

Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	DE MATTEIS AGROALIMENTARE S.P.A.	Site Code	7051424
Site name	DE MATTEIS AGROALIMENTARE S.P.A.		
Scope of audit	Production of semolina from the milling of the durum wheat. Production and packing in flexible film in polypropylene or polyethylene, paper box, paper bag of semolina Pasta, whole-wheat semolina Pasta, Egg Pasta, semolina Pasta with tomatoes/spinach, semolina Pasta with oat fibers, semolina Pasta with vegetables puree, semolina Pasta enriched with vitamin and Spelt Pasta, semolina pasta with buckwheat and quinoa.		
Exclusions from scope	Traded goods		
Justification for exclusion	Justification for exclusion		
Audit Finish Date	2019-04-11		
Re-audit due date	2020-09-27		

Additional modules included			
Modules	Result	Scope	Exclusions from scope
FSMA Preventative Controls and FSVP Preparedness	Passed	Production of semolina from the milling of the durum wheat. Production and packing in flexible film in polypropylene or polyethylene, paper box, paper bag of semolina Pasta, whole-wheat semolina Pasta, Egg Pasta, semolina Pasta with tomatoes/spinach, semolina Pasta with oat fibers, semolina Pasta with vegetables puree, semolina Pasta enriched with vitamin and Spelt Pasta, semolina pasta with buckwheat and quinoa.	None
Choose a module	Choose an item		

Head Office	No
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2.Audit Results					
Audit result	Certificated	Audit grade	AA+	Audit type	Unannounced
Previous audit grade	AA+	Previous audit date	2018-08-29		
Certificate issue date	2019-05-22	Certificate expiry date	2020-11-08		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	3

3.Company Details			
Address	Legal site: Via Amoretta 6/E, Parco S.Nicola snc Avellino 83100 Operative site: Z.I. A.S.I. Valle Ufita - 83040 FLUMERI (AV) Italy		
Country	ITALY	Site Telephone Number	0825421248
Commercial representative Name	Uberto Taliercio	Email	uberto.taliercio@dematteisfood.it
Technical representative Name	Giuditta Gambarota	Email	Giuditta.gambarota@dematteisfood.it

4.Company Profile					
Plant size (metres square)	>25K sq.m s	No. of employees	51-500	No. of HACCP plans	1-3
Shift Pattern	3 turns /8 hour				

Subcontracted processes	No
Other certificates held	IFS / ISO 9001 / ISO 14000/ SA8000/ SMETA/ Kosher, Halal, Organic,SCS
Regions exported to	Europe North America Asia Africa Oceania Choose a region
Company registration number	U5010106403210
Major changes since last BRC audit	Installation of the new short pasta line R and increasing the packaging lines for short pasta. Conversion of the line D for the production of the short pasta replacement of the line A for the long pasta, increasing of the semolina.

Company Description

Name and age of company: De Matteis Agroalimentare s.p.a. founded on 1993
 Ownership of company (private, public, part of larger company, link to other sites): Private
 Age of site: 1986

Product types:

Durum wheat semolina, dried pasta, pasta specialty.

Key processes for each family group products:

- Wheat and semolina receiving
- Water receiving
- Wheat Pre-cleaning
- Wheat storing
- Wheat mixing and weightening
- Wheat first and second cleaning
- Decortications
- Wheat first and second conditioning
- Milling

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- Milling
- Semolina storage (mill)
- Semolina transferring
- Semolina storage (pasta factory)
- Semolina sieving
- Pasta storing and stripping
- Dough, extrusion and cut
- Pasta drying and cooling
- Semolina mixing
- Packaging receiving
- Packaging storing
- Pasta packing
- Pasta delivering
- Pasta storing
- Pasta palletizing

traded products excluded from the scope: Gluten free dumplings (Gluten free potato gnocchi, Potato gnocchi), durum wheat semolina pasta made by De Matteis Natural Food (other site of the company) and stored and shipped on this site

Main clients (retailers, manufacturers. Food service etc): Retailers and food services

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Annual production volume/throughput or turnover:

- 124000 tons
- 120.000.000 €

The percentage for retail branded products is about the 87 % of the global turnover. Type of clients:

private labels/own brands, European a and worldwide.
 Seasonality of the site: NO
 Detail of any sister sites: De Matteis Natural Food s.r.l.
 Surface: 210.000 Sq Ft
 of which covered: 112.000
 Pasta capacity: 27.000 t
 Head office audit date if applicable: NO
 Subcontracted processes (detail if yes):NO
 Details of any AVM: The site has been owned by the de Matteis and Grillo families since 1993.
 Registration Number: U5010106403210.61.10001169S as provided by the Reg. CE n. 852/2004 with protocol n. 283 on 27/01/2010.
 There are 12 production lines: 3 long pasta, 5 short pasta and 4 for specialties including nests and lasagna and 29 packing lines.
 Total number of full-time staff: 174, Total number of temporary staff: 43, for a total of 217 people full time on 3 sheet.
 The total site area, including internal and external area's factory is 65000 square meters;
 Products groups:
 - Durum wheat semolina pasta
 - Durum wheat semolina pasta enriched with vitamin
 - Whole-wheat durum wheat semolina pasta
 - Organic durum wheat semolina pasta
 - Organic whole-wheat durum wheat semolina pasta
 - Durum wheat semolina pasta with tomatoes/spinach
 - Durum wheat semolina pasta with oat fibers
 - Durum wheat semolina pasta with vegetables puree
 - Egg pasta
 - Whole-wheat durum wheat semolina pasta with oat fibers
 - Durum wheat semolina pasta with quinoa and buckwheat
 - Whole Wheat spelt pasta
 USE OF LOGO: None.
 other certificate: IFS / ISO 9001 / ISO 14000/ SA8000/ SMETA/ Kosher, Halal, Organic,SCS
 contact in case of emergency: Giuditta Gambarota giuditta.gambarota@dematteisfood.it

5.Product Characteristics					
Product categories		15 - Dried food and ingredients VM - FSMA Preventative Controls and FSVP Preparedness Category Category			
Finished product safety rationale		umidity < 12,5%, aw<0,6			
High care	No	High risk	No	Ambient high care	No
Justification for area		Decision tree, Answer 1: not perishable, answer 2: No for the mill, yes for the pasta factory, for the pasta factory answer 3 yes			

Allergens handled on site	<p>Cereals containing gluten Egg Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen</p>
Product claims made e.g. IP, organic	Organic; IFS
Product recalls in last 12 Months	No
Products in production at the time of the audit	Organic Penne rigate line H, packaging of spaghetti line 21

6. Audit Duration Details			
On-site duration	20man hours	Duration of production facility inspection	10man hours
Reasons for deviation from typical or expected audit duration	ADDITIONAL MODULE FSMA – AUDIT JOINT TO IFS AUDIT (grade a for 3 years and 50% of the total site size utilised as storage space)		
Next audit type selected	Unannounced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1	2019-04-09	09:00	18:00
2	2019-04-10	09:00	18:00
3	2019-04-11	09:00	18:00

	Auditor (s) number	Name	Role
Auditor Number	136204	MARIA AURORA ATONNA	Lead Auditor
Second Auditor Number	N/A		Please select

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
	Marco De Matteis General Manage CEO	X			
Giuditta Gambarota Quality Assurance Manager	X	X	X	X	X
Antonio D'Auria Quality Assurance	X	X	X	X	X

ANGELO Cardinale Quality Control	X	X	X	X
Antonio Festa Managertecnology	X		X	X
Luca de Concilio Resp of produzione	X	X		X
Michele del Regno Plant Manager	X	X	X	X
Antonio Carofalo quality control		X	X	X
Daniele Cerullo Maintenance Manager		X		

Non-Conformity Summary Sheet



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

Critical			
No.	Requirement ref.	Details of non-conformity	Anticipated re-audit date

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

Minor							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	4.4.2	During the audit on site observed a little part of the damaged floor whitout the resins between the line H and L	It is in course the reparation of the floor	The floor was damaged for the high pressure of the equipments in movements. Pap: identification with more attentions of the need reparation	Photos of the reparation	2019-05-09	Maria Aurora Atonna
2	4.8.2	During the audit on site in the female changing room personal effects out from the cabinets	During the audit on site in the female changing room personal effects out from the cabinets	The employees are increased for the new implementation of the new lines. Pap: training to the employees	Training reports	2019-05-09	Maria Aurora Atonna
3	4.11.1	During the audit on site under the head of the line I long pasta observed accumulation of dust and grease not removed	Dust and grease removing	The cleaning under the lines are carried out in continuous by the dedicated operators. The non cleaned area were not cleaned as required by the cleaning plan Pap training to the	Training reports	2019-05-09	Maria Aurora Atonna

			involved employees		
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Comments on non-conformities

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No.	Requirement ref.	Details of non-conformity	Anticipated re-audit date

Major							
No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

BR Minor



BUREAU VERITAS

No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

There are a documented food safety, ambient and social policy Politica qualità/Ambiente e Sicurezza del 29/03/2018 confirmed during the management review (29/03/2018) and signed by Marco De Matteis , exposed at company offices and near processing area entrance, visible to employees, customers and visitors and are communicated to all staff during training .

Monthly meetings are carried on by the staff with the direction on food safety, problems on production , personnel and quality;

Food safety and quality objectives are established and monitored as part of Management Review carried on 29/3/2018 the next is planned on 16/4/2019; the inputs analyzed are KPI, audits, NCs, complaints, training, supplier, customer satisfaction, security

KPI are shared for area for example:

Purchases area (index of the price of semolina and wheat, Nc on supplier,)

Quality area (index of complaints and returns, index of NCs, index of recall and withdrawal, NC on second and third part and so on)

Culture of the quality diffused in the company plan in place since February 2019 with the publishing of the complaints and internal Non conformity monthly trend.

Kpi are defined for the monitoring

Training to the kpi of food safety security to all personnel.

Previous NC's managed.

1.2 Organisational structure, responsibilities and management authority

The DE MATTEIS AGROALIMENTARE has defined its structure and lines of report and responsibility on an Organisation Chart Rev rev. 28 on December 2018 This organisational structure ensures job function, responsibility and reports relationships of staff. Substitution figures are defined for each function

The company has clear roles and responsibilities for the employees, managers and supervisors, whose activities affect product safety, legality and quality (Documento di ruolo e mansioni) Job descriptions are available for relevant staff. . There are documented arrangements in place to cover for the absence of key staff (Substitutes indicated for each position in the organization chart) .

2 The Food Safety Plan – HACCP

HACCP is managed by a multidisciplinary team comprising Company Manager, Quality Assurance Resp. Quality control Resp., Production Resp. Maintenance Resp. Packing Resp. Warehouse Resp. Giuditta Gambarota is team leader named on 19/7/2016 (degree in Food Technology).

Antonio Festa technology manager

Michele del Regno plant manager

Luca de Concilio maintenance responsible

Training for this staff on Haccp and prerequisite is carried on 13/5/2016 final questioners are available.

The “Manuale di Autocontrollo” is available on rev 27 dated 31/05/2017 and covers : flour of wheat, by-products for livestock and pasta for all type and all line , the risk assessment is carried in Rev 8 on 31/5/2017 for the new ingredients Granosaraceno and quinoa the risk assessment is carried out on 8/3/2019 for the introduction of the Hazard of radioactivity

A full description of the product has been developed, including all relevant information on food safety. This includes: composition (semolina , salt, eggs,.....) microbiological properties (total count >10000 UFC; Staph. ufc/g <50, salmonella absent in 25g, fecal coliforms <10 UFC,...), physical properties that impact food safety (Humidity<12,5%, Aw <0,6)), treatment and processing, packaging system, storage and distribution conditions: the product have to be stored at room temperature, the shelf life for this type of product has been estimated in three years, instructions for use (cooking in hot water before to eat) – The product can be used by all the people with more than one year.

Parameters of food safety are for dry pasta 12,5% Humidity and Aw <0,6

The “Manuale di Autocontrollo” covers : flour of wheat, by-products for livestock and pasta for all type and all line

A series of 8 flow diagrams are in place covering each product category and process all Flow chart are updated on 23/1/2018, seen for example:

DF01 –mill and wheat long and short pasta

DF02 – mill and organic pasta

DF03 – mill and all wheat semolina pasta

DF04 – mill and all wheat organic pasta

All flow diagrams are confirmed on site.

There was a hazard analysis in place with likelihood and severity scored giving risk ratings. Qualitative evaluation of hazards was included, e.g. they have assessed physical, chemical and microbiological hazards and vulnerability of the raw materials using experience, process and product knowledge, scientific and technical data, News letter and RASF . The effects of: Temperature /Humidity / Thermal Processing were also considered.

Appropriate critical control points (CCPs) relating to product safety have been identified for the process by risk assessment and the use of a decision tree :

2 CCP's have been identified and the monitoring system are:

- Egg incoming & storage (hazard: contamination by Staphylococcus Aureus, critical limits are T>0°C and T<4°C) - monitoring in continuous by data logger and every 4 hours by operators.

- Metal foreign bodies monitoring every hour by tester (critical limits :Fe 1,5 mm, Not ferrous 2,00; Stainless steel 2-2,5 mm; on catering packing line Fe 2,5 mm, Not ferrous 3,00 and SS 3,5 mm) and memory test at the beginning and at the end of the production shift

Validation of the CCPs, CP and the cleaning procedure, pest management are carried on 28/3/2019 and Annual Haccp review is carried on the last is dated 25/2/2019

Evaluation of vulnerability and fraud is carried on 26/3/2018 for all raw materials are analyzed: wheat, semolina, spelt, dry spinach and tomato, oat fiber, vitamins, puree of vegetables, eggs and mixed eggs For the wheat for example is considered : infestation, contamination for the presence of moulds, different origin for the Italian products, organic certification

For egg are analyzed: presence of dyes, presence of carbonate, enriched on soda or CO2, presence of medicines and dioxins for example.

3. Food safety and quality management system

3.1 Food safety and quality manual

The DE MATTEIS AGROALIMENTARE has a fully implemented Quality System. The company is ISO 9001 certified since 2000. There are one complete document (Quality Food safety Manual, Etc and Environment) – rev. 2 on 16/7/2018) contains an overview and is largely ISO 9001:2015 and 14001, BRC andIFS, SA8000 based. Procedures, work instructions and registration forms are in place. Lists of documents are available (27/3/19). Documents related to the food safety and legality are available in the company and are well stored and kept for at least time of shelf life of product (3 years) more one year.

The company obtains technical and legislative updates and support through its Quality Manager, industrial association (UNIPI and ITALMOPA), external laboratory and technical consultant.

3.2 Document Control

Documents related to the food safety and legality are available in the company and are well stored and kept for at least time of shelf life of product (3 years) more one year.

3.3 Record completion and maintenance

Records related to the food safety and legality are available in the company and are well stored and kept for at least time of shelf life of product (3 years) more one year.

3.4 Internal audits

Company has implemented a system for internal audits of the systems and procedures (PI24 – 20/3/2019) that are critical to product quality, legality and safety. Plan of audit and internal inspection is available and based on the risk assessment and dated 20/3/2019: programme is scheduled throughout the year and covers Haccp programme, PRP and all procedures implemented to achieve this standard. Verified report of integrated internal audit on 06/06/2018 based on the results of 9 audit report carried out on different areas- by Gambarota, Festa and D’Auria the emerged Ncs were quickly managed. The site inspections are carried on every 15 days by quality control staff

Inspection on the plant are carried out by internal personnel every 15 days. Check list Igiene e Sicurezza, CCP, Norme generali e specifiche aree di lavorazione e magazzini updated Rev 22/6/2015. Seen the checklist dated on 29/3/2019

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

Company has a documented procedure for supplier approval and a assessment program in place based on risk assessment

Purchased products and services are checked in accordance with the existing specifications

Quality and evaluation of supplier of raw materials and services PI 13 rev 17/7/15. The annual qualification is based on the results of the furniture during the previous year(

how many NC)

The company acquires both the wheat and the semolina. The wheat by Italian origins acquired by farmers than other wheat warehouse. The semolina by other mills

Audit are planned on all keys suppliers seen for example audit to Gasillo on 21/3/2019

New food Industry supplier of dried spinach on 27/7/2017

New Dimention Plastic on 1/8/2018

Checklist and self assessment sent to all supplier rev 7/6/2017,

Risk assessment for raw material is updated every year on 28/3/2019 raw materials eggs, wheat and semolina and other minor ingredients.

The risk assessment take in count the vulnerability assessment based Carver method: The raw material evaluated on medium risk is eggs while the other raw materials are assessed like low risk.

The company shared with the supplier its capitulate with the requirement of the food safety allergen and GMO declaration, see capitulate for the semolina T2 Rev 2 on 3/1/2017, capitulate for liquid whole egg free range "vegetable" rev on 19/03/17

The company acquires the following finished products:

Pasta gluten free supplier Mennucci GFSI Certified IFS Coid 14983 delivered with Pasta Armando Brand

Potatoes Gnocchi supplier Ciemme Alimantari s.p.a BRC certified BRC Sitecode 1253766 delivered with Baronia Brand and Sam's Choice the customer knows the supplier of gnocchi seen audit report of the customer on site dated 15/3/2019

Sporadic purchase from Broker are carried out by the company. In the analysis report are defined the primary supplier. And in the sanitary certificate seen the contract n. 463029 with Glencore supplier Altyn-Biday 200 report analysis in entry are available

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Acceptance is based on visual inspection and certificates of analysis specific to each consignment for semolina and wheat (moisture, protein, ash, black spots, soft wheat, gluten evaluation). By internal laboratory on the mill on durum wheat and semolina analysis on the commercial parameters are carried out for example, humidity, protein, gluten and ashes for each lot. Seen acceptance of batch 0119053680 semolina by Balletra

By laboratory at packaging warehouse the analysis are carried out on eggs: Temperature, sensory test, pH and fat

on the raw wheat: Humidity, proteins, radioactivity, OGM annual, DON, Tricoteceni e alfatossine total, zeralenone, Pb and Cd every 2 months, for organic materials for each

entry Phosfina, cholmequat, glifosate Soy OGM.

Seen report 18/000259045 on 25/6/18 on contract n.1834864 Micro (CTB, Salmonella moulds and yeasts)

Weekly microbiological analysis: Report n. 761 on 4/1/2019 E Coli

Afaoxines analysis report n19/000045156 on 6/2/2019 on semolina organo lot 19046 DON HT2 T2

report n.19/000030231 on 28/1/2019 Semola supplier LoIudice L0119052327 E.Coli, Enterobacteria

Gliphosate on wheat report 19LA01122 on 21/1/2019 silos 103 supplier Cereali Sementi

3.5.3 Management of suppliers of services

Supplier of services are qualified through check list and acquisition of documents required by procedure; the qualification is carried out every year based on the performance of the previous year

Seen contract with and qualification of Soges pest management on 2/2/2015 and reviewed on 2019

3.5.4 Management of outsourced processing

NA

3.6 Specifications

Specifications for raw materials, packaging materials, finished products are available and managed by SAP software directly by technical department. The specifications are updated and checked (SAP software system). About 1500 finished product specifications are managed

Verified IO43 on 08.011.12 " Aggiornamento specifiche" and following technical sheet

Seen specifics of Gustoso Linguine Brand Gustoso supplier BidFood dated 5/12/2018

Technical capitulate of the Pasta Armando rev01 on 1/1/2019

Seen capitulate with Ciemme Alimentare srl for gnocchi rev0 on 3/10/2016 seen the samples plan of the acquired gnocchi applied for each entry: Humidity, net weight, labels, Integrity of the packaging, periodical analysis on microbiological parameters Yeasts and moulds

Specifics of ALDI Australia dated 25/08/2017 for organic pasta

Vitamins supplier Stern Vitamin dated 29/8/2018

Capitulated with Eurovo for the Egg Yolk dated 2/6/2018

Capitulate for the Multigrain flours supplier DeMartinis dates 1/7/2018

Seen Capitulate of organic Semolina Type T5 e T8 rev 2 on 3/1/2017 shared with the supplier

Seen specifics of the Film Poliethilene supplier New Dimantio with the conformity declaration dated 15/11/2018

Paper box supplier Stampasud srl specification on 17/9/2018 and conformity declaration on 4/4/2019

3.6.5 Aldi audit :Supplier maintains approved copies of ALDI Product Specifications dated 25/08/2017, in ERP system as a controlled documents. Check on audit PIF Just Organic Spaghetti. Supplier maintains ALDI Corporate Responsibility (data ERP system attached to the PIF/product code identification). Supplier ensure that the product meets all food safety/safety, regulatory and quality requirements as defined in the PIF/ALDI Product Specification and ensure through the trader, that any changes to the PIF/NPL are communicated to the Buying Director : cross check on audit with the traceability test

3.7 Corrective and preventive actions

Procedure PI25 – rev 2 on 16/7/2018 is in place- Corrective and preventive actions are clear managed and implemented, records of management are recorded on the master of NC manager- Corrective action report no.5 of 25/10/2018 for spotted pasta originating from several complaints and internal NC for the same cause on long pasta lines (flat formats). Decisive actions:

- Establishment of pipe washing and planning of purchase of a pipe-washing machine**
- grinding lubrication system**
- management and cleaning of certain areas of the line by the operator on a daily basis**
- updating of cleaning specifications**

Estimated closing date: 30/04/2019 with installation and testing of the tangle-washing machine

3.8 Control of non-conforming product

Procedure PI20 – rev 6 on 27/6/2017 is in place for the management of NC. This include isolation of NC product, risk assessment, identification by labelling, decision about the further use. All NC are correctly managed appropriate root causes and corrective actions had been undertaken with appropriate time scales in all instances checked during the evaluation.

Monthly analysis on NC are carried on comparing the number of nc emerged in a month with the numbers of NC in the same month of previous year. The principals causes of nc

are packaging out of standard and burned pasta.
The company has carried out root causes analysis for all Nc and action and preventive action taken are recorded and monitored
Internal NC Sample No. 200015479 of 05/04/2109 on Member's Mark brand spaghetti product lot L9090N for isolated buttoning 90 packs. Treatment: intended for zootechnical use

3.9 Traceability

A product identification and traceability procedure PI22 rev. 07/03/2014 enables identification of all raw materials and food contact packaging and provides traceability of work in progress and finished products at all stages during manufacturing, storage and dispatch.

During the audit was carried traceability

Test from finished products to raw materials:

Organic Spirals semolina pasta brand Just Organic lot L9040 produced on 9/2/2019 packed on line 18, film lot 91122018 supplied by New dimantion plastic DDT 5681 on 7/12/2018 declaration of the conformity dated 7/12/2018.

The pasta was produced on 9/2/2019 line L number of order 20029351 used two semolina batch: DMA29053 produced by the De Matteis Mill and 0119052535 supplied by Santacrocce DDT 127/M on 2/2/2019 (available declaration of the conformity certification of the cleaning of the tank, pesticides analysis report n. 300119-007 on 30/1/2019, filter test by DMA report 19b03398-It-0 del 1/2/2019, Soy presence report n. 19/000048170 on 8/2/2019. The semolina batch DMA29053 was produced on 4/2/2019 from wheat supplier Cerealfert sementi 8 trucks arrived for example 154/1 and 174/1 seen pesticides analysis RDP 19LA01118 on 26/2/2019, glyphosate report 19LA01122 on 21/1/2019, phosphine 19LA01119 on 23/1/2019 production of semolina pesticides 190267 on 7/2/2019, piperonilbutossido and pirimiphosmetile La 1902686 on 7/2/19

Analysis on pasta pesticide fosfina 180219-035 on 19/2/19

There is a detailed rework procedure PI22 on 07.03.14 that takes into account the safety or legal status of the finished product, ingredient declaration, allergen information, identity preservation.

From raw material semolina organidot 0119052535 arrived on 2/2/2019 by Santacrocce used on production order from 5/2/19 to 11/2/2019 all used kg 31640.

The company planned several tests of traceability seen internal test on Fusilli Bio Despar on 14/3/2019

3.9 ALDI AUDIT TRACEABILITY: Organic Spirals semolina pasta brand Just Organic lot L9040 produced on 9/2/2019 packed on line 18, film lot 91122018 supplied by New dimantion plastic DDT 5681 on 7/12/2018 declaration of the conformity dated 7/12/2018. The pasta was produced on 9/2/2019 line L number of order 20029351 used two semolina batch: DMA29053 produced by the De Matteis Mill and 0119052535 supplied by Santacrocce DDT 127/M on 2/2/2019 (available declaration of the conformity certification of the cleaning of the tank, pesticides analysis report n. 300119-007 on 30/1/2019, filter test by DMA report 19b03398-It-0 del 1/2/2019, Soy presence report n. 19/000048170 on 8/2/2019. The semolina batch DMA29053 was produced on 4/2/2019 from wheat supplier

Cerealfert sementi8 trucks arrived forexample 154/1 and 174/1seen pesticides analysis RDP 19LA01118 on 26/2/2019, glyphosate repor19LA01122 on 21/1/2019, phosfine 19LA01119 on 23/1/2019 production of semolinpesticides190267 on 782/2019, piperonilbutossido and pirimiphosnetile La1902686 on 7/2/19 Analysis on pasta pesticide fosfina 180219-035on 19/2/19

3.10 Complaint-handling

A clearcomplaints procedurPI23 on 23.04.12 is present. The complaintsre managed by SAP, a software that allow very effective analysis of complaints. Complaint data is reviewed monthly throughtrend analysis anddiscussed at the management meetings..
- Complaints- 23% comparedto 2017 (main causes of contamination (dirty/spotted/misked paste)non-standardpackagingbreakageforeign bodies, labelling). Total foreign bodies 9 (e.g. parts ofubber strips)
Samplingcomplaint no. 200015157 Esselungaustomer for spottedpasta communicated by mail on04/02/2019format linguindot L8297NA, registered in the system on 09/08/2018. The customerreports a package with some wires of tonguestained withblack condensation. The problemis confined to the package reported bythe customer. Mail processing complaint of 11/02/2019 withanalysis causes and guarantee thátis an episode confined to thabnly package

3.11 Management of incidents, product withdrawal and product recall

The DE MATTEIS AGROALIMENTARE has an effective incident management p 29 gestione emergenze Rev 3 on 24/10/2018 and product recall procedure PI06 -rev 05 on 20/01/2019 -The procedures includes the required actions in case of: disruption key services (water,energy, transport, staff availability and communications) fire, flood and natural disastemaliciouscontaminationor sabotage.
It includes: members ofthe incidentmanagementteam, a listof the relevant and key contacts,details of appropriate external agenciesproduct recall and withdrawal procedures, corrective actionand business recovery, communication plan Giuditta Gambarotás team leaderof crisis team.

Internaltest on 1/2/2019 on 365 Pennerigate L 90145 time usedB,37 hours

4. Site standards

4.1 External standards

The factory is located on a8.000 sq m site and issuitably maintainThere are no adverse local activities in thámmmediate vicinity of the factory. All external areas are finished and maintainedto an appropriate standardThe monthly internal audit process includes assessmentof the condition ofthe site.

4.2 Site security and food defence VERITAS

The site is fully fenced. There is manned security and the gates are kept locked out of production hours. Access points are designated and restricted areas are defined on the site plan and clearly marked. Procedures are monitored, controlled and reviewed (seen IO068 rev2 on 30.10.17 "Food Defence" the team leader is Mr Del Regno. Evaluation of the Security System is carried out with the check list on 21/3/2018, the stress test is carried out on 15/6/2018 annual training to all employees is carried out seen for example the training report on 4/12/2018, quarterly the company carries out the valuation of the plan through a checklist the last on 21/12/2018. The Food defence plan is reviewed annually since the end of 2018 is certified for the Supplier Chain Security. Site security was maintained by Gatehouse security, All external doors locked, 24-hour manning of site. All the doors were closed during the audit - Chemical storage is in a locked cupboard. The flour silos are kept locked.

4.3 Layout, product flow and segregation

Layout updated with the flows of personnel, waste, processing and reworking. Whole plant is assessed as low risk area. Separate rooms are in place between raw material storage, production area, packing area and finished products storage. Dedicated and separate drawplates washing greases in place. Maps of risk areas updated on 21/7/2015, areas are defined in low risk area and enclosed product area.

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

The fabrication of the site, buildings and facilities is very suitable for the intended purpose. Walls and floors are in satisfactory condition, being of impervious resin finish and able to meet demands of the process. Drainage is of satisfactory design, with flow away from high risk. Externally opening windows in production and storage areas are screened against pest ingress - On the third floor of the mill pens fences were reset. All lights and EFK tubes are suitably protected against breakage. Oven chamber lights are covered with a fine mesh and inspected daily for damage. There is a dust extraction system installed in the dry powder handling area. Ventilation and extraction throughout the site is satisfactory.

4.4.2 During the audit on site observed a little part of the damaged floor whit out the resins between the line H and L

4.5 Utilities – water, ice, air and other gases

Water in processing is drawn from the potable water supply and included in the water quality monitoring (chemical analysis are conducted every six months and microbiological analysis every three months). Map of the water system is described on 4/8/2014 rev7. Seen IO 0.40 "Gestion rete idrica" the samples plan requires chemical and physical analysis every 6 months while microbiological parameters every 3 months. Seen report of Merieux Nutriscience rep 18/000446980 on 17/10/2018 (complete) on Line E - Microbiological analysis report 19/000058725 on 18/2/2019 on microbiological

parameters. the water is chlorinated and de-chlorinated every day.

No Backflow in place

The chlorine concentration of the de chlorination devices carried out every week and recorded on M1434, this activity is recorded

4.6 Equipment

12 production lines: 3 long pasta, 5 short pasta and 4 for specialties including nests and lasagna and 29 packing lines. The whole packaging process is fully automated with mechanical bundling, palletizing robots, shuttles and spools flanking end of the finished product in stock. Equipment is maintained to minimise the risk of product contamination

4.7 Maintenance

PI17 rev8 on 05.03.15 "Maintenance" is in place both by internal personnel than by external company Baronia Services.

For all equipment critical to the safety, legality and quality of the product there is a "sheet of machinery", on which RMAN to planned operations of maintenance. The registrations are carried on the scheduled maintenance operations both ordinary and extraordinary interventions with date, the input used and signature of the operator involved.

There is a system in place for the release of equipment back to production after maintenance to ensure thorough cleaning has been implemented. Where appropriate, lubricating oils and paints are food grade: list of grease and oil and their classes is available. The cleaning of the area and equipment is checked on M207 rev 1 the cleaning and the removal of the foreign bodies and waste, seen record of the intervention on 20/3/2019 extruder L

During the audit the installation of a new production line and several other intervention. For each external company the DMA has defined the operative instruction for the hygiene and behavior and food defence. Specific training is carried on 12/3/2019 for Lorenz pan contract 28/11/2018 the emergency contact are available.

4.8 Staff facilities

Staff facilities are designed and operated so as to minimize the risk of product contamination. Changing facilities have been provided for all personnel entering production, packing and storage areas. Separate lockers are provided to allow outdoor clothing and other personal items to be stored separately from work wear and washing facilities, provided with non-hand operated taps, suitable soap and towels are situated at the entrance to production and at various points within the area.

4.8.2 During the audit on site in the female changing room personal effects out from the cabinets

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

4.9.1 Chemical control

VERITAS

The chemicals used are all food suitable and personnel are trained in their use. They are stored in a dedicated, bounded external container in the yards. There is a documented policy for the control of the use of metal knives/cutting blades/needles/wires. There are no staples or similar items used in packaging.
The chemicals used are all food suitable and personnel are trained in their use. They are stored in a dedicated, bounded external container in the yards. Updated list of chemical products is available.

4.9.2 Metal control

The risk assessment for the hazard of the foreign body presence in the pasta factory and for the plant sister on 14/3/2017 is carried on. Semolina is passed through sieves and online magnets prior to use. The sieve integrity is checked every week for the change shape with records. Documented knife policy - numbered and inspected daily. Metal detectors after packing. Weekly glass audit (verified last on 15.09.16 and 22.09.16 recorded on check list "Igiene Sicurezza" by quality control) and fortnightly Plexiglas audit

There are documented policy for the control of the use of sharp metal implements including knives, cutting blades on equipment, needles and wires. The company carries on monthly inspection for damage and the investigation of any lost items. There are no staples or similar items used in packaging.

4.9.3 Glass, brittle plastic, ceramics and similar materials

The presence of brittle materials are minimized and protected against breakage in all areas. Maps of brittle plastic is available they are monitored fortnightly and recorded on check list "Igiene Sicurezza" by quality control weekly for the glass and for plastic every 15 days last monitoring glasses on 04/04/2018 and 28/3/2019 for hard plastic. The check list have the position and the number of the object.

4.9.4 Products packed into glass or other brittle containers

NA

4.9.5 Wood

Wood is not used in open product areas only in packing area on the end of the lines. The condition of wood are monitored to ensure it is in good condition and free from damage or splinters which could contaminate products or the ambient

4.9.6 Other physical contaminants

Debugging activities are minimized only for powdery ingredients. they are managed separate area and filters are present. Pens in production area were detectable.

4.10 Foreign-body detection and removal equipment

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

Risk analysis is carried in HA plan filters, magnets, and metal detectors are in place
Packed pastais passed through in line metal detectors.
 - ***Metal detectors are monitored every hour by test (critical limits :Fe 1,5 mm, Not ferrous 2,00; Stainless steel 2-2,5 mm; on catering packing line F2,5 mm, Not ferrous 3,00 and SS 3,5 mm) and memory test at the beginning and at the end of the production shift***
Validation of Metalis carried on 17/03/2017: IO 065 rev 2 on 14/8/2015 management of metal magnets with functionality control available memory test for each turn (used the sample of ferrous 27 mm).
Calibration by Almatec no of all metal detector is carried on 22/10/2018

4.10.2 Filters and sieves

Semolina is passed through sieves and online magnets prior to use
The sieve integrity is checked every change shape with records (seen mod MP09/2 on 1.09.12 "pulizie filtritrafile and) . Filtri con frolo set accini locale sfarini 32 rev 5 on 2/9/2013 every days.
Seen plansichter list on 25.06.12 (8 in mill and 10 in Silos area)

4.10.3 Metal detectors and X-ray equipment

Packed pastais passed through in line metal detectors.
 - ***Metal detectors are monitored every hour by test (critical limits :Fe 1,5 mm, Not ferrous 2,00; Stainless steel 2-2,5 mm; on catering packing line F2,5 mm, Not ferrous 3,00 and SS 3,5 mm) and memory test at the beginning and at the end of the production shift***
Validation of Metalis carried on: IO 065 rev 2 on 14/8/2015 management of metal magnets with functionality control, available memory test for each turn (used the sample of ferrous 27 mm).
Calibration by Almatec no of all metal detector is carried on 22/10/2018

4.10.4 Magnets

Magnets are installed in the mill and pasta factor . Seen magnets List dated 31.08.12: 40 magnets are in place and checked every day for the packaging

4.10.5 Optical sorting equipment

NA

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

NA

4.11 Housekeeping and hygiene

Cleaning are performed by external company "Multilabor srl" : contracts are in place with annex about plan of cleaning PQC 05 on rev 6 on 3/1/2019 for ordinary cleaning activities with identification of the areas, time and equipments to used. For each line are defined the Capitulate with more evidence of the point and nodalities to cleaned. In the last year there are increasing on the number of hour on site for the operators. Cleaning records are taken

on Module MP distinct for operator andrea .

Monitoring of cleaning activities is carried on by quality control department during the daily start up controls

activities are described for the mill pastafarm and silos area and for each operator the timing, the dilution, the modalities and the equipments are defined

the visual monitoring are verified by the quality control every 15 days

Validation is carried out:

- **Weekly microbiological lab test on the fresh extruded product (stafilococcus)**
- **Weekly microbiological lab test on finished product (E. coli)**
- **Monthly microbiological test on mixing containers (Stafilococcus e coliformas) d**
- **on operators Coliforms report 166/29 del 3/4/2019**
- **Every 6 months on dye (stafilococcus and TBC)**
- **After every cleaning run : chemical risk by monitoring ohPh**
- **Every 6 months (stafilococcus e TBC, E. Coli) on pump of eggs**

Changeover of the production after the eggspasta seen analysis on loom and extruder G report 19LA03028 del 11/2/2019 and on mixing tank report 19LA03027 on 11/2/2019

Extruder matr 2181704 report 18LA21804 del 14/9/2018 CTB and stafilococcus

For egg dosing are used a disposable pipe and only the pump is cleaned report 18LA21802 del 14/9/2018 CTB E coli stafilococcus

4.11.1: During the audit on site under the head of the line I long pasta observed accumulation of dust and grease not removed

4.11.7 Cleaning in place (CIP)

NA

4.11.8 Environmental monitoring

Environmental monitoring is carried out by the company mapping the contact points of the raw materials and finished products with the lines and when the products are exposed. Swab tests are planned on the surfaces and on the operators hands and clothes and identified the microbiological indicator

4.12 Waste

Discarded pasta is destined for animal feed. Registration for Reg JE 183 is available. Other waste is well divided and stored in external areas in cleaned containers. Waste is well and correctly managed

4.13 Management of surplus food and products for animal feed

Operative instruction for management of egg grind and waste is available IO 27 rev 2 on 27/07/2015 with identification of type of products both for mill then pasta farm. Authorization for feed production IT 064032001 on 23/1/2007 reg CE 183/2005 is available. In the pasta farm are identified: fresh pasta destined to external companies for production of combustible, while waste dried pasta are destined for feed.

For the products with customer's brand the company has implemented a Policy to manage the waste customer's brand products communicated to customers. Verified last communication (authorization to destruction) for reformed dated 11.8.16

4.13 AUDIT ALDI : Procedure in place to ensure that any ALDI branded product or packaging rejected by ALDI due to discontinuation, obsolete packaging and/or product not fit for purpose (including withdrawn and recalled products) is disposed of in an appropriate manner as agreed with the Buying Director and is not sold through staff, factory or other retail outlets.

ID product code (univocal), recipe and label, are set into our ERP system.

When there is a new code (new pack, new recipe), the old one is deactivated (it is not possible to buy and use the old pack production, it is no possible to produce the old recipe in production).

Withdrawn and recalled products do not entry in our WH: they are coded in a different way for animal feed destination after pack removal

4.14 Pest management

Pest control is managed by external company Sogest srl contract n 31/11/2014- automatically annually renewable- IO 005 Monitoraggio e controllo infestanti di natura biologica rev 24 del 27/3/2019 is in place where for each department of the mill and the pasta farm thresholds are defined for each pest.

Plan of traps is dated on 30/1/2019 but is available online on the Soges's web site: monitoring is full implemented on internal and external areas of mill and pasta farm.

Monitoring is carried on every 15 days for insects and every months for rodents.

Seen report of the monitoring of insects on 29/3/2019 and 13/3/2019 complete.

Quarterly report are carried out with the trend analysis of the captures seen report dated 3/4/2018 no NCs or alert are recorded

Every 6 months inspection by field biologist is carried seen report dated 29/10/2018 the next is fixed on 15/4/2019 the NC emerged by the inspection are managed by the company like internal NC, action plan and timing of closure is define.

External company Soges had trained on 09/1/2018 the field biologist of the Soges to responsible of the internal monitoring and the cleaning personnel.

It is available training to all personnel carried out by Quality assurance about pest monitoring 3-4/1/2018

On the automatic warehouse every month a floor treatment is carried out with Deltametrina

On internal area (mill and pasta farm) the floor treatments are carried out with Piretro

On external area on May and September treatment with Cipermetrina.

On the pasta farm area and mill are carried on heat treatments: the last on the mill since 3/6/2018 at pasta farm while in the mill the heat treatments was in place during the audit

On the Silos treatments with phosphine and Difluoro d'olforinile are carried every year, the last on 13/8/2018. Absence on treatment on raw materials is checked after each interventions verify on the first production of the semolina, seen report n18LA19919 on 22/8/2018 semolina batch 18377. Phosfina absent

On the automatic warehouse treatment with deltametrina are carried on the floor.

4.15 Storage facilities
<p>PI15 on 26.04.12 "Ricezione e stoccaggio materie prime, stoccaggio e trasporto prodotto finito" is in place to ensure the storage of raw material, finish products and packaging – No temperature control and controlled atmosphere required during storage</p>
4.16 Dispatch and transport
<p>PI15 on 26.04.12 is in place to hygienic checks of vehicles during loading and transportation . Stable temperatures during transport . Only for the eggs entrance the temperature of the transport is monitored for each entry. Contract with the transporter of the finished product are in place complete of the requirements on hygiene and food defence</p>
5. Product control
5.1 Product design/development
<p>A procedure for product development PI07 04.02.13 is in place. Seen project for Aldi Bio Kids begun on 12/11/2018 the evaluation of the project on food safety, environment, involved production lines is carried out any modification at the risk assessment Seen specifics of Great value Walmart specification 10/4/2019 uploaded on the customer portal. Seen development of new line of products under customer brand begun on 9/1/2018 with analysis of the capitulate, test of production and validation of the shelf life. Shelf life tests are performed yearly. No changes in the product recipe have occurred during the last year only pack/artwork for restyling The shelf life is 36 months. Report of shelf life. Organic pasta order n° 20028482 from 30/06/2017 with internal and external tests. verified test by Bonassisa Lab n. 12836 on 30.06.17 (Aw, Acidity, moisture , TBC, coliforms E. Coli, staphilococchi, mould and yeast, kreiss test) Organic pasta order n° 20028482 from 30/06/2018 with internal and external tests. verified test by Merieux on 30.06.17 (Aw, Acidity, moisture , TBC, coliforms E. Coli, staphilococchi, mould and yeast, kreiss test)</p>
5.2 Product labelling
<p>All products are labelled to meet legal requirements for the designated country of use .the labels include information to allow the safe handling, display, storage, preparation and use of the product within the food supply chain or by the customer For the European labels and</p>

USA labels dedicate office that checks on M125 seen verified of the labels for the spaghetti Great value

5.3 Management of allergens

The DE MATTEIS AGROALIMENTARE has conducted a risk assessment and has identified all products on site which may contain allergens, and requires special handling procedures. The allergens on site are gluten and egg (declared on the label). - Seen IO69 ref 2 on 28/8/18 "Gestione allergeni" with risk analysis carried on for each line, allergen managed are Gluten, egg. the company declared the possible presence of egg and soy like cross contaminations.

Validation is carried on 14/3/2017 and verified through analysis plan on surfaces and products.

For the soy visual inspections are carried out for each entry of wheat, on mass semolina per supplier weekly analysis are carried out on soy proteins, for the eggs the extruder and every 6 months (products and equipment).

Appropriate, validated cleaning procedures are in place.

Procedure is validated on 26/3/2018 based on analysis on the finished products produced after the allergens (egg to no egg), swab test on the line and on the extruder

5.4 Product authenticity, claims and chain of custody

Risk assessment for raw material is updated every year on 28/3/2019 raw materials eggs, wheat and semolina and other minor ingredients.

The risk assessment takes into account the vulnerability assessment based on Carver method: The raw material evaluated on medium risk is egg while the other raw materials are assessed as low risk.

Periodic evaluation of the alert for the vulnerability of the raw materials is carried out using the main of the official sources like Rasf or news letter of the specialized organization of the sectors.

Mitigation activities are identified and planned both through the analysis and by the audit and capitulated with the supplier.

For the glyphosate emergency hazards reinforced analysis plan is carried out.

Organic materials are handled and are adequately segregated, the company declares the subsequent claim:

- **100% Italian wheat is controlled in entrance in bases of morphologic parameters and through annual test of traceability on supplier, the company knows the supplier chain, traceability tests, and seeds recognition in acceptance.**
- **Free range verified through traceability test on supplier and declaration in entrance**

5.5 Product packaging

Contract for the supply of film for packaging no D075 of 03/12/2014 with New Dimension Plastic S.r.l. with stamp and signature of acceptance of both parties with definition of the approval time for printing and delivery, defective material, prices related to quantities ODA n. 4500114994 to supplier New Dimension Plastic S.r.l. for 3,500 kg of Grand Tasty various formats

Verification in acceptance recorded on Goods Entry Document No 180026626 of 18/03/2019 reference DDT No 1323 of 18/03/2019 with the following checks:

- Room hygiene
- Foreign bodies
- Pest
- Damage
- Merchandise integrity
- Absence of substances of porcine origin
- Absence of substances of animal origin or alcohol

Attachment Certificate of quality packaging lot 2171 of 18/03/2019 with result of internal tests (e.g. solderability test, corona treatment, internal/external COF)

Quality control report of 18/03/2019 internal batch 010000394141 with definition of: deterioration, printing errors, foreign odours, barcode readings, size, weight, weldability test, certified/supplier certificate, surface tension, static COF, dynamic COF, text control.

Declaration of conformity and suitability for food contact by New Dimension Plastic S.r.l. dated 15/11/2018 concerning the material LDPE+LDPE

Technical datasheet primary packaging of the film in question no. FL_18083 PE50+PE50 Tasty mark of 03/06/2013 flexo printing with pdf attachment of the approved sample.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Product controls are present and are organized by a sampling plan for the raw materials and packaging PCQ 01 rev.33 on 24/5/2017 for packaging and raw materials, PCQ02 Rev 19 on 27/2/2018 for the mill, PCQ 03 rev 32 on 30/6/2017

By internal laboratory on the mill on the durum wheat and semolina analysis on the commercial parameters are carried out for example, humidity, protein, gluten and ashes for each lot.

By laboratory at packaging warehouse the analysis are carried out on eggs: Temperature, sensory test, pH and fat

By external laboratory every 2 months are carried random: contaminants, heavy metal, Pesticides annual and phosphine every 6 months on raw wheat, on the eggs every 6 months colour, and microbiological parameters, annually OGM and Dioxine.

For example on the raw wheat Seen report 18/000259045 on 25/6/18 on production order n. 1834864 Micro (CTB, Staffles, Salmonella yeasts)

Weekly microbiological analysis: Report n. 761 on 4/1/2019 E Coli

Afaoxines analysis report n. 19/000045156 on 6/2/2019 on semolina organic lot 19046 DON HT2 T2

Semolina acquired report n. 19/000030231 on 28/1/2019 Semola Lo Iudice L0119052327 E.Coli Enterobacteria

Gliphosate on wheat report 19LA01122 on 21/1/2019 silos 103 supplier Cerealfert sementi

Seen report. N. 17La15315 on 1/8/2017 DON and Arsenic on wheat, report n. 18/000096729 on 9/3/2018 Aflatoxines

Report 19LA01447 on 23/1/2019 Fosfina. Lot 19026

Nutritional parameters on organic pasta with oat fiber declared high fiber: report 19/000108290 on 21/3/2019 fiber 9,3 gr/100 gr
 Change over egg and no eggs: analysis on the first production order n. 239640 report n. 19LA04763 on 7/3/2019

The company has a schedule of analysis of finished product upon risk assessment and covering all critical parameters. PCQ 03 rev 32 on 30/6/2017

By pasta factory laboratory every day: humidity ashes, proof stability, acidity

By external laboratory microbiological parameters every week and chemicals:

Report n. 18/0000335128 on 10/8/2018 E.Coli, report 18/000268858 on 29/6/2028 micro complete

Aflatoxine and heavy metal report n. 18/000255518 on 21/6/2018

Filth test report n. 18LA14290 on 27/6/2018

Most product analysis is conducted in the on-site 2 laboratories (mill laboratory and general laboratory) well separated from production activities.

Appropriate, documented controls are in place which carries only chemical and rheological testing.

Pathogen testing and nutritional analysis are carried out by a contract laboratories operates in accordance with the requirements and principles of ISO 17025. Organoleptic testing is carried out in line with specifications. Cooking tests are conducted daily, panel tests weekly.

5.6.1 ALDI AUDIT. Analysis tests carried out by third part lab are available.

All products supplied to ALDI Australia meet the agreed microbiological, pesticide residues, heavy metals, food additives, chemical and contaminants criteria. Supplier has documented, implemented and maintained a testing program (PCQ 01, 02, 03 Quality Plan). The test are carried out by external accredited lab (ChelabSilliker, Neutron, Blab, Bilacon, Eurofin, ecc.). The supporting documentation in relation to chemical and microbial testing are available at time of audit.

5.6.2 Laboratory testing

The company has a schedule of analysis of finished product and raw materials based upon risk assessment and covering all critical parameters. Most product analysis is conducted in the on-site 2 laboratories (mill laboratory and general laboratory) well separated from production activities.

Appropriate, documented controls are in place which carries only chemical and rheological testing.

Pathogen testing and nutritional analysis are carried out by a contract laboratories operates in accordance with the requirements and principles of ISO 17025. Organoleptic testing is carried out in line with specifications. Cooking tests are conducted daily, panel tests weekly.

5.7 Product release

Release of the product is performed and recorded by the CQ of packaging boards.

Each batch of finished products is release after positive check of each step of production on SAP

5.8 Pet Food

NA

6. Process control

6.1 Control of operations

Procedures are in place to verify that processes and equipment employed are capable of producing consistently safe and legal products with the desired quality characteristics. EsBottatura, humidity of pasta cooking time.

Process monitoring checks conducted include: chlorine water measurement every day, dye filter control for each change of shape, moisture, ash, temperature, pressure, cooling, vacuum level checks and traced on PLC during the production process. metal detection sensitivity checks (every hour), weight control (20 packs every 2 hours), label checks and date coding checks). For Process parameters that are controlled by in-line monitoring device (e.g. cooling temperature or drying parameter), control systems are alarmed in the event of failure

6.2 Labelling and pack control

IO 031 rev 6 on 04/5/2016 is in place to assure the correct use of packaging on packing line. Operator of line control the code of packing authorized on Sap for the daily production. Every hour this control is carried out verifying the bar code on the film used matching with the bar code of the production order

6.3 Quantity, weight, volume and number control

The frequency and methodology of quantity checking meet the requirements of legislation governing quantity verification (Law 690/78). Product is also passed over an in line check weighed with reject mechanism tested hourly .

6.4 Calibration and control of measuring and monitoring devices

All instruments used for monitoring Critical Control Points and safety / legality of the product are identified. Updated list is available .They are subject to periodic adjustment based on their criticality, against national champion recognized by the Italian Calibration Service (Accredia).

PI18 rev4 on 24.10.14 “calibrazione e taratura degli strumenti”

The critical tools are subject to adjustment by:

- Weight Control Scales
- Line Scales
- Probes thermo hygrometric production lines
- Laboratory instruments (eg thermostat muffle thermo balance, technical or analytical scales, micrometers, gauges, etc..)
- Metal detectors

List of instruments/equipment updated to 28/08/2018

Instrument no. SS228 OHAUS MB90 thermobalance located in production, last internal calibration 10/01/2019 expiry 10/07/2019 (six-monthly frequency)

View of the instrument sheet with evidence of calibration of 10/01/2019 at 1g and 10 g and metrological traceability with instrument SS30 Weights last certified on 14/06/2016 no. LAT 117 16/1660 masses from 1g to 5kg

Instrument no. SS93 Rotronic thermohygrometric probe last calibration on 21/12/2018 expiring on 21/06/2018 (six-monthly frequency)

View Instrument sheet with history of certifications and attached certificate Rotronic Hydrogen that auto-calibrates and calibrates the probes Rotronic of 21/12/2018. Confirmation of the metrological chain with Hydrogen2 probe calibrated annually by Rotronic SS173 (last on 11/10/2018 with calibration certificate

no. SZ-20160509 of 29/03/2016)
 View Instrument card SS112 checkweigher for weight of line 1/3 serial no. 905307 metrological basket 180164 according to the new DM 21/04/2017 no. 93 (last annual periodic check of 05/03/2019 with supplier calibration report Cutino Sistemi di Pesatura S.r.l. no. 190002 of 05/03/2019 with metrological traceability calibration certificate CTMA 662-18 of 06/08/2018)
 Instrument board SS193 metal detector CEIA serial no. 972250 range of use 1.5 FE - 2.0 NON FE - 2.5 AISI 316-27 AISI, line 1/1 annual calibration frequency. Last calibration on 22/10/2018 (annual frequency) carried out by Almatecno with verification of the general conditions and installation, verification of the operational operation of the CEIA system and connected devices.

7. Personnel

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

Company is able to demonstrate by a specific and detailed training program that all employees performing work critical to the safety, health, legal and product quality is competent, based on a certain route selection qualification, experience and training. In particular, it is always made training to new staff assumes that the tasks inherent in Critical Control Points. For each role company define a profile (job descriptions), which defines tasks, responsibilities, minimum requirements and basic training. Basic education is always about the legal aspects concerning mandatory occupational safety and HACCP, but also provides a period of mentoring by senior staff (variable depending on the type of activities) which serves to validate the competence of personnel reached again.

Plan of training for 2019 is available, several session are planned for all personnel .

Training is always evaluated in terms of effectiveness in monitoring the achievement of the objective by various methods: direct observation, interview or interviews, internal audit, tests, etc..The training courses and teaching materials to support are in Italian because there aren't foreign workers. Training activities related to the regulation hygienic aspects of binding legislation on food safety, the monitoring of CCPs and cleaning procedures are performed at least annually. Even temporary workers and service providers receive adequate training for the task before starting any activity was verified. They are always supervised by an appropriate period by senior staff so to evaluate effectiveness of training

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

An appropriate procedure (REGOLAMENTO IGIENICO- IO003 on 18.12.15 rev. 16 - e NORME IGIENICO-SANITARIE PER APPALTATORI , VISITATORI E FORNITORI – IO044 on 24.06.15) regarding the wearing and changing of protective clothing in specified work areas is in place. Seen records of internal audit about personnel hygiene.

7.3 Medical screening

All staff are in possession of the training course for nutritionists provided by law. In particular the executive DR n ° 46 of February 23, 2005 the Campania Region. Health status is verified annually as part of health surveillance provided by the current regulations regarding health and safety in the workplace (Legislative Decree 81/2008). In particular, the medical examination must ensure that those who work in food production is not a carrier of diseases that are transmissible through food. Any person accessing the production departments (visitors, clients or personnel employee) must sign a personal declaration, with which claims not to be suffering from infectious diseases, as reported in the form "Declaration of Health"

and declare that I have read the NORME IGIENICO-SANITARIE PER APPALTATORI , VISITATORI FORNITORI – IO044 Rev 2 del 24.06.15

7.4 Protective clothing: employees or visitors to production areas

All personnel wearing only work clothing supplied by the company (jacket and pants, shoes, hats or caps, etc..). IO003 rev 16 on 18/12/2015 In particular, work clothes to the staff handling food are without pockets and buttons. These clothes are washed by an approved contracted laundry CIRIELLO (seen contract on 02.01.12). Verification of the effectiveness of the laundering process is by quarterly microbiological swabs, rotating between the person handling the products.

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

Note where sites do not have a high care or high risk facility this section is not applicable

Confirm how high care and high risk areas are segregated from other areas of the factory, how product and personnel enter the area.

8.2 Building fabric in high-risk and high-care zones

In high risk areas – more detail to be given to the type and method of ventilation – air source; frequency of changes; size of filter, changes of filters and how positive pressure can be assured, particularly when adjacent to low care areas. Micro sampling of air may also be mentioned where appropriate.

Confirmation of drain plans in high risk/care areas and direction of flow.

8.3 Maintenance in high-risk and high-care zones

Describe the maintenance procedures particular to high risk high care areas to reduce the risk of microbial contamination as a result of maintenance work.

8.4 Staff facilities for high-risk and high-care zones

Overview of facilities for high care and how this is achieved. Every facility is different, therefore sufficient site specific detail to be given.

Describe the procedure to prevent contamination of high risk/care protective clothing during changing.

8.5 Housekeeping and hygiene in the high-risk high-care zones

Confirm the cleaning systems used in the area and sanitisers used.

Comment on identification system of cleaning equipment specific to the area. How is the effectiveness of cleaning confirmed and any systems such as ATP monitoring or microbiological swabbing in place.

Comment on the suitability of the cleaning system and any equipment cleaning reviewed at the audit.

8.6 Waste/Waste disposal in high risk, high care zones

Confirm systems in place to ensure waste disposal process does not present a risk of contamination

8.7 Protective clothing in the high-risk high-care zones

Confirm how protective clothing is differentiated from that worn in other factory areas and the changing procedures.

Confirm the process for laundering protective clothing.

Details of non-applicable clauses with justification

Clause/section reference	Justification
4.3.5	No high-risk area
4.3.6	No high- care area
4.3.7	No ambient high-care area
4.3.9	No temporary structures
4.4.4	No high-risk/care area
4.4.13	No high-risk area
4.8.4	No high-risk area
4.8.5	No high-care area
4.9.4.	No glass or brittle containers are used
4.10.5	No optical sorting equipment
4.10.6	No glass jars, cans and rigid containers are used

4.11.7.1	CIP is not used
4.14.3	External company for pest control
7.4.4	No high-risk/care areas

9 - Traded Products

9.1 Approval and performance monitoring of manufacturers/packers of traded food products

The auditing of this section where applicable is voluntary and may or may not be included within the audit. Where it is included the information required is as follows (1 hour should have been added to audit duration at application review to cover this section, any NC's raised will affect final audit outcome):

Describe the process in place for the approval of suppliers of traded products.

Identify a check carried out to confirm the process is operating effectively.

9.2 Specifications

Confirm that specifications are in place and suitably detailed for traded products. Confirm specifications reviewed.

9.3 Product inspection and laboratory testing

Confirm the checks carried out on traded goods on receipt to ensure these are safe legal and in line with specifications. Where external laboratories are used for testing or certificates of analysis provided comment upon this

Describe product test results assessed as part of the audit

9.4 Product legality

Describe the procedures in place to ensure the legality of traded products e.g. label and compositional checks.

9.5 Traceability

Confirm how traceability is managed for traded products.

Give information on a traceability test undertaken for a traded product

Module 11: Meat supply chain assurance	
Scope	
11.1 Traceability	
11.2 Approval of meat supply chain	
11.3 Raw material receipt and inspection	
11.4 Management of cross-contamination between species	
11.5 Product testing	
11.6 Training	

Module 12: AO ECS Gluten-free Foods

Scope

12.1 Senior management

12.2 Management of suppliers of raw materials and packaging

12.3 Outsourced production

12.4 Specifications

12.5 Management of gluten cross-contamination

12.6 Management of incidents, product withdrawal and product recall

12.7 Labelling

12.8 Product inspection and laboratory testing

Module 13 FSMA Preventive Controls Preparedness Module
Version 2 July 2018

Item no.	Clause	Module item	Conforms (Y/N) or Not Applicable (NA)	Comments
1	13.1.1	Hand washing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.	Y	Light is adequate
2	13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping	Y	<i>Water in processing is drawn from the potable water supply and included in the water quality</i>



		systems that discharge waste water or sewage.		<p>monitoring(chemical analysis are conducted every six months and microbiological analysis every three months). Map of the water system is described on 4/8/2014 rev7</p> <p>Seen IO 0.40 "Gestionerete idrica" the samples plan requires chemical and physical analysis every 6 months while microbiological parameters every 3 months.</p>
3	13.1.3	<p>All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant.</p> <p>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.</p>	Y	The company has mapped all surfaces on Plan dated 13 Jun 2018 for each type of surfaces declaration of the conformity are available, the surfaces were ok
4	13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.	NA	Ice is not used
5	13.1.5	<p>Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible.</p> <p>Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.</p>	Y	<p>The plant of the analysis required filth test on semolina and finished products. Limits are defined on filth test and On Pasta di semola di grano duro elbows L90567 Filth test report 19D00678-It-0 on 8/4/2019. The defectosity are defined in the capitulate for each type of the finished products and for packaging The defects are verified by the quality control laboratory like the cooking test, verified of the performance of the product</p> <p>The samples plan on the semolina requires the weekly analysis of the filth test and every 6 months on the finished products</p>

6	13.1.6	<p>The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility:</p> <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 	y	<p><i>Risk assessment for raw material is updated every year on 28/3/2019 raw materials eggs, wheat and semolina and other minor ingredients.</i></p> <p><i>The risk assessment takes in count the vulnerability assessment based on Carver method: The raw material evaluated on medium risk is eggs while the other raw material are assessed like low risk.</i></p>
7	13.1.7	<p>All identified known or reasonably foreseeable hazards must be evaluated to determine “hazards requiring a preventive control” (i.e., significant hazards).</p>	Y	<p><i>Food safety plan on 23/1/2018 for dried raw material, conventional and organic pasta, spinach and tomato pasta, enriched pasta and egg pasta. The food safety plan is carried out for each raw material and each step of the production</i></p> <p><i>The last Internal audit is carried out 9/5/2018, the next audit will be carried out 18/4/2019</i></p>
8	13.1.8	<p>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.</p>	y	<p><i>Defined preventive control, monitoring and action act for each significant hazard</i></p> <p><i>Every week the PCQI verify on the model Weekly verification records all production for the USA base on the point defined on the food safety plan the following activities are defined:</i></p> <p><i>Wheat receiving doc</i></p> <p><i>M1 accettazione prodotti</i></p>

			<p><i>alimentarisfusi, Third part analysis, supplier contract corrective action records.</i></p> <p><i>Phase of egg receiving: temperature of receiving, third part analysis, corrective action.</i></p> <p><i>Pack receiving: allergen label verification, corrective action.</i></p> <p><i>Egg Storing: M71 Temperature of the cold cells</i></p> <p><i>Third part analysis, corrective action.</i></p> <p><i>Semolina receiving; supplier certification, qualify supplier, supplier contract, corrective action.</i></p> <p><i>Semolina sieving: M31 Setacci e sfarinati, Corrective actions.</i></p> <p><i>Pasta packing M60 scheda controllo selezionatrice, M026 controllo cart MD</i></p> <p><i>Allergen Change over MP 61 Pulizie area sfarinati e presse changeover uovo e tricolore verso altri</i></p> <p><i>M41 pulizia impastatrice, pompa e lavorazione nuovo ed attrezzi</i></p> <p><i>Third part analysis</i></p> <p><i>M89 checklist avvio convezionamento</i></p> <p><i>Verified the delivery of the week 14 2019 seen for example the</i></p>
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				<p>monitoring of Wegmans linguine lot 90942 and 90952</p>
9	13.1.9	<p>Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following:</p> <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 • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product 	Y	<p><i>The DE MATTEIS AGROALIMENTARE has an effective incident management p 29 gestione emergenza Rev 3 on 24/10/2018 and product recall procedure PI06 -rev 05 on 20/01/2019 -The procedures includes the required actions in case of: disruption to key services (water, energy, transport, staff availability and communications) fire, flood and natural disaster malicious contamination or sabotage. It includes: members of the incident management team, a list of the relevant and key contacts, details of appropriate external agencies. product recall and withdrawal procedures, corrective action and business recovery, communication plan Giuditta Gambarota's team leader of crisis team .</i></p>
10	13.1.10	<p>Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.</p>	Y	<p><i>Procedure PI20 - rev 6 on 27/6/2017 is in place for the management of NC. This include isolation of NC product, risk assessment, identification by labelling, decision about the further use. All NC are correctly managed appropriate root causes and corrective actions had been undertaken with appropriate time scales in all instances checked during the evaluation</i></p>
11	13.1.11	<p>Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of</p>	Y	<p><i>Microbiological parameters on dried pasta (Enterobacteria, B.Cereus,</i></p>



		<p>BRC 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>		<p><i>Stafilococcus aureus, yeasts and molds salmonella, clostridium, Listeria, clostridium perfringens clostridi solfitoriduttori annuali while E.coli every week),, Stafilococoon fresh pasta every week, Swab teston surfaces and hands of the employees (coliform)</i></p>
12	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>	Y	<p><i>The validation is carried on 23/1/2018 process is not change but is updated the MD</i></p> <p><i>The CCPs are validated on 28/3/2019</i></p>
13	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>	Y	<p><i>PCQI is Giuditta Gambarota</i></p>
14	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 	Y	<p><i>Product controls are present and are organized by a sampling plan PCQ 01 rev 33 on 24/05/2017-02 rev 19 on 27/2/2018-03 rev.32 on 30/6/2017</i></p>



15	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 	Y	<p><i>Compressed air does not in contact with the product every 2 years is analyzed report 17LA3579 on 14/3/2017 CTB yeasts, molds, enterobacterial</i></p>
16	13.1.16	<p>Devices used to verify preventive controls must be calibrated.</p>	Y	<p>All instruments used for monitoring Critical Control Points and safety / legality of the product are identified. Updated list is available .They are subject to periodic adjustment based on their criticality, against national champion recognized by the Italian Calibration Service (Accredia). P118 rev4 on 24.10.14 “calibrazione e taratura degli strumenti” The critical tools are subject to adjustment by:</p> <ul style="list-style-type: none"> • Weight Control Scales • Line Scales • Probes thermo hygrometric production lines • Laboratory instruments (eg thermostat muffle thermo balance, technical or analytical scales, micrometers, gauges, etc..) • Metal detectors <p>List of instruments/equipment updated to 28/08/2018 Instrument no. SS228 OHAUS MB90 thermobalance located in production, last internal calibration 10/01/2019 expiry 10/07/2019 (six-monthly frequency) View of the instrument sheet with evidence of calibration of 10/01/2019 at 1g and 10 g and metrological traceability with instrument SS30 Weights last certified on 14/06/2016 no. LAT 117 16/1660 masses from 1g to 5kg Instrument no. SS93 Rotronic thermohygrometric probe last calibration on 21/12/2018 expiring on 21/06/2018 (six-monthly frequency)</p>



				<p>View Instrument sheet with history of certifications and attached certificate. Rotronic Hydrogen that auto-calibrates and calibrates the probes Rotronic of 21/12/2018. Confirmation of the metrological chain with Hydrogen2 probe calibrated annually by Rotronic SS173 (last on 11/10/2018 with calibration certificate no. SZ-20160509 of 29/03/2016)</p> <p>View Instrument card SS112 checkweigher for weight of line 1/3 serial no. 905307 metrological booklet 180164 according to the new DM 21/04/2017 no. 93 (last annual periodic check of 05/03/2019 with supplier calibration report Cutino Sistemi di Pesatura S.r.l. no. 190002 of 05/03/2019 with metrological traceability calibration certificate CTMA 662-18 of 06/08/2018)</p> <p>Instrument board SS193 metal detector CEIA serial no. 972250 range of use 1.5 FE - 2.0 NON FE - 2.5 AISI 316-27 AISI, line 1/1 annual calibration frequency. Last calibration on 22/10/2018 (annual frequency) carried out by Almatecno with verification of the general conditions and installation, verification of the operational operation of the CEIA system and connected devices.</p>
17	13.1.17	<p>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.</p> <p>Document the PCQI's training and qualification via job experience.</p>	Y	Giuditta Gambarota trained on 8/2/2017
18	13.1.18	<p>All records required by 21 CFR § 117 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 	Y	The process control records is carried out for line and lot of production. The modules are signed by the responsible and CQ

19	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.	Y	
20	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.	Y	4 years on paper and by software
21	13.1.21	<p>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.</p> <p>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.</p>	Y	<p><i>Company has a documented procedure for supplier approval and assessment program in place based on risk assessment</i></p> <p><i>Purchased products and services are checked in accordance with the existing specifications</i></p> <p><i>Qualify and evaluation of supplier of raw materials and services PI 13 rev3 on 17/7/15. The annual qualification is based on the result of the furniture during the previous year (how many NC)</i></p> <p><i>The company acquires both the wheat and the semolina. The wheat by Italian origin is acquired by farmer than other wheat warehouse. The semolina by other mills</i></p> <p><i>Audit are planned on all keys suppliers seen for example audit to Casillo on 21/3/2019</i></p> <p><i>New food Industry supplier of dried spinach on 27/7/2017</i></p> <p><i>New Dimantion Plastion 1/8/2018</i></p>



				<p>Checklist and a self assessment sent to all supplier rev 7/6/2017</p> <p>Risk assessment for raw material is updated every year on 28/3/2019 raw materials eggs, wheat and semolina and other minor ingredients.</p> <p>The risk assessment take in count the vulnerability assessment based on Carver method: The raw material evaluated on medium risk is eggs while the other raw material are assessed like low risk.</p> <p>The company shared with the supplier its capitulate with the requirement of the food safety allergen and GMO declaration, see capitulate for the semolina T2 Rev 2 on 3/1/2017, capitulate for liquid whole egg free range "vegetable" rev 0 on 19/03/17</p> <p>The company acquires the following finished products:</p> <p>Pasta gluten free supplier Mennucci GFSI Certified IFS Coid 14983 delivered with Pasta Armando Brand</p> <p>Potatoes Gnocchi supplier Ciemme Alimantari srl BRC certified BRC Site code 1253766 delivered with Baronina Brand and Sam's Choise the customer knows the supplier of gnocchi seen audit report of the customer on site dated 15/3/2019</p>
22	13.1.22	<p>Supplier approval must be documented before receiving and using raw materials and ingredients.</p> <p>Verification activities must be conducted before receiving and using raw materials and ingredients</p>	Y	<p>Qualify and evaluation of supplier of raw materials and services PI 13 rev 3 on 17/7/15.</p> <p>Checklist of the self assessment sent to all supplier</p> <p>Evaluation of the supplier is</p>



		on a temporary basis from unapproved suppliers.		<i>carried out every year</i>
23	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.	Y	<i>Checklist of the self assessment sent to all supplier Evaluation of the supplier is carried out every year</i>
24	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.	Y	<i>Operative instruction for management of grind and waste is available IQ27 rev 2 on 27/07/2015 with identification of type of by products both for mill then pasta farm. Authorization for feed production n.IT064032001 on 23/1/2007 reg CE 183/2005 is available In the pasta farm are identified: fresh pasta destined to external company for production of combustible, while waste dried pasta are destined for feed.</i>
25	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 conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart.	Y	

		One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.		
26	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 	Y	<p><i>The site is fully fenced. There is manned security and the gates are kept locked out of production hours. Access points are designated and restricted areas are defined on the site plan and clearly marked. Procedures are monitored, controlled and reviewed (seen IO068 rev2 on 30.10.17 "Food Defence" the team leader is Mr Del Regno. Evaluation of the Security System is carried out with the check list on 21/3/2018, the stress test is carried out on 15/6/2018 annual training to all employees is carried out seen for example the training report on 4/12/2018, quarterly the company carries out the valuation of the plant through a checklist the last on 21/12/2018. The Food defence plan is reviewed annually Since the end on the 2018 is certified for the Supplier Chain Security Site security was maintained by Gatehouse security, All external doors locked, 24-hour manning of site. All the doors were closed during the audit - Chemical storage is in a locked cupboard. The flour silos are kept locked.</i></p>
27	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 	Y	<p><i>Risk assessment for raw material is updated every year on 28/3/2019 raw materials eggs, wheat and semolina and other minor ingredients.</i></p> <p><i>The risk assessment takes in count the vulnerability assessment based on Carver method: The raw material evaluated on medium</i></p>



		<p>to the product</p> <ul style="list-style-type: none"> 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>	<p><i>risk is eggs while the other raw material are assessed like low risk</i></p> <p><i>Periodical evaluation of the alert for the vulnerability of the raw materials is carried using the main of the official sources like Rasf or news letter of the specialized organization of the sectors.</i></p> <p><i>Mitigation activities are identified and planned both through the analysis and by the audit and capitulated with the supplier.</i></p> <p><i>For the glyphosate emergent hazards reinforced analysis plan is carried out.</i></p> <p><i>Organic materials are handled and are adequately segregated, the company declares the sequent claim:</i></p> <ul style="list-style-type: none"> <i>100% Italian the wheat is controlled in entrance bases of morphologic parameters and through annual test of traceability on supplier, the company know the supplier chain, traceability tests, and seeds recognition in acceptance.</i> <i>Free range verified through traceability test on supplier and declaration in entrance</i>
28	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>	<p>Y</p> <p><i>Risk assessment for raw material is updated every year on 28/3/2019 raw materials eggs, wheat and semolina and other minor ingredients.</i></p> <p><i>The risk assessment take in count the vulnerability assessment based on Carver method: The raw material evaluated on medium risk is eggs while the other raw material are assessed like low risk.</i></p>



				<p>Periodical evaluation of the alert for the vulnerability of the materials carried using the main of the official sources like Rasf or news letter of the specialized organization of the sectors.</p> <p>Mitigation activities are identified and planned both through the analysis and by the audit and capitulated with the supplier.</p> <p>For the glyphosate emergent hazards reinforced analysis plan is carried out.</p> <p>Organic materials are handled and are adequately segregated, the company declares the sequent claim:</p> <ul style="list-style-type: none"> - 100% Italian wheat is controlled in entrance bases of morphologic parameters and through annual test of traceability on supplier, the company know the supplier chain, traceability tests, and seeds recognition in acceptance. - Free range verified through traceability test on supplier and declaration in entrance
29	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>	Y	<p>Evaluation of the Security System is carried out with the check list on 21/3/2018, the stress test is carried out on 15/6/2018 annual training to all employees is carried out seen for example the training report on 4/12/2018, quarterly the company carries out the valuation of the plan through a checklist the last on 21/12/2018. The Food defence plan is reviewed annually Since the end on the 2018 is certified for the Supplier Chain Security</p>



				<p>Site security was maintained by Gatehouse security, All external doors locked, 24-hour manning of site. All the doors were closed during the audit - Chemical storage is in a locked cupboard. The flour silos are kept locked.</p>
30	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 	Y	<p>The risk assessment take in count the vulnerability assessment based on Carver method: The raw material evaluated on medium risk is eggs while the other raw material are assessed like low risk.</p> <p>Periodic evaluation of the alert for the vulnerability of the raw materials is carried using the main of the official sources like Rasf or news letter of the specialized organization of the sectors.</p> <p>Mitigation activities are identified and planned both through the analysis and by the audit and capitulated with the supplier.</p>
31	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 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 	y	<p>quarterly the company carries out the valuation of the plan through a checklist the last on 21/12/2018. The Food defence plan is reviewed annually</p> <p>Since the end on the 2018 is certified for the Supplier Chain Security</p>

		<p>reanalysis of the food defense plan was conducted</p> <ul style="list-style-type: none"> • Frequency for verification activities • Recordkeeping requirements of all verification activities 		
32	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 	Y	<p><i>quarterly the company carries out the valuation of the plan through a checklist the last on 21/12/2018. The Food defence plan is reviewed annually Since the end on the 2018 is certified for the Supplier Chain Security</i></p>
33	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 	Y	
34	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>	Y	
35	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,</p>	Y	

		they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.		
36	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>	NA	There are no internal vehicles in the vehicle with cargo van inspection M215 rev 5 of 12/10/2015
37	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 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>	Na	shippers are identified by the customers of the company
38	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</p>	Na	Not managed by the Company

		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.		
39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.	NA	Not managed by the Company
40	13.4.5	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.	Y	The company verifies the eggs temperature for each entry
41	13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. <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 	Y	<i>PI15 on 26.04.12 is in place to hygienic checks of vehicles during loading and transportation . Stable temperatures during transport Only for the eggs entrance the temperature of the transport is monitored for each entry. Contract with the transporter of the finished product are in place complete of the requirements on hygiene and food defence</i>
42	13.4.7	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers <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 	Y	

		<p>problems</p> <ul style="list-style-type: none"> Responsibilities of the carrier 		
43	13.4.8	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.	Y	4 years
44	13.4.9	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.	Y	
45	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>	Y	
46	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 	Na	
47	13.5.3	One or more supervisors or individuals responsible for the operation must have successfully completed food safety training	Na	

		equivalent to standardized curriculum recognized by the FDA.		
48	13.5.4	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.	Na	
49	13.5.5	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.	Na	
50	13.5.6	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.	Na	
51	13.5.7	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.	Na	
52	13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.	Na	
53	13.5.9	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	Na	



		<p>and microbial criteria.</p> <p>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 verification of correction to ensure water meets microbial quality criteria.</p>		
54	13.5.10	<p>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.</p> <p>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.</p>	Na	
55	13.5.11	<p>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.</p> <p>Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris).</p> <p>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.</p>	Na	
56	13.5.12	<p>Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch</p>	Na	

		the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.		
57	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.	Na	
58	13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	Na	
59	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.	Na	
60	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.	Na	
61	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 <i>Listeria</i> spp or <i>Listeria monocytogenes</i> . The environmental monitoring plan shall include the following criteria: <ul style="list-style-type: none"> • Target test (i.e., <i>Listeria</i> spp. or <i>L. mono</i>) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and 	Na	

		<p>location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces)</p> <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>		
62	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 	Na	