished products. 100% close non-conformity. Resources available and identified in order to reach objective targets. The quality objectives and strategies are coherent with the company's policy.

Quarterly meeting programs is performed by central departments and top management for all Group site (Ozzano, Fontanini, Castelguelfo). The commitment to customer satisfaction is defined in the QM and is monitored by means of CS index and analysis on complaints. Monthly and quarterly meeting programs performed by central departments and top management. Last done in date 27.04.22 – 28.1.22 and 15.7.22

Food safety culture plan in place at group level and fully detailed and developed on long term period updated 2022-2023 update the 7.07.2022, which includes: meetings where communication of food safety KPIs is carried out, last one dated 07.07.2022 increase training for all staff. Some actions are planned in order to increase food safety culture i.e. staff survey focused on food safety culture are planned for the next year and training refresh on product safety objectives is planned for September-December 2022.

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 box is in place

Site remains updated with any legislative changes being subscribed on ANICAV, external consultancy group Gelati, Authority web sites and documentation issue, RASSF, EFSA, newsletter, IFS newsletter and newspapers.

Raw tomato is practically a 0 km raw material and vegetables are of Italian origin, agronomic service follows agricultural parcels of OP organizations

No relevant changing since last year with impact on organization, equipment.

The site has a copy of the latest standard available. The company properly uses BRCGS logo.

The Corrective actions from the previous audit have been correctly implemented without recurrence.

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1.2 Organisational structure, responsibilities and management authority

The Organisation Chart was updated (Organization chart Rev 14 dated 26.04.2022) for every production site of the Company, update for Castelguelfo plant and new resourced in Purchasing department. Operators are sensitized and aware of their own skills and responsibilities, all staff have access to relevant procedures. Job descriptions (rev 4 of 15.07.2021), in place for all managers and supervisors and responsibilities, substitutes in a dedicated attachment with all signs including substitutes. Appropriate documented arrangements are in place to cover for the absence of key staff.
 Production Mr. Bonvini; Laboratory Mr. Ghiretti, Quality Control Ms. Biacchi, Quality Assurance Ms. Alice Strazer, Planning tomatoes reception Mr. Minardi.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification

2 The Food Safety Plan – HACCP

HACCP Study and Manual last updates rev.11 dated 05.07.2022.

HACCP team leader Gian Paolo Ghiretti who is trained in and experienced with HACCP, the multi-disciplinary team comprises members from the following departments: Direction (Rodolfi) Production (Fabio Bonvini), Quality Control, Maintenance (Ceci Andrea). Competencies documented in place.

The pre-requisite has been identified in HACCP Manual chapter 2 (training, supplier selection, hygiene rules, cleaning and sanitation, waste management, environmental monitoring, pest control, chemical, physical risk, allergens, transport).

PRODUCT FAMILY: tomato paste, tomato concentrates, tomato powder (not in production during the audit), tomato diced, tomato sauce, semi-finished basil (not in production during the audit) tomato flakes.

Hurdles factor: pH <4.6 from 4.3 to 4.6, pasteurization thermal treatment equivalent F0> 0.7 (aseptic pulp, puree), F100> 10 (boxes), F85> 5 (tubes).

A full description of process and products are developed and documented in the HACCP Manual, which includes all relevant information on food safety (name, main characteristics, use modality, packaging, shelf-life, destination of use, instructions in label, ingredients).

Verified the description of products: canned tomato products (tomato paste, chopped tomato, puree, sauce) in different kind of packaging (aseptic sacks, cans, glass bottles - jars, and tubes). Typical shelf life is 12 months for powder, 40 for extrude, 30 for tubes, 36 can and glass bottles.

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Literature data, legislation and customer requirements have been referred to Guidelines and codes of practice of reference, e.g., SSICA, AESIA, FDA, CFRs and other sources.

PROCESS OVERVIEW: Receipt of raw materials, fresh tomato washing, blanching, cutting, dicing, sorting, acidification, dehydration, high pasteurization, hot filling, cold storage, water chlorine treatment, packing. All flow diagrams have been updated the 05 July 2022:

Flowcharts are present to different types of products.

- DF1 fresh tomato processing, on-site verification of 25.07.2022
- DF2 extruded tomato pulp; on-site verification of 25.07.2022
- DF3 chopped tomato; on-site verification of 23.07.2022
- DF4 concentrate tomato; on-site verification of 25.07.2022
- DF5 first step tomato processing - ARDITA; on-site verification of 23.07.2022
- DF6 hot filling canned tomato; on-site verification of 21.07.2022
- DF7 products packaged in glass; on-site verification of 21.07.2022
- DF8 product packaged in tube; on-site verification of 4.07.2022
- DF9 kitchen processing; on-site verification of 21.07.2022
- DF12 tomato aseptic in minipack and macro pack; on-site verification of 21.07.2022
- DF13 Spry Drying line (not in production during the audit); on-site verification of 25.05.2022
- DF13b Drying line (not in production during the audit), on-site verification of 25.05.2022
- DF14 tomato pulp and paste; on-site verification of 21.07.2022
- DF15 warehousing; on-site verification of 25.02.2022
- DF16 pesto processing (not in production during the audit), on-site verification of 12.07.2022.

Hazard analysis carried out for each flow chart (the last one dated on 05.07.2022) with all potential hazards identified and recorded; the scope of the HACCP plan has been confirmed. 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 considered, identified as pathogen microorganism like *B. cereus*, *B. subtilis*, *B. licheniformis*, *C. botulinum*, *E. coli* O157, *L. monocytogenes*, *Salmonella* spp., *S. aureus*, chemical like residues of pesticides, mycotoxins, heavy metals, radionuclides, allergens, foreign bodies specifically plastic, wood, glass and metal.

The team has used a 4 steps decision tree according to Codex Alimentarius scheme. For each DF the company has defined a Control Plan updated in July 2022. For each step, the company has analyzed the risk (PxG) and applied a decision tree in case of risk Medium or High.

Details in HACCP study and self-control manual section 3.3.

CCPs determined as follows:

DF1 fresh tomato processing. Rev 3 of 28.02.2020, verified in date 18.07.2022. There are not CCP;

DF2 extruded tomato pulp rev 4 of 28.02.2020, verified in date 25.07.2022; CCP1 mixing tank pH control with limit <4,5, every hour, responsible lab; CCP2 metal detector, limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final, responsible line; CCP3 pasteurization with on line Taylor record, critical limits different in function of size, temperature 96-98 °C, F100 >30 (critical F100>10); CCP4 aseptic filling; presence of red bullet on the packaging with visual check recorded in mod 9.1-13 “controllo imballi primario asettico”; pack sterility check and microbiologic check every batch.

DF3 chopped tomato rev 4 of 28.02.2020, verified in date 23.07.2022; CCP1 semi processed, product pH control with limit <4,5, every hour, responsible lab; verification made by laboratory with thermostatic,

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microbial check; CCP2 metal detector, limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final; responsible line; CCP3 HTST treatment with on line Taylor record, temperature 95 – 110°C, equivalent F0> 0,7, verification made by laboratory with thermostatic 30°C, microbial check; CCP4 aseptic filling; presence of red bullet on the packaging with visual check recorded in mod 9.1-13 “controllo imballi primario asettico”; pack sterility check and microbiologic check every batch.

DF4 concentrate tomato rev 6 of 4.07.2022, verified in date 23.07.2022; CCP1 metal detector limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final; responsible line.

DF5 first step tomato processing – ARDITA rev 4 of 28.02.2020, verified in date 23.07.2022; CCP mixing tank pH control with limit <4,25 for can and pH <4,45 for minipack, every hour, responsible lab; verification made by laboratory with thermostatic, microbial check;

DF6 hot filling canned tomato rev 3 of 28.02.2020 verified in date 21.07.2022; CCP metal detector, limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final, responsible line; CCP pasteurization, hot filling, with online Taylor record, temperature 95 – 110°C, F100 >30, verification made by laboratory with thermostatic 30°C, microbial check;

DF7 product packaged in glass or can rev 7 of 28.02.2020, verified in date 21.07.2022; CCP pasteurization, with online Taylor record, temperature 95 – 110°C, F100 >30, CCP XRAY detector 1,5 mm Fe, 1,5 mm SS, 3 mm glass, frequency every 2 h, line operator, CCP empty verify, automatic check in continuous, monitored each 2 hours with incorrect package.

DF8 product packaged in tube rev 3 of 28.02.2020, verified in date 4.07.2022; CCP pasteurization, with online Taylor record, temperature 87-90°C, F85 >5, verification made by laboratory with thermostatic 30°C, microbial check;

DF9 Kitchen processing rev.3 of 28.02.2020, verified in date 21.07.2022; CCP mixing pH control with limit <3,8-4,5, every hour, responsible lab.

DF12 tomato aseptic in mini & macro pack rev.4 of 28.02.2020, verified in date 21.07.2022; CCP1 HTST treatment with online Taylor record, temperature 95 – 110°C, F100 >30; CCP2 aseptic filling; presence of red bullet on the packaging with visual check; pack sterility checks and microbiologic check every batch.

DF13 spry dehydration lines rev.4 of 22.03.202, verified in date 25.05.2022; CCP1 sieve with critical limit <0,8 mm, monitoring every batch, monitoring by online operator, record in mod 9-21-5; CCP2 metal detector, limit 1,0 mm Fe, 2,0 mm ss, 1,6 mm no Fe, initial, 4 hours, final; responsible line, records in modulo controllo MD.

DF13b dehydration line rev.4 of 22.03.2021, verified in date 25.05.2022: CCP1 sieve with critical limit <1,3 mm, monitoring every batch, monitoring by online operator, record in MOD.9.21-5_

DF14 tomato diced/pulp/sauce and paste rev.4 of 05.07.2022, verified in date 21.07.2022; CCP1 mixing tank pH control with limit pH 3,80 - 4,50 manual control every batch, lab operator; CCP2 pasteurization with on line Taylor record, temperature 95 – 110°C, F100 >30;; CCP3 XRAY detector 1,5 mm Fe, 2,5 SS, 3 mm glass, frequency every 2 h, line operator, CCP4: Bottles sealing and dud detector, verification every 2 h, on line operator empty verify, automatic check in continuous, monitored each 2 hours with incorrect package.

DF15 warehousing rev 2 of 28.02.2020, verified in date 25.02.2022. There are not CCP;

DF16 semi-processed pesto processing rev7 of 15.06.21 verified in date 12.07.2022; CCP1 mixing tank pH control with limit <4,6 and % of salt according to recipe every batch responsible lab; verification made by laboratory.

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All records are signed by responsible (Quality Control and Laboratory operator) for the monitoring and verified by an authorized person. Records of monitoring were available. The method of monitoring and corrective actions to be taken in case of deviation. HACCP verification during management review.

Furthermore, CPs were identified, e.g.:

DF1 fresh tomato processing: Step washing and sorting fresh tomato puree extruded and diced lines: CP water potability Cl residual after cleaning 0,5 ppm, manual check every 2 h, corrective action Hypochlorite dosage adjustment.

DF2 extruded tomato pulp: Step empty metal tinplate cans blowing: CP blowing air pressure CL >2 bars, monitoring continuously with automatic line stoppages, record air blow pressure 1/shift by line operator; Sealing metal tinplate cans step CP % overlap CL according with diameter of can; Step cooling metal tinplate cans, cooling drums: CP water potability Cl residual after cleaning 0,1 ppm, manual check every 2 h, corrective action Hypochlorite dosage adjustment

DF3 chopped tomato: Step cooling drums: CP water potability Cl residual after cleaning 0,1 ppm, manual check every 2 h, corrective action Hypochlorite dosage adjustment.

DF4 concentrate tomato; Piping to filing lines step CP sieve 2mm, monitoring 1/shift.

DF5 first step tomato processing: there are not CP

DF6 hot filling canned tomato: Step empty metal tinplate cans blowing: CP blowing steam pressure CL >2 bars, monitoring continuously with automatic line stoppages, record steam blow pressure 1/shift by line operator; Sealing metal tinplate cans step CP % overlap CL according with diameter of can; Step cooling metal tinplate cans, cooling drums: CP water potability Cl residual after cleaning 0,1 ppm, manual check every 2 h, corrective action Hypochlorite dosage adjustment

DF7 product packaged in glass or can; Step empty metal tinplate cans or glass jars blowing: CP blowing air pressure CL >2 bars, monitoring continuously with automatic line stoppages, record air blow pressure 1/shift by line operator; Sealing metal tinplate cans step CP % overlap CL according with diameter of can

DF8 product packaged in tube: Step cooling tubes: CP t°<40°C

DF9 Kitchen processing; there are not CP

DF12 tomato aseptic in mini & macro pack; Step cooling drums: CP water potability Cl residual after cleaning 0,1 ppm, manual check every 2 h, corrective action Hypochlorite dosage adjustment

DF13 spray dehydration lines: pre-heating step: CP t°>96°C continuously monitoring; spray drying step CL 0.8 mm nozzles 240-260 °C air in the exsiccation chamber; Drying step CL moisture <4% monitoring 1/4hs; Cooling step CL >26°C monitoring 1/4hs; grinding step sieve CL diameter 1000 µm, sieve integrity every 4 h

DF13b dehydration line: Drying step CL moisture <4% monitoring 1/4hs; packing step sieve CL <6 mm, sieve integrity every 2 h and magnet 6000 gauss, record on mod MOD.9.21-6

DF14 tomato diced/pulp/sauce and paste; deaerator step sieves CL 4mm, monitoring 1/shift; Sieving step CL 4,0 mmm, monitoring integrity sieve 1/production batch; Step empty bottles glass blowing: CP blowing

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air pressure CL >2 bars, monitoring continuously with automatic line stoppages, record air blow pressure 1/shift by line operator; hot filling glass bottle step : CL 87°C monitoring continuously with automatic line stoppages, record filling temperature 1/shift by line operator; Capping machine step: CP overlap, CL > 5mm, monitoring every 2 h; Step cooling glass bottle: CP water potability CI residual after cleaning 0,1 ppm, manual check every 2 h, corrective action Hypochlorite dosage adjustment

DF16 semi-processed pesto processing. Sieving step: CL 5mm monitoring 1/shift;

Validation method of CCPs: Critical limits had been agreed and signed off by team. All CCPs are validated considering legislation, validation studies, industry best practice and commissioning studies, take in account Good Practice for tomato production according, seen Metal Detector dated 05/07/2022 and X-Ray the 06.07.2022.

Example of validation test performed by stability test on aseptic process on Tomato Pulp Aseptic Saks lines of 03.08.2022, with worst scenario for capacity of 12 tons

On pasteurizers test with probe inside 400g can in the cooler point, last the 28.7.2022 on Polpa Fine 400 g, filling temperature min. 65°C, hold time in tunnel hot area of 84 minutes. Result FZ10/100 = 52,17.

The company's HACCP plan is based on following updated and comprehensive information

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

The critical limits were validated with bibliographic study, for blowing phase.

Verification of HACCP system planned minimum annually, last documented dated 26.07.2022.

Last HACCP review dated 26.07.2022 after the completion of the verification process.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification

3. Food safety and quality management system

3.1 Food safety and quality manual

The company has implemented a Quality Management System in conformity to standard ISO model and

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documented in the Quality and SHE Management System Manual issue issue 0 dated 21.07.2017 with department specific work instruction manuals available on the company intranet; this was certified on refer IFS and BRCGS standard. Main Quality Management System with department specific work instruction manuals available on a shared drive within the company's network system. The documents are clearly legible in sufficient detail and in appropriate languages.

3.2 Document Control

Procedures PG1.1 rev1 of 28.07.2020 and PG1.2 rev1 of 30.07.219 in place for document and records management with Documentation. List updated on 14/06/2022 (related group documentation and site documentation). Documents available on paper and file too.

Evidence of compliance of documents clearly legible in sufficient detail and in appropriate languages. Verified the procedures for the Documentation and Registrations Management. The System was working effectively. Collection, review, maintenance, storage and retrieval of all records relating to product safety, legality and quality are properly managed.

1 NC raised

3.3 Record completion and maintenance

Records retained for a time consistent with the shelf life of products as indicated on technical sheets. The timing of the documentation and retention of records is 5 years. The max products shelf-life is 36 months.

3.4 Internal audits

Audit Plan ALPG.10.1 according to procedure PG 10 rev 1 of 15.5.2020 which covers all activities and departments at least annually with more than 4 internal audits assuring an ongoing and throughout the year activity and based on risk assessment and detailed on ALPG 10.1.

Seen report dated 27.10.2021 (3 NC), 03.02.2022 (6 NC), 12.04.2022 (5 NC), 04.05.2022 (4 NC), 14.6.2022 (no NC), 26.7.2022 (3 NC). Next planned in October 2022.

Audit report summary on Module "Verbale Verifica Ispettive" with activities defined as critical to food safety and product specifications and related areas: HACCP and quality system, PRPs, CCP/CP monitoring, plant structural conditions, production and process controls, traceability system. Audits carried out by trained competent external consultants (Gelati Group, Dott. Daniele Burani) based on GFSI checklist. NC are correctly reported in audit report and corrective actions have been defined and verified in subsequent audit.

Inspections on building/equipment performed daily by line leader and recorded in mod.9.1-1 Controllo avvio linea, seen records during the traceability test and during the site inspection. Monthly inspections are performed by quality office and recorded in mod.10.1 Checklist igienico structural (Structure, flour, building, external area, pest control, food defence), seen records dated 11.07.2022 and 18.06.2022. Also form Mod. PG 10.4 on prerequisite programs GMPs, hygiene, cleaning as dated 18.06.2022 and 06.07.2022

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

Common procedure PG 5 rev 4 of 28.03.2022 cover both RODOLFI MANSUETO SPA Fontanini and Collecchio sites for the evaluation and approval of suppliers.

Raw and packaging material risk and vulnerability assessment documented ALPG5.1 done for all raw materials, ingredients and packaging, annually reviewed and updated, seen last of 10.01.2022, confirmed also during management review 07.07.2022. 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. This

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is based on details from a raw material questionnaire. The suppliers are subject to audit or BRCGS/IFS certificate or Questionnaire (every year) before approval. Risk assessment is based on hygiene risk (defined in HACCP manual and in risk and vulnerability assessment done) and quality impact to the product with suppliers / raw materials: allergen contamination, foreign-bodies risk, micro/chemical contamination, substitution or fraud are taken into account in supplier's risk assessment.

The suppliers are subject to audit, or BRCGS/IFS certificate in possess or Questionnaire before approval. Raw material assessments at analysis form part of the ongoing review of supplier performance. Repeated analysis is carried out for possible problems.

Suppliers are continuously monitored on their performance with details inserted in approved suppliers list MOD 05.4 and final approval is done during management review, last on 07.07.2022

Scoring system used for risk evaluation based on parameters according to Standard (1-3: approved; 3-5 approved, but under observation; >6: not approved).

All raw materials are considered low risk, except for fresh tomatoes. Raw material assessments at analysis form part of the ongoing review of supplier performance. All suppliers of tomato have been considered low risk because the companies (OP Producers Organization) are ISO 22005 certified and perform audits on producers. Tomato producers are followed by agronomic services of OPs. The OPs filed for each producers' certificates, origin declaration, documental controls, campaign records and GMO-free declarations as well as laboratory analysis. All documents are available for company at the end of fresh production.

All suppliers of raw tomato are qualified based on certification traceability ISO 22005 as seen for AINPO expiry 10-11-2024.

The supplier of frozen basil is Ponzio, questionnaire 14.07.2021, BRCGS certified; EVO oil supplier Speroni BRCGS and Organic certified; garlic flavour supplier Bell Flavour questionnaire 19.05.2021.

Seen also examples of suppliers of packaging as glass bottle Zignago FSSC certified and questionnaire 21.4.2022; cans supplier Eviosis certified BRCGS Pack and questionnaire 24.05.2022; aseptic sacks Goglio questionnaire 19.07.2022 and certified BRCGS Pack; Termoplastica Nevianese supplier of plastic sacks for semi-processed basil is no certified and evaluated by questionnaire 04.07.2022.

Brokers are used, eg: Torchiani supplier of Chemical and additives certified ISO 9001, 14001, traceability test of 2021. Acid citric producer UNION certified BRCGS

No exceptions are managed.

Supplier records sampled as part of the vertical audit.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Raw materials are assessed on receipt, IO 09.2.1 di Programma annuale controlli sul prodotto rev. 10 Jan.2022. Raw materials are assessed on receipt. Acceptance control verified: product sampling and testing; visual inspection on receipt; certificates of analysis – specific to the consignment; certificates of conformance, Incoming check on tomato is classified as quality assurance inspector takes a sample to be subjected to the search for: inert, rotten tomato, green tomato, qualitative parameters. Tomato trucks enter after having had a code given by the company being the first traceability data entered into the system.

At the audit time randomly verified some incoming check, Eg.:

- Fresh tomatoes supplier Green Star di Sarzi Sartori Dino – ASIPO Pomodoro tondo cultivar 072 HEINZ 1879 delivery of 04 Aug. 2022, brix, pH, colour, defects. Sampling criteria based on 20 Kg randomly checked via automatic sampling. Conforming results from control done.
- Tubes supplier "A" batch OF-CMN202201474 delivery date 31.03.2022

3.5.3 Management of suppliers of services

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The same system is in place for suppliers of services as MM finished product storage service, CISA and Artoni for Transport, Stazione Sperimentale Parma SSICA for external lab analysis, Sistema Ambiente for pest control, Parma Control calibration, RAY-TEC for maintenance X-Ray detector. Contracts are available and yearly renewed. All suppliers of services have to be approved by the Quality manager and purchasing and entered onto the list MOD 05.4 before they can be used, last update for annual evaluation dated 07.07.2022.

3.5.4 Management of Outsourced processing

N/A, no outsourced processes or products.



3.6 Specifications

Raw material, ingredients and additives, packaging and finished product specifications are prepared, evaluated and managed in collaboration with both sites of RODOLFI MANSUETO SPA Fontanini and Collecchio and the contracts with suppliers are done by purchasing manager. Specifications are maintained by each site, QA department in charge for specifications. Specifications are available to interested staff and there are reviewed minimum each three years and each time modifications/changes occur. At the audit time randomly checked PRODUCT SPECIFICATION, eg:

FINISH Product

Finished product specifications are archived for products produced at company brands and for private labels. Checked product specification for:

“ORTOLINA POLPA PER PIZZA” in can 500gr Rev.1 04/07/2022 product code 111343001; “ARDITA SUPER PIZZA in can 5 Kg” rev.9 .18-05.2022 product code 11120522; “MINI PACK BAG IN BOX” aseptic 10 Kg Rev.8 13/05/2021, product code 111256002; “CHOPPED TOMATOES R6” drums and combo Rev. 8 01/03/2021 product code 12111003; “TOMATO PASTE 28/30 CB” in drums Rev. 10 11/02/2021 product code 125110008; “TOMATO PASTE 28/30 ALPINO” in tube 130g Rev.10 12/04/2012 product code 114111001; “TOMATO POWDER COLD BREAK” bag in box 25Kg Rev 10 13/04/2021 product code 117963002

Products at private labels are present, checked randomly “Cargill Japan” agreement contract KDA-22-TPI-1 “Tomato Paste Cold Break 28-30” of 28.06.2022 and Hengsternberg contract 504930 – 01.07.2022 “Oro Di Parma TB 200 g”.

RAW MATERIALS:

Raw tomato specifications are managed through contract with Producer’s Association (O.P.) and which are subjected to acceptance procedure at each receipt. Checked during the site inspection “Raw tomato, specification based on “Contratto pomodoro da Industria type A North Italy” crop 2022 with AINPO Società Agricola Cooperativa Parma. date 05.05.2022; Citric acid, specification, rev.1 of 18.2.2020 accompanied by conformity declarations received by supplier Torchiani, producer S.A. Citrique Belge), Frozen Basil, supplier “Ponzio” Techn. Spec of 1.09.2020 rev.10 Parsley juice aseptic bag 205 kg, supplier “Aureli”, Techn. Spec.rev.6 – 24.01.2022

Other raw materials specifications are electronically saved into personal computer for each supplier.

PACKAGING MATERIALS SPECIFICATIONS:

Tin cans from supplier “Eliosio”, specification rev. 4 dated 10.01.2022, (white enamel inside) and food contact compliance 24.03.2022; Glass bottles from supplier “Zignago”, technical specification dated 29.11.2021 and DoC of 05.01.2022; Plastic tubes from supplier “All Tube”, (capsule into PP + white enamel for food contact) of 02.12.2021 and food contact compliance 26.04.2022.; Aseptic bags from supplier “Scholle IPN” (metalized barrier laminate PE metal polyester/PE/EVOH/PE specification rev.20 November 2021 and food contact compliance 26.07.2021; White Cup glass Bottles, Supplier “Eliosio”, technical spec rev. 7 of 07/12/2021, DoC with migration test 24.05.2022.; Bag in Box supplier Goglio aseptic sack 10 l technical spec rev July 2022, DoC with migration test 06.04.2022.

Update status is verified by QA/QC personnel every 3 years.

1 NCs raised.

3.7 Corrective and preventive actions

CAs/PAs managed according to QM and procedure PG07 “Gestione nc, ac e reclami clienti”, rev.1 of 13.05.2022. All CA/PA sheets contain suitable root cause analysis and verification on effectiveness. Seen management on relevant register Mod 7.1 of CA date 11.5.2022 coming from complaint referred to “Polpa

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Super pizza 10 kg” lot R1LF061 due to foreign body (piece of label”). CA was refresh training to involved operators, closed and verified 27.7.2022.

3.8 Control of non-conforming product

NC managed by software and pc. Procedure PG07 rev.1 of 13.05.2022. Clear process well understood by staff interviewed during the audit according to procedure described. No major trends considering the very large number of produced goods. In general NC are detected directly during process controls and consequently managed real time. The number of NC is part of KPI/objectives. Seen appropriate management of NC product during the audit. Checked NC 5.5.2022 referred to “Pizza sauce origano” lot LF125 due to rheological defect, product was blocked and re-processed.

3.9 Traceability

Traceability system according to procedure PG.06_Rintracciabilita_ritiro-richiamo rev 8 of 13.04.2022. Traceability system operates through IT system and paper documentation, enables trace of tomato, other ingredients and packaging from supplier through processes, to packing and despatch and vice versa. Appropriate management of rework material. Tomato is traced by intake records and pool batch combined with receipt day. Traceability system reaches up to tomato producers considering a "pool" batch.

TESTS PERFORMED BY AUDITOR:

- 1) Doppio concentrato BIO CENTO 130 g batch R1LF103, produced 62880 units on 13.04.2022, BB 2025-04, at audit time delivered to “A./C.F.F.” the 28.04.2022 41808 units, the 29.04.2022 4032 units, the 3.05.2022 12096 units and the 12.07.2022 792 units. Losses 4152 units for damages. Seen traceability of raw material 12.07.2022 batch R2U214 (of 2.08.2021), BB 31.08.2023, 16 drums from Rodolfi Mansueto Castelguelfo plant, delivered to Ozzano plant the 08.04.2022 and batch R2U215 (of 3.08.2021) BB 31.08.2023 12 drums from Rodolfi Mansueto Castelguelfo plant the 7.7.2021, Tubes batch R2U215 supplier “A”,. Reconciliation with quantity packed, in-process controls up to raw materials receipt document and shipping documents accompanying, confirming correct lot received as declared. Accurate results with test completed in 2 hours.
- 2) Passata Basilico Cles BTG 700 g batch R1LF080 BB 21.09.2024, produced the 21.03.2022, 67626 units, delivered 67626 units to customer “T” from 06.04.2022 to 17.06.2022, 282 units losses for damages. Reconciliation with quantity packed, in-process controls up to raw materials receipt document and shipping documents accompanying, confirming correct lot received as declared. Accurate results with test completed in 2,5 hours.

Company traceability test carried out every year on both directions, up/downstream:

- From Finish Product to raw material carried out the 30.05.2022 on 100 Petite Diced Tomatoes SC 400 g batch R1LU261 of 18.09.2021 produced 125160pz from fresh tomatoes delivery of 10.08.2020, citric acid batch UJ023/1.24004-761, salt ATI batch LC 19/05/26. Fresh tomatoes from 22 suppliers, based on supply chain specification eg.: supplier Azienda Agricola Bulfari ddt 004402, according with “pool” batch.
- From raw material to finish product carried out the 20.09.2022 for fresh tomatoes supplier GOGNI enrico, Società Agricola Ponte Molino, Paganini Antonio for finish product Popla Ardita cans 3 kg lotto batch R1LU263

Tests were completed within 40 min with accurate results including mass balance check.

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3.10 Complaint-handling

Complaint managed according with Procedure PG07 Gestione nc, ac e reclami clienti rev.1 of 13.05.2022. QAM, Comm. manager and QC are in charge for complaints. Records on Mod. 14.1.

A total nr. of 10 complaints (some of which were declared unjustified by the company) from customers have been received since last audit, of which 7 for foreign bodies :2 for plastics, 1 for glass piece, 1 for wood, 1 for cotton wire, 2 label/paper. Other were referred to sealing of plastic sack, product characteristic, organoleptic. No complaints from other sources (e.g. Authorities) are present.

Checked complaint management on relevant register Mod 7.1 of CA date 11.5.2022 coming from customer and Richetti referred to “Polpa Super pizza 10 kg” lot R1LF061 due to foreign body (piece of label”). CA was refresh training to involved operators, closed and verified 27.7.2022.

3.11 Management of incidents, product withdrawal and product recall

According to group procedure PG6 “Rintracciabilità e ritiro e richiamo del prodotto”, rev 8 of 13.04.2022. A Crisis team is described including functions from different sites (many products are produced partially at a site and completed at another). Including CEO (A. Rodolfi), Head of Tomato receipt (G. Minardi), HACCP TL (G. Ghiretti), Site manager from Ozzano Taro site (F. Bonvini) and the one at Fontanini site (A. Mozzi). Crisi team is reported into “Team di crisi e lista dei contatti (ALPG 6.1. rev 4 13.04.2022). In the same document the contact list of Health Authorities, Certification body (SGS) and legal consultant are reported with contact name, phone call and e-mail. Procedure define guideline for defining the request of withdrawal or recall, communication plan. CB notification with 3 days included in emergency contact notifications. Same procedure in place for manage emergency with impact on business continuity.

The process was tested annually, last in date 19.09.2021, scenario high level of heavy metal on: pizza ardiata Bag in Box batch R1LU261 of 18.09.21, produced 10160 BiB, all sent to customers, eg customers “A”, engagement of customer by simulation letter to client. Relevant records available including accurate mass balance. Time requested < 2 h.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
3.5.1.5	No agents or brokers used
3.5.2.3	No live animal
3.5.4	No outsourced processing and packing.
3.9.4	No rework used or reworking operations carried out

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4. Site standards

4.1 External standards

The building was in good condition. In good repair and well maintained with investments regularly planned. Located in a large, light industrial estate with green fields around the plant. No local activities that would risk product contamination. Adequate maintenance of the site and in relation to pests. Suitable clear zone surrounding the site. No rivers, the train line close the plant doesn't present possible issues. The building is on satisfactory condition and maintained with investments regularly planned. Adequate maintenance of the site, perimeter fenced. All external areas are asphalted, and the only external storage is for aseptic 200 kg concentrate or tomato pulp, which is properly monitored and managed. During the site inspection the external areas were found in an acceptable level of order.

4.2 Site security and food defence

Food defense managed according to procedure PG.11 rev. 3 28.07.20. Relevant responsibilities defined within the dedicated team CEO (A. Rodolfi), Head of Tomato receipt (G. Minardi), HACCP TL (G. Ghiretti), Site manager from Ozzano Taro site (F. Bonvini), A. Strazer QA manager. Hazard Analysis and Food Defense Plan documented on All. Food defense PG.11 annually reviewed and updated 07.07.2022 (supporting Mod, 11.2 Checklist food defense). Defined vulnerable areas and related control measures to prevent voluntary contamination of product at external areas, access points, internal (production) areas, loading and unloading areas. Site registered FDA No. 10461955508. Visitors are identified, registered and access controlled. Procedure applied for the auditor on arrival. Enclosed and fenced site. Cameras installed. Staff encouraged to report unidentified or unknown visitors. Factory controlled by security service provider IVRI. Tests of effectiveness of the plan are included in the audit and inspections program and documented on relevant reports, as random checked mod.10.1 dated 11.07.2022 and 18.06.2022. Additional Alert Test done on date 06.07.2022, satisfactory results. Training provided, last on 21.06.2022 and 06-12-15.07.2022.

4.3 Layout, product flow and segregation

Linear layout documented and site map updated 28.08.2020. Process flow of one-way type. Raw tomato intake is completely separated and far away from processing area and finished product loading point. Internal movement external yard routes clearly indicated. Processes are managed in an appropriate way based on physically separated areas (warehouses / processing areas) and proper GMP's and GHP's implemented. Zoning has been conducted according to Appendix 2 BRCGS and is evidenced in the series of flow diagrams for evaluation of risk areas, last update and validation of 04.07.2022 (tomato concentrate). NO high care/High risk areas present. Most of processes are performed into enclosed system (piping for pasteurization and filling) e.g bag in box production is all enclosed products. Other areas have been found at low risk (e.g. cooking area for ingredients, "Cucina"). Working space is satisfactory. Process flow planned and suitable to minimize food safety risks. The cross-contamination risks are minimized. Separate areas as needed.

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

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The factory is suitable for the intended purpose. The walls are designed, constructed, finished and maintained to prevent the accumulation of dirt and to minimise condensation and mould growth. The cleaning operation is facilitated. The floors are adequate and maintained in good repair. Drainage doesn't pose risks for product contamination and not compromise product safety. Ceiling are proper managed and suspended tools and pipelines are under control. Absence of false ceiling. Windows have mosquito nets that prevent the ingress of pests properly maintained. External doors to raw material handling, processing, packing and storage areas are closed to prevent pest ingress. The lighting ensures a safe environment to carry out processes, inspection and cleaning operation.

4.5 Utilities – water, ice, air and other gases

Water used in production is from different sources:

- Municipal water
- Well water
- Recycled water (used only at receipt of raw tomatoes for flushing purposes only from the truck into the washing line through water transport system)

Water comes from numerous wells (>10) and is tested 2/year at common buffer tank for verification of potability according to national requirement (d. Lvo 31/01) for chemical and microbiological parameters. Municipal water is tested 2/year for potability according to potability test.

Water is chlorinated and tested daily as seen relevant register. Free Chlorine content is continuously monitored every 2 hours an employee from steam equipment Maintenance is in charge for checks with test kit and performs analysis on free chlorine content checked register in which the employee manually reports the checks at different production lines (tube, glass and metal cans production area, tomato washing area, 3 kg cans production and glass. Seen Sodium hypochlorite supplier CARINI CHEM srl Sodium hypochlorite 14-15% complies to food additive EN901 conform to to human water treatment rev.3 of 1.7.2019 and MSDS IT07.4 of 05.2020.

Plan of internal dispensing stations updated 22.04.2022.

Checked "pH srl" lab (Accredia 0069 L) nr n°22-am 01811 dated 01.02.2022, chemistry included pesticide, pH alkalinity, heavy metals, ions, hardness, nitrates, and nitrites. Microbiology tests include TVC and 22 and 26°C, Coliforms, E coli, Enterococci.

Checks also municipal water tested on report 22-am 24185 dated 29.07.22 by "pH srl" lab (Accredia 0069 L), same microbiological parameters for well water and chlorine ions, nitrates and nitrites pH, Iron, ammonia ions, free chlorine ion.

Same testes as described previously for evaluation of potability have been conducted, in all reports a final judgement by the lab for compliance with national legislation for potability is present.

STEAM GENERATION form wells water, softener treatment with ion-exchange resins, inverse osmose treatment. Water treatment used in the steam generation with additive deoxygenating CHEM AQUA 632 FDA, MSDS REV 4.1 DEL 30.05.2017 and Coordinated Phosphate, FDA NHP6C disperdente alkanization MSDS rev1 del 6.2.2018

COMPRESSED AIR, for blowing of glass packaging line. Present risk assessment of 11.06.2018, according check 1/year by lab alfa (0231), report of n° 3573/2021 of 6.08.2021 for dew point, solid contaminant, oil aerosol, micro (cbt, mould, yeast).

Nitrogen for spay dry process not in contact with food

Air quality monitoring in dry tomato powder/flake areas, and kitchen, 1/year. Last analysis report available seen in 2021 audit, next analysis is schedule in august 2022 by Laboratory R.E.I. (0508).

1 NC raised



4.6 Equipment

The plant equipment used in production are fit for purpose. Majority of the process is enclosed with equipment in stain steel. Main equipment was well maintained under routine maintenance systems. Equipment contacts surfaces all SS 316.

“Forbo” belts are used all over the company for conveyor of loose product before filling and packaging, with DoC 10.07.2014, migration test simulants D A B.
Seen rubber roller of Polpa line, supplier Cavaliere Food processing equipment techn. spec of 30.11.2020 with DoC, suitable for tomatoes products.

4.7 Maintenance

Maintenance plan is conducted from October to May when no tomato campaign is present.

Planned maintenance is arranged into a document “Piano di manutenzione ordinaria – Stabilimento di Collecchio 2022” according with PO 9.3 Gestione delle manutenzioni rev 7 of 28.6.2020). Records on the same maintenance plan. There are 15 operators for maintenance activity. Seen intervention dated 1.3.2022 on line tomato pulp; aseptic plant for tomato pulp date 2.5.2022; dated 14.2.2022 filling machine line glass bottle. Seen maintenance 2.5.2022 by service provider Protec on tomato sorting machine. Recording on form Mod 9.1.1 “Controlli avvio linea” cleaning and sanitizing when necessary and signature by the head department for the release of the machine.

The Contractors involved in maintenance activity are monitored by the Responsible of the maintenance process.

Intervention for break-down conducted during campaign are recorded into “Registro manutenzione urgente Anno 2022” checked maintenance report of 13.1.2022 on machine tomato “Scottatrice”. After that the equipment is inspected by production area responsible for cleaning efficiency and hygiene of equipment. Food grade lubricants in use e.g. Grease FOOD HT NILS H1 with attached allergen status declaration (absence) of 31.01.2022.

Dedicated separated area for maintenance facility.

1 NC raised

4.8 Staff facilities

Single large changing facility within main building maintained in clean condition by dedicated cleaning staff. The cabinets are enough to receive the personal effects of the operators and are equipped with double compartment to separate work clothes from street clothes. Washing hands before entering the production departments. The number of sinks is adequate, and the toilets are adequately separated from production areas. There is a refreshment room for short snacks through vending machine. Placards posted on proper hygiene. The HACCP Manual describes the Rules of Conduct staff. Dedicate areas for smoking was identified on external perimeter of building. Due to Pandemic situation COVID- 19 the seasonal workers arriving just, shift responsible check hygiene and cleaning of clothing.



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

4.9.1 Chemical control

The storage, handling and use of chemical products is well managed to prevent chemical contamination. Chemical products are clearly identified and correctly segregated and locked.

All chemical containers labelled and stored in a segregated and closed metallic locker managed by authorized staff only.

Chemical products used for cleaning are present. Only food grade chemical used in production areas. 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. Cleaning chemicals were supplied against specifications. Food suitability was documented for chemicals used on site. Cleaners were formally trained in-house and in chemical handling by chemical supplier where required. Collection of technical specification including chemical products.

Seen tech. Sheet of NaOH 50 % of Carini chem of 2021 and Thecn. Sheet of Nitric acid 52% of 15.01.19 with DoC of food additives. Additive deoxygenating CHEM AQUA 632 FDA, MSDS REV4.1 DEL 30.05.2017 and Coordinated Phosphate, FDA NHP6C disperdente alcalinizzante MSDS rev1 del 6.2.2018

4.9.2 Metal control

Available procedure PO.9.1_Controllo processo di produzione rev 2 dated 01.03.2003.

The knives management is verified every day with the pre-operative control before the beginning of production day. Documented knife policy.

In the monthly inspections performed by the head of shift at all areas in production, recorded on document Mod. PG 10.4 "Ispezioni Igienica GMP – GHP" the evaluation of no presence of persona items with sharp surfaces, no presence of cutters and scissors apart from those consigned by the company, the integrity of cutters and all sharp objects. Evaluation of compliance for only single-piece detectable cutters is also reported. In the company hygiene rules the prohibition of the use of staples and pins is reported.

4.9.3 Glass, brittle plastic, ceramics and similar materials

At chapter 5.1.2 of HACCP Study and Manual last updates rev.10 dated 15.07.2021 the source of glass/hard plastics sources of the plant is described to be included into a map

Head of shifts are in charge for check of integrity every 15 days during the campaign and monthly or bi-monthly depending upon production. Records of integrity of glass and hard plastics are into document "Ispezioni Igienica GMP– GHP" (Mod. PG.10.4) in which in this document inspection for evaluation of relevant GMPs and GHPs is conducted at all areas which are 4 in production (the list of all department present in the site is reported on top of document, the head of shift flags those in operation). Monthly inspections are reported from the revision date and includes also evaluation of glass and hard plastic sources at all areas in operation.

Checked for inspection dated June 2022 and July 2022 the evaluation of integrity of glass and hard plastic sources, including light protections.

A written procedure in the event of breakage is reported into HACCP Study and Manual last updates rev.10 dated 15.07.2021 at chapter 2.3.5. Intervention foresees the isolation of area where breakage occurred and chapter 5.2 treatment of breakage of glass bottles used for production purposes. Removal of fragments (glass or hard plastics) is performed with tools dedicated for class removal which are then checked for

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presence of fragments before being stored into lockers. Removal of all glasses from the filling machine (23 units) is reported in the event of breakage during filling of glass bottles.

4.9.4 Products packed into glass or other brittle containers

Criteria defined inside HACCP Study and Manual last updates rev.10 dated 15.07.2021 at chapter 5.2 and Operative instruction 41 Rottura vasi. Presence of overturning of empty glass containers and can with the air blow pressure. In case of a glass breakage an "incident report" is opened and investigated following the operative instruction. When a breakage occurs, the following actions are taken: removal and disposal of products in the vicinity of the breakage; immediate and effective cleaning of the line; documented inspection of production equipment following the cleaning; authorisation for production to restart following cleaning. Isolation of a quantity in line of filling units that could be 23 for line of puree bottle and 23 for other glass jar. Record of glass breakage on Mod9.1-10

4.9.5 Wood

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

4.9.6 Other physical contaminants

Debagging procedure in place in order to avoid introducing secondary packaging in processing area. Pens used in open product areas are detectable and controlled to minimize the risk of physical contamination.

4.10 Foreign-body detection and removal equipment

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

The control measure to detect foreign bodies are defined in HACCP Manual, according to risk assessment, the equipment to detect foreign materials were chosen as follows:

- Sieves in pre-bottling phase (0,5mm),
- Turn over air blow machine for empty glass and empty cans
- Metal Detector
- X-RAY detector
- Magnets present on tomatoes juice line and on powder line and checked every shift;
- Optical sorting equipment on two consecutive steps (machines installed in the lines) during tomato processing plus a third visual control by online operators

The containers are segregated from the storage of raw materials, product or other packaging, even though containers are not made of glass. Monitoring activity according to control measure typology in place.

4.10.2 Filters and sieves

In case of concentrated (double/triple) tomato the product passes through 2 mm sieves in the closed pipeline before aseptic filling, checked every start/end of production by operators. In case of tomato diced/pulp/sauce and paste the product passes through 4 mm sieves, classified as CP, monitoring 1/shift.

In case of tomato powder, the product is passed through sieves of 1000 µm dimension, classified as CP. Moreover, the hot air (230°C) used for spray drying is filtered by a series of 4 filters including G and final H7 class ones, regularly controlled and / or replaced according to maintenance program. In case of tomato flakes the product is passed through sieves of 6 mm dimension, classified as CCP. In case of semi-processed pesto processing the product passes through 5 mm sieve, classified as CP. Sieves are listed in the relevant HACCP Plans and are managed as CCP or CP and verified on routine basis, seen during factory tour, eg

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- Fusti asettico 235 Kg batch R1F216 BB 04.08.2024, Double Concentrate Tomato Paste 130 g lotto R1LF216 BB 08/2025: DF4 concentrate tomato - Piping to filing lines step CP sieve 2mm, monitoring 1/shift.
- Passata Ortolina 690 kg lotto lotto R1LF216 BB 08/2025: DF14 tomato diced/pulp/sauce and paste; deaerator step sieves CL 4mm, monitoring 1/shift; Sieving step CL 4,0 mmm, monitoring integrity sieve 1/production batch

4.10.3 Metal detectors and X-ray equipment

DEVICES:

- DF2 extruded tomato pulp; CCP metal detector, limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final, responsible line;
- DF3 chopped tomato; CCP metal detector, limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final; responsible line;
- DF4 concentrate tomato; CCP metal detector limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final; responsible line
- DF6 hot filling canned tomato; CCP metal detector, limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final; responsible line;
- DF7 product packaged in glass or can; CCP XRAY detector 1,5 mm Fe, 1,5 mm SS, 3 mm glass, frequency every 2 h, line operator,
- DF13 Spry dehydration line; CCP metal detector, limit 1,0 mm Fe, 2,0 mm ss, 1,6 mm no Fe, initial, 4 hours, final; responsible line, records in modulo controllo MD.
- DF14 tomato diced/pulp and paste; CCP XRAY detector 1,5 mm Fe, 2,5 SS, 3 mm glass, frequency every 2 h, line operator,

An automatic rejection device, for continuous in-line systems is in place in order to either divert contaminated product out of the product flow. In case of failure of metal detector, a re-inspection plus isolation of products produced since the last successful test. The control frequency is different according to instrument and position. The frequency is from 2 hrs for XRAY detector, 4 hours /8 hours for METAL DETECTOR according to position and product. Metal detectors are under periodical calibration activity. METTLER TOLEDO report for MD. Test done during the audit was positive. Metal detectors demonstrated effectively by staff who were aware of failure process.

At the audit time verified the correct functioning of Electronic devices . eg.:

- Polpa in pezzi ricca e gustosa Ortolina 400 g batch R1LF216 BB 12/2025: DF2 extruded tomato pulp; CCP metal detector, limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final, responsible line
- Polpa pomodoro cubetti R6 206 kg lotto R1F216 BB 04.08.2024 ; DF3 chopped tomato; CCP metal detector, limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final; responsible line;
- Fusti asettico 235 Kg batch R1F216 BB 04.08.2024 DF4 concentrate tomato; CCP metal detector limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final; responsible line
- Passata Ortolina 690 kg lotto lotto R1LF216 BB 08/2025 DF14 tomato diced/pulp and paste; CCP XRAY detector 1,5 mm Fe, 2,5 SS, 3 mm glass, frequency every 2 h, line operator,
- Polpa Pizza Fine Alpina 4050 g lotto R1LF216 BB 06/2025 DF6 hot filling canned tomato; CCP metal detector, limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final; responsible line;
- Double Concentrate Tomato Paste 130 g lotto R1LF216 BB 08/2025 DF4 concentrate tomato; CCP metal detector limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final; responsible line
- Oro di Parma Tomaten Stuckig Bella Italia 400 g lotto R1LF216 BB 12/2025: DF3 chopped tomato; CCP metal detector, limit 1,8 mm Fe, 3,5 mm SS, 2,5 mm no Fe, initial, 4 hours, final; responsible line and DF7 product packaged in glass or can CCP XRAY detector 1,5 mm Fe, 1,5 mm SS, 3 mm glass, frequency every 2 h, line operator,

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4.10.4 Magnets

Magnets present. Test with Gauss meter:

- Tubes line: 9000 9000 12300 9300 10300 check of 12/04/2022
- Glass line: 1250 1350 1350 1340 gauss check of 12/04/2022
- Packaging of Tomato flakes: 5 bars of 6000 gauss, check of 28.4.21 Concentrate Tomato t75: 9000x 6 barre. check of 12/04/2022
- Mini pack line: 2553 gauss check of 12/04/2022

4.10.5 Optical sorting equipment

Optical sorting done on two consecutive steps (machine installed in the lines) during tomato processing plus a third visual check by online operators.

The tomato passes under an optical sorting to eliminate gross defects. Subsequently, after another wash, the product passes under an optical sorting and manual sorting. Additional sorting in dehydrated department before final customer packaging.

Seen records of the optical sorting equipment checks of 04.08.2022

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

Criteria defined inside HACCP Study and Manual at 5.2 and Operative instruction 41 Rottura vasi. Presence of overturning of empty glass containers and can with the air blow pressure. In case of a glass breakage an “incident report” is opened and investigated following the operative instruction. When a breakage occurs, the following action are taken removal and disposal of products in the vicinity of the breakage; immediate and effective cleaning of the line; documented inspection of production equipment following the cleaning; authorisation for production to restart following cleaning. Isolation of a quantity in line of filling units that could be 23 for line of puree bottle and 23 for other glass jar. Record of glass breakage on Mod9.1- 10, seen of 04.08.2022, no breakage recorded.

4.11 Housekeeping and hygiene

A cleaning plans is into Procedure “SSOP – pulizia e sanificazione” (rev. 0 21.07.17) in which instruction for performance of cleaning of all areas and equipment is reported.

Cleaning activities are divided for different departments and describe ho to perform cleaning activities.

In the attachment a long series of work instructions (“Disposizioni di lavoro”) are described for specific cleaning instructions.

Frequency is depending on end of each production cycle (same production process may be continued for many days).

Cleaning is conducted on food contact surfaces by internal personnel while an external service provider is in charge for cleaning into production areas (floors, external equipment, walls, utilities, staff facilities, toilet). Checked “MOD.SSOP.2_CONTROLLO IGIENE AMBIENTE” per capoturno.

Checked from 22.07.22 to 29-07-22 record of intervention at all areas of production for glass bottles and metal cans. Cleaning records are conducted for evaluation of clean status. In adding evaluate CONTROLLO AVVIO LINEA (MOD.9.1-1. – Rev 4 18/06/2020) of w30-2022

Pre-op inspections are conducted at start of each production cycle, then continuous production for 3 shifts/days for 7 days/week is conducted. Cleaning agents are stored into locked areas inside production areas. Found plant in appropriate cleaning conditions



At the time of audit, all production lines and equipment were functioning, used and running, proper cleaning and integrity were observed. In case of equipment which is not running, not used or not functioning, cleaning is correctly carried out and integrity is periodically checked in order to keep the area in hygienically good condition.

4.11.7 Cleaning in place (CIP)

A CIP system is placed into all aseptic process lines and is tested at each cycle at last rinsing water for pH and with a bio luminometer.

CIP system is performed with mobile tanks which are transferred to the line when CIP must be performed. CIP is conducted during campaign depending upon some conditions (e.g. in presence of heavy rain production stops, then CIP step is performed), while out of campaign CIP is performed at end of week.

The cycle foresees a first rinsing with water, then NaOH contact, rinsing, further treatment with nitric acid and a final overall flushing until pH is not the same of well water. Checks are conducted on last rinsing for pH content by internal lab, records are done into appropriate record sheets (excel file) confirming pH of potable water, seen record of 2.08.2022 Minipack filling line after production of Polpa Demetra batch LF214.

A luminometer is also present and used for evaluation of RLU after washing, a value at 3000 RLU is defined for effective cleaning. Seen record of 2.08.2022 Minipack filling line after production of Polpa Demetra batch LF214. Seen record of rinsing water MOD SSOP 3H LINEA Minipack filling line of 31.07.2022 after production of POLPA ALFINAS 2x5

Seen thecn. Sheet of NaOH 50 % of Carini chem of 2021 and Thecn. Sheet of Nitric acid 52% of 15.01.19 with DoC of food additives.

4.11.8 Environmental monitoring

Environmental programmed is reviewed every year, last one according with IO 09.2.1 Programma annuale controlli sul prodotto rev. 10 confirmed the 7.7.2022

Environmental monitoring procedure in dried and spray-dry powders/flakes products departments in place with visual and analytical verification in order to verify the effectiveness of cleaning procedure and environment status.

Target microorganisms and limits are defined for each parameter, including corrective actions in the event of exceeding results: Swab Surfaces: Entero <100 UFC/ dm², unacceptable > 100 UFC/ dm²; CBT <5000 UFC/dm², unacceptable > 5000 UFC/dm²;

Two samples are taken every year one on flour area and one in drying area.

Last validation of environmental program of December 2021 based on trends analysis. Trends show issues have identified no non-conformity in 2021 and YTD 2022.

Seen records of transport belt of NIRO department date 04.07.2022 (internal lab) CBT, mould and yeast. Rinsing water check and process validation by pH control, frequency and limits defined in IO 09.2.1

4.12 Waste

The system of waste is adequate. Waste disposal resulted managed according to procedure of section 2.3.2 of Manuale Autocontrollo HACCP rev. 11 of 05.07.2022.

Different types of wastes are present at this company. Most abundant wastes are from tomato peels and

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skins, which are automatically transferred by the equipment for their removal from conveyor belts to a container placed outside at a side of raw tomato washing area. This product is disposed from a qualified provider “Chiesa Virginio” and transferred to biogas production plant.

Paper and cardboard are collected into a large tank outside, provider Bertani, while clean plastics is compressed into an external compactor and disposed by provider “Cavozza”. Metal wastes (mostly cans) are disposed by an external provider (“Padana Recupero”) where the separation by tomato product and metal cans is performed for recycling. Glass from bottles (empty and filled) are disposed by “Padana Recupero” for separation and recovery of glass for recycling. Same recovery is foreseen for plastic tubes filled with product and destined to waste. Mixes wastes (e.g. aluminium bags dirty with tomato) are disposed by the municipal company (“IREN”). All waste containers and compactors are placed externally from the company, in different areas. A responsible engineer is in charge for waste disposal and contracts management (mr. F. Chierici).

4.13 Management of surplus food and products for animal feed

Surplus of customer branded products is totally destroyed.
 In case of costumer brand product, any operation of transfer to charity organisations or other organisations must be approved by the brand’s owner.
 No animal feed destination.

4.14 Pest management

Pest control is managed as described in procedure section 2.3.3 HACCP Manual rev.11 – 05.11.2022.

A contract is in place with specialized company external provider Sistema Ambiente issued 10.01.2021 expiry 31.12.2022, to manage pest control on site: 12 routine visits each year per rodent and creeping; 8 per flying insects; 4 disinfections.

All the monitoring places are indicated in plan of the site dated 12.12.2018.
 UV electrical lamps installed for the insects catching are correctly sited and inspected according to plan.

Appropriate limits of intervention are defined for all pests.

In case of detection over the stated limits corrective actions are defined (analysis of causes, focused interventions).

The contracting company regularly releases reports of the interventions.

Year 2021 full records of inspections were available, and records seen.
 Also records of inspections year 2022 were verified with satisfactory results, e.g. dated 9.5, 14.6, 16.7.2022 (Notrac Blox /Bromadiolone, relevant MSDS available).

Ongoing trend analysis was updated at every intervention and evaluation was taking place; seen last referred to July 2022.

No particular problems evidenced. Satisfactory results seen.

GMP section 2.3.3 HACCP Manual rev.11 – 05.11.2022 in place to prevent birds from entering buildings, no problems highlighted in the loading/unloading areas; the aspect is object of site inspections and in case of necessity focused interventions are carried out by the service supplier company. No signs of significance were observed during site tour.

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Based on risk assessment the activity is under survey of the expert Daniela Sacchelli who undertakes an in-depth documented annual pest control survey, seen report dated 30.6.2022. No issues highlighted through.

Employees were trained to understand the signs of pest activity and be aware of the need to report any evidence of pest activity to the production site manager (last done 06_12_15.07.2022).

No evidence of infestation was found during the audit or had recently been reported. Not observed presence of live or dead insects.

4.15 Storage facilities

Empty bottles and finished products are correctly stored.

Stock rotation formula is in place on a first-in first-out basis (FIFO) and inventory turnover ratio is calculated and properly monitored. Tomato tanks are stored outside (properly managed). Cold storage cell with manual registration. At the audit time checked registration for 4-5/08/2022.

Cold storage cell is used for powder in bags, fresh vegetable, frozen vegetable ingredient. In total are present 3 cold storage 2 positive and one a negative temperature. The registration is made every shift e.g. CELLA 1 August 2022 range temperature +5°C – 10°C; e.g. CELLA 2 August 2022 range temperature +2°C – 5°C; e.g. CELLA 3 August 2022 range temperature - 18°C

At audit time observed storage, eg.:

- Polvere Pom.CB Box 25 kg batch R1LF208 BB 27.07.2023 t°+4°C
- Garlic Falvour dat of production 23.06.2022 BB 23.12.2022 supplier “B” t° +5°C
- Carrot Puree Production date 11.11.21 BB 11.11.23 supplier “A” t° -10°C
- Cipolla Bianco a cubetti surgelata batch 19.05.2022 BB 05-24 supplier “P” t° -18°C
- Passata pomodoro Ortolina batch R1LU247 BB 08.2024 room temperature
- Tomato Paste 28/30 Alpino 410 g batch R1LF212 BB 31.07.2022 room temperature

4.16 Dispatch and transport

Finished product transport was managed according to procedure PO 23.1 rev.0 by means of service’s providers according to rules defined in the internal document “Disciplinare di Trasporto”, including transport security specifications. The trucks before the loading are subject to checks on hygienically suitability record on ddt. of 6.4.2022 and 23.05.2022 for customer “T”, seen inspection of vehicle. Seen order n°37874444-1 customer F.J. Tytherleigh the 5.08.2022, inspection of container.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification

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4.3.5	No temporary structures present.
4.5.3	No legislation that specifically permits the use of water which may not be potable for initial cleaning.
4.9.1.2	No strongly scented or taint-forming materials present.
4.13.3	No products intended for animal feed
4.14.3	The site doesn't undertake its own pest control.
4.15.4	No controlled atmosphere is required

5. Product control

5.1 Product design/development

The activity is managed under procedure PG 12 "Sviluppo nuovi prodotti" rev 1 of 26.08.2019 requirements. The hazard analysis is included in the Design & Development inputs, review, and verification. Results of shelf-life tests are validated by Quality Assurance in accordance with the procedure. The nutritional information is part of product technical specification. Shelf-life test planned. Aseptic bag verified every year by sterility test.

No presence of new products or new raw material suppliers since last audit.

Due to the absence of new products the weekly meetings combined with production meeting were not done since last audit.

Nutritional value test rotation 1/3 year of standard product and every new recipe. Seen report of Doppio concentrato pomodoro con sale batch R1U212, customer "S", report n° 21/00486685 by lab Merieux (0051)

5.2 Product labelling

Appropriate labelling management complies with legal requirements. Creation, approval, modification and management of labelling process is described in procedure PG 12 "Sviluppo nuovi prodotti" rev 1 of 26.08.2019

Relevant regulations in terms of composition, quantities, claims etc. are verified by Marketing and AQ in collaboration with external law consultant as needed, by MKTG unit, in charge for graphic and legal compliance evaluation. Nutritional values are confirmed by specific analysis approved by Eurofins laboratory. In case of private label products, the label is developed in collaboration with customers. Responsibility for correct labelling remains to the company. In case of private labels stock, marketing department requires customer approval to run out of stock or for destruction.

All labels at receipt are subjected to incoming acceptance procedure which foresees 2 steps: a preliminary check for integrity of pallets, no signs of presence of pests and correspondence with order, and a second

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step for checks performed on some samples taken from the delivery and are transferred to the internal label where a dedicated employee (Mrs. Manuela Biacchi) is in charge for compliance with approved labels with the one available into intranet which has been approved.

Seen label approval of Tomato Paste 147 ml with e-mail by company to customer on March 2021 and artwork approval by customer of 09.09.2021. First delivery” the 15.07.2022, incoming check recorded on mod 14.2 with label copy.

At the audit time randomly checked the compliance with Reg. 1169 and FDA instructions of:

- Italian Passata Tomato & Basil Coles 700 g : Tomatoes (98%), Basil, Salt, Onion, Food Acid (Citric Acid) Suitable for vegetarian and vegans.
- Double concentrated organic Tomato Paste 100% Italiana Cento 4.56 oz (130 g): Organic Tomato paste, salt

5.3 Management of allergens

The procedure for allergens risk, defined in accordance to the procedure PO.24.1_Gestione allergeni rev.2 of 07.03.2022 and DISP.24.1 codice colore allergeni of 07.07.2021

An assessment of potential risk from allergen contamination is documents into the risk assessment also for supplier qualification into HACCP Study and Manual last updates rev.11 dated 05.07.2022.

Allergens present at the company are milk (from Parmigiano cheese into pesto), eggs, celery and cashew (into pesto)

Allergen materials are declared on the ingredients lists of the relevant products. There is a supplier approval questionnaire that assesses the allergen status of each raw material.

Documented allergen risk assessments include an assessment of all procedures to ensure the effective management of allergenic materials.

Allergens tests are conducted both by internal lab and by external analysis labs (Eurofins – Chemical Control),

Seen example of rinsing water analysis of extracting unit for casein, beta lactoglobulin, DNA cashew after production of Pesto sauce report n°22-AM07057 of 7.3.2022 by lab eurofins (0490); report n°22-AM14004 of 3.5.2002 by lab eurofins (0490); of rinsing water of tubes filling equipment for DNA celery; glass jars filling equipment report °22-AM07059 of 7.03.22 by lab eurofins (0490) for casein, betal lactoglobulin, DNA cashew after production of Pesto sauce.

5.4 Product authenticity, claims and chain of custody

Company has access information on historical and emerging threats to the supply chain which may present a risk of adulteration of raw materials that come from trade associations, government sources, consultant. Reference Procedure PG 5 Valutazione e qualifica fornitori rev 4 of 28/03/2022. The risk assessment for adulteration, substitution or fraud is documented in the document Allegato 5.2 “Valutazione Frodi”, annually reviewed, last rev.1 of 10.01.2022. It was considered:

- historical 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
- the nature of the raw material.

Scoring system used for risk evaluation based on parameters according to Standard. >2 high risk.

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Defined as fraud risk raw tomato for geographic origin (100% Italian coming from Emilia Romagna, Lombardia, Veneto) as defined by internal company document SCP 005 Disciplinaire Di tracciabilità rev. 13 – 13.08.2021 object of certification ISO 22005.

Mitigation: selection of suppliers all certified ISO 22005, inspection for provenance at every raw tomato receipt.

Claims are present on some products (e.g. most tomato products describe 100% Italian tomato), the origin is under control of certification body for certification of supply chain for Italian origin of tomato (certificate expiry 12.09.2023). During the annual management review the company annually evaluates the status of the assessment.

Organic products are obtained even if organic raw materials are only received at Fontanini site (BRC/IFS certified company).

Site certified for organic products by ICEA code 5286 IT BIO 006 H1753 certificate expiry 05.08.2024. Mass balance regularly performed, minimum every 6 months. Last inspection of 14.6.2022. Products with organic status are all evaluated for pesticides according to the internal analysis plan. Ongoing Halal Certification, audit on 15/07/2022.

1 NC raised

5.5 Product packaging

Types of packaging are:

- Metal cans (different formats)
- Glass bottles, glass jars, Jars and Cup glass Bottles.
- Tubes
- Aseptic bags (different formats)
- Bag in Box
- Aluminium bags for powders)
- Plastic bags (for tomato flakes)

Checked specifications and declaration of conformity for food contact:

Tin cans from supplier “Eliosio”, specification rev. 4 dated 10.01.2022, (white enamel inside) and food contact compliance 24.03.2022.

Glass bottles from supplier “Zignago”, technical specification dated 29.11.2021 and DoC of 05.01.2022

Plastic tubes from supplier “All Tube”, (capsule into PP + white enamel for food contact) of 02.12.2021 and food contact compliance 26.04.2022.

Aseptic bags from supplier “Scholle IPN” (metalized barrier laminate PE metal polyester/PE/EVOH/PE specification rev.20 November 2021 and food contact compliance 26.07.2021

White Cup glass Bottles, Supplier “Eliosio”, technical spec rev. 7 of 07/12/2021, DoC with migration test 24.05.2022.

Bag in Box supplier Goglio aseptic sack 10 l technical spec rev July 2022, DoC with migration test 06.04.2022.

Obsolete materials are properly identified and labelled as “Obsolete” and no longer used

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

An analysis plan is present “Piano campionamento analisi 2022” (excel file) confirmed during management review of 7.7.2022 in which the material on which analyses are conducted, type of analysis conducted, and frequency are reported. The analysis plan takes in account customers request also.

Vegetable ingredients (carrots, onions, parsley, celery, Basel) are only tested for compliance at receipt

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because they are received at Fontanini site of the company and are analyzed at this site. Intermediates are only received by this company. Tomato is analyzed at each receipt for compliance with agreed specifications with producer association.

An internal lab is present in which chemical, physical and microbiological analysis (only for tomato powder and with test kits) are conducted. Most analyses are chemical-physical and are referred to Brix content (optical residue) acidity, colour (Gardner), pH, sugar, Bostwick. Lactic acid.

Vuotometer is present for glass bottles. Molds (Howard) are conducted and analysed with a microscope. Microbiological analysis by internal laboratory: CBT, yeast, mold, Entero, e. coli. In addition, rapid Kit for salmonella.

The laboratory is in a separate area from production. Yearly comparison test with accredited laboratory: Microbiological, chemical and physical analysis done by internal lab as well by accredited external labs AGRO.BIO LAB (0293), Merieux (0051), SSICA (0122), Eurofins (0490).

Pesticide analysis is conducted on finished product, a set of 30 analysis/campaign is foreseen by the company. Pesticides analysis is also conducted on raw tomatoes batch, a set of 10 analyses/year is reported,) Pesticide analysis includes also heavy metals analysis (copper, cadmium, lead)

GMO analysis is conducted once every 2 years on raw tomato, Gluten is testes annually on a product inserted into "AIC" approved (gluten free),

At the audit time randomly checked:

Finish products

Internal analysis report Tomato pulp cubes R6 206 kg lot F217 BB 05.08.2024 date 05/08/2022 : °Brix, Colour (Gardner), Acidity, Mold (Howard), pH, Lactic acid

Double concentrate batch R1U233 of 21.08.2021 report n°2137626.001 by Agrobiolab (0293) on pesticides, report n°2137626.002 on chlorates and perchlorates

On raw materials:

Tomato supplier Azienda Agricola Sara Alberto report n°2137629.001 by Agrobiolab (0293) on pesticides.

Allergen residual on rinsing water (celery, casein, beta lactoglobulin, cashew) after production of products with allergen. Nutritional value test rotation 1/3 year of standard product and every new recipe Shelf-life test by internal lab considering sensory, ph and colour rotation 1/3 year of standard product and every new recipe.

Seen shelf-life test with sensory evaluation by internal lab of Arrabbiata sauce Rodolfi 400 g batch LA 279 BB 30.4 21, test of 30.6.21, verified color, flavour, pH, acidity, Bostwick, vacuum check, rust.

Seen shelf-life test report of 27.01.2022 n°1512 by SSICA of Passato Basilico Colse batch E287 glass bottle 700 g, with dat on l-ascorbic acid, 5-idrossimetil fluorate, colour, sensory evaluation every 3 months

5.6.2 Laboratory testing

Microbiological, chemical and physical analysis done by internal lab as well by accredited external labs AGRO.BIO LAB (0293), Merieux (0051), SSICA (0122), Eurofins (0490), Laboratorio merceologico srl (0941), pH laboratory (0069).

Onsite lab is well managed and is separate from any production or warehousing areas. Laboratory training and procedures manual was in place which covered all reliability requirements.

Lab results are acted upon and actions taken to address unsatisfactory results and trended; no evidence so far of non-conforming results in analysis.

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An internal ring test between all tomato producing companies using as external reference an accredited lab ("Stazione Sperimentale delle Conserve Alimentari di Parma, Accredia nr 0122) and into which also some customers of the company (processors) are also present. Analyses conducted by the participants (anonymous) are pH, Brix content (optical residue), Bostwick, sugar content, acidity. Currently no z-score has been defined by the reference. For this year, a sample has been received and analyses are in progress. Checked results from the last ring test into report dated 19.10.2021 "Circuit analisi pomodoro campagna 2021 –". Light differences were found in the internal lab compared to the reference. For 2022 a reference sample has been recently received by the company.
Yearly comparison test with accredited laboratory.

5.7 Product release

Positive release, according to "DISP.26_liberalizzazione prodotti" rev0 of 29.01.2021, is conducted on all lots by the company after evaluation of commercial stability by putting for every shift 2 sample (taken in the middle of the shift) are transferred into internal lab for introduction into 2 thermostats

- at 30°C for 14 days
- at 55°C for 7 days

Customer "D.C." requires the sampling of production and the products can be delivered only after positive release, seen release regarding to Ardita bag in box Kg 10 batch LF206 and Superpizza Ardita batch LF207

5.8 Pet Food

Not applicable

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
5.3.7	No claims made regarding suitability for allergy or food sensitivity sufferers
5.8	No pet food produced/present.

6. Process control

6.1 Control of operations

Process controls are present all along the flow diagram and are described on appropriate sheets Suitable validation measures in place through whole processing. Operations are under appropriate control, process specifications resulted being in accordance with the finished product specification, verified eg in occasion of traceability/vertical audit exercise for Doppio concentrato BIO CENTO 130 g batch R1LF103 BB 2025-

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04 produced on 13.04.2022 and Passata Basilico Cles BTG 700 g batch R1LF080 BB 21.09.2024, produced the 21.03.2022 and during site tour production of:

- Polpa in pezzi ricca e gustosa Ortolina 400 g batch R1LF216 BB 12/2025 (flow sheets DF1 + DF2)
- Polpa pomodoro cubetti R6 206 kg lotto R1F216 BB 04.08.2024 (Flow sheets DF1 + DF3)
- Polpa Ardita Super Pizza 2x5 kg lotto R1LF216 BB 08/2024 (Flow sheets DF1 + DF9 + DF12)
- Fusti asettico 235 Kg batch R1F216 BB 04.08.2024 (Flow sheets DF1 + DF4 + DF12)
- Passata Ortolina 690 kg lotto lotto R1LF216 BB 08/2025 (Flow sheets DF1 + DF14)
- Polpa Pizza Fine Alpina 4050 g lotto R1LF216 BB 06/2025 (Flow sheet DF1 + DF5 + DF6)
- Double Concentrate Tomato Paste 130 g lotto R1LF216 BB 08/2025 (Flow sheet DF1 + DF4 + DF8)
- Oro di Parma Tomaten Stuckig Bella Italia 400 g lotto R1LF216 BB 12/2025 (Flow sheet DF1 + DF3 + DF7)

Process monitoring checks conducted include tomato receiving checks, process parameters monitoring and relevant CPs, CCPs controls according to plan, recipes checks, content control (as below), label checks (every batch) and date coding checks (every batch). The correct labelling was verified during the audit, checks on changing production are recorded on process control sheets. Alarm system in place and functioning for pasteurization plant. Appropriate examples of records seen e.g. the following records were verified:

Mod 9.1.1 Line startup check , preoperational checks including packaging verification, Mod 9.19-2 check of finish product packaging, Mod9.1-14 weight check, Mod.9.1-10 X-Ray, CP bowling air pressure, Mod9.1-5 pasteurization check, pasteurization diagram, Mod 9.1-8 Magnetic trap, Mod 9.1-18B glass breakage record, Mod9.1-10 Vacuum check

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

6.2 Labelling and pack control

Label application and compliance with BB/expiry date is managed by the QC Lab head, in charge for daily delivery to all production lines with a document in which the instruction for label application and printing data are reported. On this document ("Comunicazione Interna") the information of product name / label, the Checked for:

- Polpa in pezzi ricca e gustosa Ortolina 400 g batch R1LF216 BB 12/2025
- Polpa pomodoro cubetti R6 206 kg lotto R1F216 BB 04.08.2024
- Polpa Ardita Super Pizza 2x5 kg lotto R1LF216 BB 08/2024
- Fusti asettico 235 Kg batch R1F216 BB 04.08.2024
- Passata Ortolina 690 kg lotto lotto R1LF216 BB 08/2025
- Polpa Pizza Fine Alpina 4050 g lotto R1LF216 BB 06/2025
- Double Concentrate Tomato Paste 130 g lotto R1LF216 BB 08/2025
- Oro di Parma Tomaten Stuckig Bella Italia 400 g lotto R1LF216 BB 12/2025

information includes product code and name, lot nr and BB date to applies. A copy of the labels for cartons and pallets are also present (printed by the internal lab).

No changeover seen during the audit.

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6.3 Quantity, weight, volume and number control

Frequency of checks: every batch 80 samples/h for tubes and 40/h for glass jars are taken. Statistical check: every batch. The frequency of quantity checking respected on refer Italian legislative requirements DPR 690/78. At the audit time randomly checked process verification in the following workshops.

At the audit time verified the quantity check process for products in process during the site inspection and during the traceability test, exg.: Passata Basilico Cles BTG 700 g batch R1LF080 BB 21.09.2024 produced on 21.03.2022 average weight 707,2 - 711,9 g record on Mod. 9.1- 14, hourly check of tara before pasteurizer, according with IOLAB 9.2.10 Determinazione del peso e del prodotto sgocciolato.doc, record on form MOD.9.1-controllo pesi e codici.xlsx

Bulk products B2B check weight every single units.

The company uses “e” mark on packaging of products B2C for EU market

6.4 Calibration and control of measuring and monitoring devices

Reference calibration procedure PG 18 rev.0 – 25.7.2017. Critical measuring equipment are identified and calibrated to a National Standard. List of measuring instruments “Register Strumenti Di Misura Ozzano Taro” updated 23.7.2022, scales, metal detector, X-Ray detectors, temperature probes, refractometers; A dedicated list of equipment into internal lab under calibration is present into “Strumenti di misura di laboratorio”, including refractometer, scales, colorimeter, pH-meter, thermometers. Labels applied to instruments for identification of the status and relevant expiry dates.

Checked the following: scale aseptic plant calibration F&B date 29.6.2022 including references to national standards used; content control scale calibration by F&B date 03.05.2022, legally authorized expiry 05/2025; metal detectors by Mettler Toledo date 05/07/2022 using certificated testers; X-Ray by Parma Control date 06.07.2022; temperature probes are calibrated by Mosca Luciano service provider as seen referred to PT100 aseptic plant for tomato pulp date 15.07.2022 temperature evaluated from 20 to 140°C; refractometer Maselli at raw tomato receiving calibrated 23.06.2022

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
6.2.4	No on-line vision equipment used to check product labels and printing

7. Personnel

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

The procedure for training activity was defined according with procedure PG 08 rev.0 “Formazione del personale” date 08.05.2017 and the training program 2022 Mod PG.8.1 updated on 4.5.2022. The training is assessed ad refreshment consequently planned to ensure that all staffs can comply with both legal requirements and in-house requirements. Seen records on form “Verbale Di Formazione”. Training provided, last on 21.06.2022 and 06_12_15.07.2022.

Checked series of training activities provided:

Series of dates starting from 21.06.2022 completed on 22.07.2022 for temporary employees of tomato

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campaign 2022, eg “A.M.M.” and “B.S.”

- Date 21.06.2022 and 06_12_15.07.2022 to all production employees referred to hygiene, GMP, GHP, cleaning, food defense, allergens, pest control, eg: “E.G.” and “L.S”
- Date 21.06, 06.07.2022 HACCP and CCP management to people involved.eg:” V.E.” and “B.S.”
- Date 07.07.2022 raw material and packaging receiving control, eg: “S.B.”
- Date 14.07.2022 labelling eg: “D.F.” and “C.E.”
- Date 08.07.2022 for people involved in tomato receiving, e.g. “M.B.” and “C.B.”

Records contain reference to trainer, material, signature, verification. Italian language only, no other language needed. Effectiveness of training is by means of tests and on the job observation.

Verified training of people involved in CCP and other control measures management, interviewed during the audit, demonstrated good competence and awareness.

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

Personal hygiene standards are detailed in the HACCP Study and Manual, last updates rev.11 dated 05.07.2022.

The hygienic requirements inside the production departments are defined and communicated to the staff. All staff were noted to be observing the rules and contractors and visitors, including the auditor, are briefed before entry to the factory and are required to sign to confirm understanding of the hygiene rules.

The Organization defined and documented the hygienic standards for the personnel of manufacturing department. Clothing, cup, shoes, gloves rules, food rules. All cuts and grazes on exposed skin are covered by a blue plaster that are detectable (tests carried out), and correctly monitored when used by QC (record of checks was available). The company’s jewelry policy is clearly defined: the only permitted jewellery is a plain wedding ring, all the others are not permitted. Fingernail rules are in place, for example: excessive perfume or aftershave is not permitted, are used only metal detectable blue pens, it's possible to use only blue detectable patches are available, it's not possible wear false nails, wear the correct clothing, etc.

Microbiological swabs on operator hand and protective clothing 1/year, last dated 14.6.21 on operator hands (internal lab) CBT, not analysis performed since last audit, next scheduled in August 2022.

1 NC raised

7.3 Medical screening

Notification by employees regarding infections and similar is properly managed. Medical screening according to Italian law requirements. Medical questionnaires were completed by new employees, visitors and contractors. Illness reporting requirements were suitably detailed and included procedure for action to be taken in event of employers reporting/suffering from infectious disease. Procedures in place whereby staff (or visitors) that are returning to work after illness that maybe/are infectious to prevent them contaminating product.

7.4 Protective clothing: employees or visitors to production areas

The company has defined a low-risk areas and enclosed product area.

Company issued clothing 2 gowns sets, provided to all production staff. Disposable mob hats provided. Safety shoes also provided. Disposable visitors’ coats and hat provided. Home laundry of clothing with cleaning temperature of 60 – 90°C, managed by chapter 2.1.6. of HACCP rev.11 dated 05.07.2022 “GESTIONE ABBIGLIAMENTO DA LAVORO”

Microbiological swabs on operator hand and protective clothing 1/year, last dated 14.6.21 on operator hands (internal lab) CBT, not analysis performed since last audit, next scheduled in August 2022.



Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
7.4.6	No items of personal protective clothing that are not suitable for laundering are provided

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8. High-Risk, High-Care and Ambient High-Care Production Risk Zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
Not applicable
8.2 Building fabric in high-risk and high-care zones
Not applicable
8.3 Maintenance in high-risk and high-care zones
Not applicable
8.4 Staff facilities for high-risk and high-care zones
Not applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not applicable
8.7 Protective clothing in the high-risk high-care zones
Not applicable

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



9 - Traded Products	
9.1 Approval and performance monitoring of manufacturers/packers of traded food products	
Not applicable	
9.2 Specifications	
Not applicable	
9.3 Product inspection and laboratory testing	
Not applicable	
9.4 Product legality	
Not applicable	
9.5 Traceability	
Not applicable	

Module 11: Meat supply chain assurance	
Scope	Click or tap here to enter text.
11.1 Traceability	
Click or tap here to enter text.	
11.2 Approval of meat supply chain	
Click or tap here to enter text.	
11.3 Raw material receipt and inspection	
Click or tap here to enter text.	
11.4 Management of cross-contamination between species	



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11.5 Product testing

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11.6 Training

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Module 13 FSMA Preventive Controls Preparedness Module			
Version 2 July 2018			
Clause	Module item	Conforms Y/N	Comments
13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge wastewater or sewage.		
13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: <ul style="list-style-type: none"> • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety 		
13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).		
13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: <ul style="list-style-type: none"> • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out 		

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	<ul style="list-style-type: none"> • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product 		
13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRCGS section 2.10.		
13.1.11	<p>Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRCGS sections 2.11 and 3.7.</p> <p>Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).</p>		
13.1.12	<p>Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production.</p> <p>Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.</p>		
13.1.13	<p>The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification.</p> <p>The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.</p>		
13.1.14	<p>Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following:</p> <ul style="list-style-type: none"> • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected 		
13.1.15	<p>Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following:</p> <ul style="list-style-type: none"> • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected 		
13.1.16	Devices used to verify preventive controls must be calibrated.		
13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan.		



	Document the PCQI's training and qualification via job experience.		
13.1.18	All records required by 21 CFR § 117 must include: <ul style="list-style-type: none"> • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable 		
13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.		
13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		
13.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		
13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.		
13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and		

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	<p>conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart.</p> <p>One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.</p>		
13.3.2	<p>The site shall have a written food defense plan, which includes the following:</p> <ul style="list-style-type: none"> • A vulnerability assessment identifying significant vulnerabilities and actionable process steps • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification 		
13.3.3	<p>A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum):</p> <ul style="list-style-type: none"> • Scale and severity of threat if a contaminant is added to product • Degree of physical access to the product • Ability of an attacker to successfully contaminate product—including consideration of an inside attacker <p>A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.</p>		
13.3.4	<p>Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment.</p> <p>Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.</p>		
13.3.5	<p>Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies.</p> <p>Procedures shall include recordkeeping requirements for all monitoring activities.</p>		
13.3.6	<p>Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria:</p> <ul style="list-style-type: none"> • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions 		
13.3.7	<p>Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe</p>		



	<p>activities to verify implementation of mitigation strategies.</p> <p>Verification procedures shall include:</p> <ul style="list-style-type: none"> • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities 		
13.3.8	<p>Reanalysis of the food defense plan shall be documented and performed every three years or whenever</p> <ul style="list-style-type: none"> • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence 		
13.3.9	<p>All records required by 21 CFR § 121 must include:</p> <ul style="list-style-type: none"> • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable 		
13.3.10	<p>The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.</p>		
13.3.11	<p>All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.</p>		
13.4.1	<p>Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used.</p> <p>A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.</p>		
13.4.2	<p>The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary</p>		

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	<p>Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule.</p> <p>Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.</p>		
13.4.3	<p>Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier.</p> <p>Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.</p>		
13.4.4	<p>Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.</p>		
13.4.5	<p>Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.</p>		
13.4.6	<p>Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper.</p> <ul style="list-style-type: none"> • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper 		
13.4.7	<p>Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers</p> <ul style="list-style-type: none"> • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems • Responsibilities of the carrier 		
13.4.8	<p>The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.</p>		
13.4.9	<p>The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.</p>		

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13.5.1	<p>Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following:</p> <ul style="list-style-type: none"> Principles of food hygiene and food safety <p>Produce safety standards applicable to an individual's job</p>		
13.5.2	<p>Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following:</p> <ul style="list-style-type: none"> Recognizing produce contaminated with known or reasonably foreseeable hazards Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards Correcting problems with harvest containers or equipment 		
13.5.3	<p>One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.</p>		
13.5.4	<p>A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.</p>		
13.5.5	<p>Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.</p>		
13.5.6	<p>The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.</p>		
13.5.7	<p>Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.</p>		
13.5.8	<p>Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.</p>		
13.5.9	<p>Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria. Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and</p>		

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	verification of correction to ensure water meets microbial quality criteria.		
13.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA-821-R-09-007," December, 2009 or equivalent method.		
13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.		
13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.		
13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.		
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.		
13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.		
13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts. Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria: <ul style="list-style-type: none"> • Target test (i.e., Listeria spp. or L. mono) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) 		

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	<ul style="list-style-type: none"> Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) <p>The plan shall describe aseptic methods for sample collection and testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent).</p>		
13.5.18	<p>Specific additional requirements for the harvesting, packing, and holding of sprouts.</p> <p>The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono.</p> <p>If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process:</p> <ul style="list-style-type: none"> Resample positive surfaces and the surrounding area to determine the extent of contamination Clean and sanitize the affected and surrounding areas Resample and re-test to confirm the elimination of Listeria spp. or L. mono Conduct finished product testing as appropriate Take additional action to prevent recurrence and to prevent adulterated food from entering commerce 		

14.1 Additional Specifier requirements

14.1 Traceability

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14.2 Environmental Monitoring

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14.3 Product inspection and laboratory testing

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14.4 Protective clothing: Employees or visitors to production areas

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