Audit Report

Global Standard for Food Safety Issue 7: July 2015

1.Audit Summary			
Company name	NATURAL WORLD S.r.l.	BRC Site Code	BRC Site code
Site name	NATURAL WORLD S.r.l.		
Scope of audit	Production of semi-processed products in powder for food industry. Trading of raw materials, ingredients and additives		
Exclusions from scope	N/A		
Justification for exclusion	N/A		
Audit Finish Date	2016-01-08		
Re-audit due date	2017-01-08		

Voluntary modules included		
Modules	Result	Details
Traded Goods	Passed	
Choose a module	Choose an item	

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	Choose an item	Previous audit date	Select a date		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	6

3.Company Details

Address	Via Rambaldo Jacchia, 8 48022 Lugo (RAVENNA)		
Country	ITALY	Site Telephone Number	(+39) 0545 27100
Commercial representative Name	Alcide Resta	Email	a.resta@naturalworld.it
Technical representative Name	Elena Resta	Email	e.resta@naturalworld.it

4.Company Profile

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

Subcontracted processes	Yes
Other certificates held	ISO 9001, KOSHER, HALAL, ORGANIC, RSPO
Regions exported to	Europe Choose a region Choose a region Choose a region Choose a region Choose a region
Company registration number	n°115
Major changes since last BRC audit	First Audit

4.Company Profile

Company Description

Natural World srl was founded in 1996 and since then the company scope has been the production of semi-processed products in powder for food industry and trading of raw materials, ingredients and additives.
Trading represents the 90% of activities, only 10% of production of semi processed powder.
The main clients are bakery and dairy companies for the production of ice cream, yogurt and cheese.
During the years of activity the company has acquired specific experience in order to guide and advice the client in the R&D of new products.
The packed product returns in Natural World srl, which delivers it to clients.
In 2007, the Company has been bought by the chemical group Brenntag Spa.
The Company is also ISO 9001, KOSHER, HALAL, RSPO and ORGANIC certified.
Sanitary Authorization released by the Municipality of Lugo n° 115 dated 11.11.2006.
Contact person: Resta Elena, Mobile (+39) 335 7507758, Fax (+39) 054533739, Mail e.resta@naturalworld.it

5.Product Characteristics

Product categories	15 - Dried food and ingredients Category Category Category
Finished product safety rationale	Product in powder, low WA, Storage at ambient temperature

High care	No	High risk	No	Ambient high care	No

Justification for area	Product in powder, low WA, Storage at ambient temperature
Allergens handled on site	Cereals containing gluten Soya Milk 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

5.Product Characteristics	
Product claims made e.g. IP, organic	Soya and Maltodextrine from corn.
Product recalls in last 12 Months	No
Products in production at the time of the audit	Dosing of powder in 20Kg bags

6.Audit Duration Details			
On-site duration	16 man hours	Duration of production facility inspection	8 man hours
Reasons for deviation from typical or expected audit duration	None		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2016-01-07	0900	1800
2 (end date)	2016-01-08	0900	1800

	Auditor (s) number(s)	Names and roles of others
Auditor Number	051018	Alfredo Stefani - Lead Auditor

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.9) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Elena Resta – Quality Assurance Manager	X	X	X	X
Fabio Ferruzzi – External Consultant	X	X	X	X
Dragoni Giorgio – Dosing Operator	X	X		X

Non-Conformity Summary Sheet

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

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

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

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	2.4.1	The intended use of the product by the customer and the consumer target groups, including the suitability of the product for vulnerable groups of the population is not clearly described.	The intended use of the product by the customer and the consumer target groups, including the suitability of the product for vulnerable groups of the population has been defined on HACCP Plan.	The intended use of the product was not sufficiently documented. Updated HACCP Plan	HACCP Plan rev. 6 updated on 2016.01.09 with intended use defined.	2016-01-10	Alfredo Stefani
2	3.3.2	The retention period of record of 5 years is not sufficient in case of product with best before date of 5 years.	The procedure has been update	Some products have the Best Before of 5 years. Updated procedure	Procedure P0401 rev. 2 updated on 2016.01.09 with retention period	2016-01-10	Alfredo Stefani

3	3.4.1	Internal audit to supplier, dated 04/12/2015, does not give evidence of the CCP verification during the audit.	The check list has been updated with documented the CCP verification.	The check list used was not sufficiently detailed. The check list has been reviewed.	Check list “Audit e Valutazione Fornitore” rev. 4 updated on 2016.01.09	2016-01-10	Alfredo Stefani
4	3.9.1	In blends dosing area, some sample of product are not correctly identified as “Sampling product”.	The Sampling products has been identified.	The sampling products was not correctly managed. Refresh training of workers	Training record to 3 operators dated 2016.01.09	2016-01-10	Alfredo Stefani
5	4.15.2	In blends dosing area, some packaging materials suitable for use is not effectively protected from contamination.	The packaging material has been protected and segregated.	The recovery locker old. The new locker has been installed.	Training record and photos showing packaging material has been protected and segregated	2016-01-10	Alfredo Stefani
6	5.3.4	In blend dosing area, the not-used clean bailers are not properly separated to avoid cross-contamination.	The Bailers (Sessole) has been protected and segregated.	The Bailers (Sessole) was not correctly managed. Refresh training of workers	Training record to 3 operators dated 2016.01.09	2016-01-10	Alfredo Stefani

Comments on non-conformities

Voluntary Modules Non-Conformity Summary Sheet

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

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

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

Detailed Audit Report

Details of non-applicable clauses with justification	
Clause reference	**Justification**
1.1.8 ; 1.1.10	Initial audit
2.9.1; 2.9.2; 2.10.1; 2.10.2; 2.11.1; 7.1.2	No CCPs defined
3.5.1.3	No agents or brokers used
3.9.4; 5.3.5	No rework used or reworking operations carried out
3.12.1; 3.12.2	No specific customer policies or requirements in place
4.2.3	No external storage tanks, silos or intake pipes with external opening.
4.3.5; 4.8.4	No high-risk areas defined
4.3.6; 4.8.5	No high-care areas defined
4.3.7	No ambient high-care areas defined
4.3.9	No temporary structures constructed
4.4.4; 4.4.13; 7.4.4	No high-risk / high-care areas defined
4.4.6	No suspended ceilings or roof voids present
4.5.3	No legislation that specifically permits the use of water which may not be potable for initial cleaning.
4.5.4	No air, other gasses or steam used in direct contact, or as ingredient in, products. No compressed air used directly in contact with the product.
4.7.3	No temporary maintenance
4.8.10	No catering facilities provided. No vending machines in place.
4.9.4.1; 4.9.4.2; 4.9.4.3	No products packed into glass or other brittle containers
4.10.1.2; 4.10.1.3; 4.10.1.4	No foreign-body or removal equipment in place
4.10.2.1; 4.10.2.2	No filters or sieves in place
4.10.3.2; 4.10.3.3;	No metal detector or X-ray equipment in place

4.10.3.4; 4.10.3.5	
4.10.4.1	No magnets in place
4.10.5.1	No optical sorting equipment in place
4.10.6.1; 4.10.6.2	No products packed into glass jars, cans or other rigid containers
4.11.7.1; 4.11.7.2; 4.11.7.3	No CIP
4.12.1	Licensing for the removal of waste isn't required by law
4.13.1, 4.13.2	No customer branded products made
4.13.3	No products intended for animal feed
4.14.3	The site doesn't undertake its own pest control
4.15.3	No temperature control is required
4.15.4	No controlled atmosphere is required
4.15.5	No outside storage
4.16.3	No temperature control is required
4.16.6	No transport third-party contractors hired
5.1.3	Trials are not necessary for the product(s) produced
5.2.3	No claims made to satisfy a consumer group (no nutritional claims)
5.2.4	No customers or nominated third party responsible for label information
5.3.7	No claims made regarding suitability for allergy or food sensitivity sufferers
5.6.2.2; 5.6.2.4	No on-site lab
6.1.3	No in-line monitoring devices in place
6.2.4	No on-line vision equipment used to check product labels and printing
6.3.2	No bulk quantities packed
7.2.4	No metal detector in place
7.4.7	No items of personal protective clothing that are not suitable for laundering are provided.

1. Senior management commitment

1.1 Senior management commitment and continual improvement

There is an integrated Company policy: Quality, environment and food safety dated 2015-06-17 which is signed by the Company President, is displayed both at the site entrance and other points of the factory, furthermore presented at all levels during training.

Management review last dated 2015.04-17. Clear targets are set on document enclosed to management review: Customer Satisfaction, complaints, to decrease NC in production and from supplier.

Quality, legality and food safety parameters are monthly monitored by top management consulting updated results supplied by QA Department and HACCP team. Monitoring shows levels on targets. HACCP plan review base on analysis record- supplier change- R&D activity- processing changes- external alert and new law- recall/withdrawal , sanitization and pest procedures efficiency, with discussion and evaluation outputs as management decisions.

Seen all monthly records of 2015, e.g. that of 2015-12-10.

The objectives are analysed at least quarterly

The company's senior management thanks to Food Companies Association is kept informed of scientific and technical developments, industry codes of practice and all relevant legislation applicable in the country of raw material supply, production and, where known, the country where the product will be sold.

First BRC audit for the Company.

1.2 Organisational structure, responsibilities and management authority

Overview of Management Structure verified.
The current Organisation Chart dated 2015-06-17.
Seen table of key roles with replacement functions.
The multi-disciplinary team comprises members from the following departments:
General Manager: Alcide Resta, Quality Assurance Manager: Elena Resta, Purchasing: cristina cavina, Technical Office: S. Fiori, Administration: R. Poletti.
In the absence of the Responsible Person, the substitute Staff is properly defined in job description.Job descriptions Mansionario, in place for all managers and supervisors and responsibilities, substitutes in a dedicated attachment with all signs including substitutes. Appropriate documented arrangements are in place to cover for the absence of key staff.

2 The Food Safety Plan – HACCP

HACCP study "Manuale Autocontrollo" rev 5 dated 2015-11.24.

Prerequisite programs defined, Hazard Analysis verified "Schema Monitoraggio HACCP" issue 4 dated 2015-06-17. Literature data, legislation and customer requirements have been referred to. Guidelines and codes of practice of reference. HACCP Team led by RLAB & Food Safety manager Elena Resta has documented HACCP training and experience and by Fabio Ferruzzi (external consultant) HACCP CAMPDEN - RSPH L3 11.11.2014 trained. Team defined in HACCP, multi-disciplinary team comprises members from the quality and production department: DIR STAB, RQA,

LAB, Heads of Prod. Dep.
Products are: Powder for dairy and bakery Companies packed in plastic bags, ambient stable. The product is not sold directly to the final consumer. Date codes ink-jet sprayed onto packaging as best before. The Allergens are described on label: specific targets of consumers identified.
A full description of the products are developed and documented in HACCP Plans, which includes all required items as composition, physical and chemical properties, treatment and processing. Flow diagrams documented on same edition of relevant HACCP studies were detailed and verified, e.g. dated 2015-04-17.
Hazards: Significant hazards have been identified on 2015-04-17 Significant hazards considered in hazard analysis identified as pathogen microorganism; chemical as heavy metals; physical as foreign bodies. Allergens valued. Each identified hazard was reviewed and given a risk rating to define the severity and likeliness of hazard occurring. Suitable controls for each hazard were documented, in many cases these formed part of the prerequisite programs
After hazard analysis and decision tree, no CCPs were identified by the Company. The production consists in the dosing of powder. Mixing process is carried out by external certified and audited Companies.
No CCPs identified.
Last HACCP review dated 2015-05-17. During next Management Review, March 2016, the efficiency of HACCP system will be evaluated.

3. Food safety and quality management system

3.1 Food safety and quality manual

Quality Manual, issue 3 dated 2015-10-01 reviewed and approved by GM. very detailed document with due reference to ISO 9001:2008 and BRC standards requirements.
Main Quality Management System with department specific work instruction manuals available on a shared drive within the company's network system.
Evidence of compliance of documents clearly legible in sufficient detail and in appropriate languages.

3.2 Documentation control

Procedure P0401 “Struttura e gestione documentazione” issue 01.
Manuals and procedures available in the IT company system and by means of controlled paper copies signed for receipt. Folders had limited write access to designated personnel.
Access to documentation is controlled with video surveillance.

3.3 Record completion and maintenance

Procedure P0401 “Struttura e gestione documentazione” issue 01.
Records retained for a time consistent with the shelf life of products as indicated on technical sheets (from 6 to 60 months months), record keeping 5 years.
CAR raised on record keeping time.

3.4 Internal audit

Procedures and Audit plan defined in order to guarantee that audits are conducted on those systems and procedures which cover the requirements of the Global Standard for Food Safety.
More auditors are in place to assure independence. Auditors are trained and has Food and Agronomy Degree. Internal audit programme is audited by external consultant
Audit Plan (dated 2015-06-16) covers all activities and departments at least annually. Audits carried out by trained competent external consultants. Audit conducted by independent external personnel.
Dedicated report on purpose. BRC based check-list.
The program includes monthly checks on infrastructures and plant last one dated 2015-12-10 by external consultant Fabio Ferruzzi raised 2 NCs for non conforming balances calibration. CAs carried out properly.
Other Audit carried out on June 2015 , NC raised for a non conforming water analysis.
Audit to supplier carried out on 2015-12-04 by Elena Resta and F. Roncalli.
NCs raised from last internal audit with due CA . In case of NCs, section managers are in charge for relative CARs implementation.

Dedicated report on purpose. BRC based check-list. Some NCs resulted from last audit all followed by CAs. Furthermore, site inspections performed monthly.
Seen those dated 2015-12-03 for GHPs, personnel hygiene and structural requirements. Plant inspections done by QAM.

Furthermore, monthly site inspections based on structural and maintenance status check-list and GHPs, dedicated reports available e.g. inspections of 2015-11-20: some observation raised relating to doors.
Non conformities are reported to the section manager and reviewed at monthly management meetings.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials and packaging

Supplier approval procedure P07.02 “GESTIONE DEL SERVIZIO”.
All product and service suppliers approved by QAM in collaboration with purchasing manager. Entered in the company network system.
Risk assessment done.
Approved suppliers list updated according to approval deadlines. Scoring system based on the following parameters: NCs, historical supplier evaluation data, quality/price, supplier’s audits. Evaluation based on a scoring level. Questionnaires and supplier’s audit applied too. Already certified suppliers preferred.
Suppliers audit once annually.

All suppliers of products and services have to be approved by the QA and Purchasing department and entered onto the list of approved suppliers before they can be used. The suppliers approval list is divided in parts: raw materials, outsourced processes, packaging, equipments, consuming, services, couriers and transport.

3.5.2 Raw material and packaging acceptance and monitoring procedures

Control in acceptance following P07.02 “GESTIONE DEL SERVIZIO”.
Raw materials are assessed on receipt and NC are fundamental criteria for monitoring and approval of

suppliers. The same system is in place for suppliers of packaging.
Seen acceptance control on raw materials.
A checks recorded and monitored. Seen pc record with conforming values.

3.5.3 Management of suppliers of services

Procedure for service supplier evaluation P07.02 “GESTIONE DEL SERVIZIO”.
Risk assessment is based on hygiene risk and quality impact to the product with suppliers / raw materials categorized in risk levels. The procedures for approval are based on details from a raw material questionnaire, audits, certifications and certificates of analysis.
Raw material assessments at intake form part of the ongoing review of supplier performance.
Complaints and issues monitored and used for a score card.
Certificates of analysis/conformance declarations are foreseen and managed for some goods.
Preventive certifications also for tomato primary product asked by producers and suppliers before campaign start.
Questionnaires are updated every three years, seen last compiled questionnaires sent by suppliers on 2015

3.5.4 Management of outsourced processing and packing

Subcontracted process: after dosing process, which is carried out directly by Natural World srl, the mixing and packaging (in bags of 15-20-25 kg) of powders are outsourced to external Companies, BRC certified or yearly audited, seen last audit dated 2015-12-04.

3.6 Specifications

The various kinds of specifications were verified for availability (dedicated files managed according to the rules defined in the Quality Manual). Specifications resulted being updated and available to interested staff.
The following specifications, of main products processed, were verified:

- Product BFP65PLMMB dated 2014-11-20.
- Product ESL issue 01 dated Jan 2016.

These are reviewed minimum every three years or in the event of any change.
Rules are defined for the communication from supplier in the event of change/updating of characteristic.

3.7 Corrective and preventive actions

Seen procedure P0801 “Gestione delle NC-AC-AP” issue 02.
Seen appropriate examples of CA management recorded on dedicated data base.
All CA/PA sheets contain suitable root cause analysis and verification on effectiveness.
Properly documented on company network dedicated Form. Action taken within short time. QAM in charge and signs the closure of corrective action implemented. CAs properly implemented with identification of the cause and relative corrective action, positive trend observed. QAM is in charge for CA implementation.
Regularly done as described in the procedure.
CA dated 2015-10-07 verified.

3.8 Control of non-conforming product

Procedure P0801 “Gestione delle NC-AC-AP” issue 02.
NC managed by software and pc.
Clear process well understood by staff interviewed during the audit according to procedure described.
No major trends considering the very large number of produced goods. In general NC are detected directly during process controls and consequently managed real time. The number of NC is part of KPI/objectives.

Seen appropriate management of NC product during the audit.
Seen NCs dated:

- 2015-12-21 for raw materials arrived from supplier which was not the one ordered. CA: mail to supplier.

3.9 Traceability

Procedure “RINTRACCIABILITA' RICHIAMO E RITIRO”.
Traceability system operates through IT system enables trace of incoming, other production phase and ingredients and packaging from supplier through processes, to packing and despatch are traced by paper records.

Upstream traceability tested regularly done, mass balance product to customer.
Traceability test carried out every year to cover both directions (from raw materials to finished product and vice versa). Seen relevant records
Traceability from raw material carried out by the Company on 2015-11-02 on product “OVALET UPF MB” production date 2015-09-27, batch L143420 expiring on 2016-03-27. Seen PC traceability and quantity produced 2860 Kg received, all sent on 2015-09-15. Seen acceptance control of packaging. Clients seen and supplier. Mass balance correctly carried out. Time: 1o minutes,h.

Suppliers approved by questionnaire sent a traceability test to be performed. No reply at the moment, the QA responsible will follow up the request and press for a reply by the supplier.

During the audit done a test on “Emulsionante BFP65PLM”, production date 2015-10-27, batch 2015WR000053, expiring date 2016-10-27. Seen recipe and quantity produced (1178 Kg). See ingredients and date of purchase, analysis of supplier. Mass balance carried out. See client B. Time: 8 minutes.

3.10 Complaint handling

The Complaint Management flow process specified in Procedure P0801 “Gestione delle NC-AC-AP” issue 02.
Positive trend over last 3 years. System in course of update for better information including final consumers. QAM is in charge. Customer complaint analysis data included as input during management review. Complaints is a target of KPI system.
Complaints logged by customer services department are handed to technical department for investigation.
The Customer Complaints Investigation report form included consideration of root cause.
Complaints data was summarised and reported weekly. Complaints per million units (CPMU) was monitored continuously and reviewed at management review meetings.
No complaints during 2014.
No complaints were raised in 2015, nor from authorities, retailers nor consumers; No complaint related to foreign material found in finished products.

3.11 Management of incidents, product withdrawal and product recall

An effective procedure is in place according to P07.5.3A “Gestione incidenti, ritiro e richiamo del prodotto dal mercato”, for incidents, product withdrawal and product recall is available and effective. Seen schedule “Gestione test ritiro/richiamo”.
The company has documented procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, legality or quality.
The procedure indicate, to call the certification body in 3 working days in case of real recall.
Crisis team defined including QAM and Company vice president.

The process was tested, seen relevant records referred to test carried out on August 2015 on product "NW2YME" 100g, produced on 2015-08-24, expiring on 2016-08-24, batch 50806P1407, Produced 2000Kg and sold 200Kg to client G.B. Mock cause: non conforming colour. Clients list and crisis team summoned. Traceability and communication. Seen traceability of raw material. Mass balance correctly carried out. Total time: 15 minutes.
No recalls nor withdrawals in the last year.

3.12 Customer focus and communication

Description of relative impact on product safety in relation to different situations and time connected.
Information are kept up to date and communicated out to relevant personnel and suppliers.
No Specific requests by Clients so far.

4. Site standards

4.1 External standards

The factory was build in 2000 and continuously renewed and maintained.
Site of suitable size, location, construction, design and well maintained.
The factory is located in an industrial area, surrounded by ship repairing Companies.
The factory external areas are in quite good condition and order.
Working and storage areas present sufficient conditions of organization, structure and functionality.
Local neighbouring activities are: industrial activity. No environmental dangers had been noticed.
A regular maintenance activity is performed to minimise potential for product contamination.

4.2 Security

Vigilance and defences maintain site security and ensure that only authorized staff have access to production and storage areas via designated access points.
The accesses are closed and the entrance is monitored.
Visitors and contractors access are recorded.
Authorization released by the Municipality of Lugo n° 115 dated 2006-11-11.
Cameras and alarm devices are in place to ensure the plant security. A gate is present.
Food defence described in "Allegato al manuale HACCP" issue 0 dated 2015-07-23.

4.3 Layout, product flow and segregation

The buildings are maintained in order to control the risk of product contamination and to comply with the relevant legislation. To allow access through production areas, designated walkways are provided that ensure there is adequate segregation from materials.
The process flow was arranged. A plan of the site is available with the flows of processes, raw materials, finished products and personnel. No high care/risk area because the products is ambient stable and enclosed.
The measures in place to avoid contamination were adequate in the production-areas.
Adequate segregation was in place according to the type of different processes and products.
Risk area defined in HACCP manual enclosed and low risk area defined.
Working and storage areas result in quite good conditions of organization, structure and functionality.
No temporary structures

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

The factory is suitable for the intended purpose.
The walls are designed, constructed, finished and maintained to prevent the accumulation of dirt and to minimise condensation and mould growth. The cleaning operation is facilitated.
The floors are adequate and maintained in good repair.
Drainage does not increase the risk of product contamination and not compromises product safety.
Ceilings are proper managed and suspended ceilings are under control.
Windows are quite properly managed. Doors are maintained in quite good condition.
The lighting ensures a safe working environment to carry out processes, inspection and cleaning operation.
Ventilation is conforming and the maintenance of filters of ventilation equipment used is documented.

4.5 Utilities – water, ice, air and other gases

Potable water in use available from aqueduct.
Relevant daily records are maintained. Pluming system map detailing all sampling points was available.
Water is tested twice in a year for micro and chemical-physical parameters with reference to D. Lgs. 31/2001. Results of monitoring were available e.g. analysis done by external accredited lab Neotron (Accredia 0026) dated 2015-12-29 for mb and for chemical: conforming results.
No use of non- potable water.

4.6 Equipment

All equipment was to a good standard and to alimentary use.
Equipment is positioned so as to make cleaning operation easy to be carried out.
Certificates of conformity for equipment in direct contact with food seen.
1 production lines in place for dosing process.
Equipment in Stainless steel.

4.7 Maintenance

Procedure described in QM Chapter 6.4.
A maintenance calendar was maintained and included scheduled intervals.
Maintenance log sheets were used to record completion of maintenance tasks (preventive, unplanned and breakdown works). Task completion was monitored as a KPI.
Pre-start production checks were carried out in production areas and strip-down inspection carried out.
No temporary repairs.
Food grade lubricants were used. No allergens in food lubricants
Maintenance workshops were present on site and were suitably controlled, including a ‘clean’ workshop in the main building, an external container for heavy/dirty works and a factory area for dismantling equipment (no dirty maintenance carried out).
Verified cleaning after maintenance.

4.8 Staff facilities

The staff facilities are adequate to accommodate the required number of personnel.
Designated changing facilities are provided. Direct access to the production ensured.
Storage facilities of sufficient size are present. One large changing rooms, equipped with double partition

lockers and outdoor clothing is segregated by working clothes.
Adequate hand washing facilities available.
Toilets are segregated. Toilets are provided with hand washing facilities.
Eat and drink is not permitted in production area.
Smoking permitted only in external designated areas.
No vending machine. No Catering facilities. No high risk controls are necessary for this production.

4.9 Chemical and physical product contamination control

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

Daily preoperative checks (at start and end of production) for glass, hard plastic, wood, metals, blades, belts.
The storage of the containers are segregated from the storage of raw materials, product or other packaging, even though containers are not made of glass.
The procedure to prevent the risk of chemical or physical contamination of product was defined.
Regular audits are carried out every month. Wood is well managed according GMP requirement, described in HACCP Manual. Pallets only at the end of the processing lines.
Glass and similar material are listed on the Glass Register. Daily check carried out.
The management of containers is adequate; the storage, segregation and handling is appropriate to prevent any event of breakages that could cause contamination of products.
Wood use to the minimum.

4.9.1 Chemical control

Procedure defined in HACCP Manual chapter 19 “Pulizia, sanificazione e gestione dei prodotti chimici”.
Chemicals are under control; their storage, labelling and handling is well carried out.
Chemical products used for cleaning are present. Only food grade chemical used in production areas.
Material Safety Data Sheets are available.
Chemicals were well controlled within the factory as all containers labelled and dispensed via dosers.
Cleaning chemicals stored in a locked room, restricted access.
A list of approved chemicals used at the facility was maintained for maintenance and cleaning chemicals. General Chemical awareness training was given to personnel at induction. Food grade lubricants policy in place.
Cleaning chemicals were supplied against specifications. Food suitability was documented for chemicals used on site. Cleaners were formally trained in-house and in chemical handling by chemical supplier where required.

4.9.2 Metal control

A metal check is described in HACCP Manual. Snap-off blade knives are not used. No staples are used.
There is no metal detector and/or filters since the product is not destined to final consumer.

4.9.3 Glass, brittle plastic, ceramics and similar materials

The procedure for handling glass, brittle or hard plastic, ceramic or other materials control, was defined in accordance to specific procedure. Glass list available
Glass and hard plastic breakage procedure.
Glass and hard clear register was risk assessed and items audited daily, monthly and annually according to risk. No glass incidents to date. Staff well trained in process and mock incident has taken place for training.

4.9.4 Products packed into glass or other brittle containers
N/A
4.9.5 Wood
Wood in the factory is correctly managed and controlled. Wooden pallets used only for finished products where the product is protected.
4.10 Foreign-body detection and removal equipment
4.10.1 Foreign-body detection and removal equipment
Consideration of potential foreign body hazards formed part of the risk assessment. No Foreign-body detection nor removal equipment was considered necessary, since the product is not destined to final consumers. Moreover the Company carries out only the dosing process, while mixing and packaging are carried out by external companies.
4.10.2 Filters and sieves
N/A
4.10.3 Metal detectors and X-ray equipment
N/A
4.10.4 Magnets
N/A
4.10.5 Optical sorting equipment
N/A
4.10.6 Container cleanliness – glass jars, cans and other rigid containers
N/A
4.11 Housekeeping and hygiene
Seen procedure P19.1 “Procedura di pulizia e sanificazione magazzino”, recorded on R19.1A “Registro pulizie e sanificazione magazzino”. Seen MSDS of chemical used. Swab analysis carried out every month on the surfaces in contact with the product. Last analysis dated December 2015 carried out by Neotron (Accredia 0026). Good results. Cleaning chemicals and equipment adequate. Monthly visual inspection to operators carried out by QAM Elena Resta.
4.11.7 Cleaning in place (CIP)
N/A
4.12 Waste / waste disposal

Procedure P06.4R “Gestione dei rifiuti”.
A system for the collection, collocation and disposal of waste material is in place.
Waste container and flow correctly managed.
The waste system is manages in compliance with legislative requirements: separated waste, specific waste and municipal waste. Disposed by municipal company HERA.

4.13 Management of surplus food and products for animal feed

N/A

4.14 Pest Control

Procedure P06.4.1 “Derattizzazione disinfestazione”.
Pest control is conducted by external company (supplier “Eco Buster”, contract dated 2015-04-01 seen) for monthly inspection.
Plan updated 2015-04-01 seen. Product used “Solo Blox” seen: MSDS with 16 points seen.
12 interventions planned every year.
Last intervention date 2015-11-03 and previous dated 2015-09-07.
Flying insects weekly controls carried out by internal staff.
Statistical trend and review done every 12 month. Seen record 2015.
Internal bait of glue, secured in place. Limits defined.
Pest control Technical expert review done every 3 months by external consultant Damiano Visani. Last one done on 2015-12-09.

4.15 Storage facilities

Products are correctly managed and stored on dedicated pallets.
Logistic and expedition following FIFO.
Seen raw materials warehouse.
Production based on the order received.
The storage conditions are specified and effectively controlled.
There are proper records of receipt and / or identification of products that facilitate the correct rotation of storage of raw materials, intermediate products and finished products.

4.16 Dispatch and transport

Finished products transport is regulated by specific contracts with the companies that provides the service: supplier ARCO, contract dated 2015-10-16.
Supplier evaluated on NCs, vehicles are controlled.

5. Product control

5.1 Product design/development

No development of new products to date.
Formulas are defined.
Modification are communicated by clients.

5.2 Product labelling

Seen procedure “Istruzione di lavoro per etichettatura” issue 00 dated 2013-03.05.
Labelling is in line with legal requirements.
Detail any recent changes/reviews to labels. Allergens described on label.

5.3 Management of allergens

Seen in HACCP Manual chapter 26 “Gestione Allergeni”..
The allergens on site have been identified as the following: Cereals containing gluten, Milk and Soya.
There is a separated storage, intermediate cleaning after allergen products.
Allergens are taken into consideration during production planning.
Dedicated bailers on site for allergen management, systematically cleaned.
Each allergen is validated once a year.
Seen allergens analysis by Neotron (Accredia 0026) dated 2015-12-10 on product BIO NW lot. 16.10.2015 for casein absence: conforming results.

5.4 Product authenticity, claims and chain of custody

Identity preserved product are soya and maltodextrin from corn.
Halal, Kosher and RSPO certification on site: certificates verified.
Organic products are traded (certification ICEA last one released on 2015-10-15.
No packaging of Organic products.

5.5 Product packaging

Packaging material used for the final products is:

- LD-PE plastic Film: 25Kg.

Packaging was stored in a dedicated packaging store. Part-used packaging materials suitable for use were effectively protected. During the audit the primary packaging material was adequately protected stored. Packaging specifications included in product description logs.

Conformity declarations of packaging with specifications sent by suppliers.
Migration film test results given by suppliers as well as following test performed foreseen to be done by company itself.
The current specification details the safety use of the packaging material conforming to Reg. 1935/04

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

An analytical plan for products control is available and implemented. Analysis Plan defines products to monitor for microbiological and chemical- physical parameters.

5.6.2 Laboratory testing

No internal lab.
Analysis carried out by external accredited lab are: microbiological, CB, aflatoxin, chemical, physical, filth tests and shelf life.
External accredited lab Neotron (Accredia 0026)..

Seen analysis on product “PRE E 5” dated 2015-12-29 for nutritional values and sugar: conforming results.
Seen another analysis Filth test on product organic BIO NW lot. 16.10.2015 dated 2015-12-10.

5.7 Product release

The release of raw materials and finished products is bounded by positive results of acceptance test and all subsequent tests throughout the manufacturing processes.

6. Process control

6.1 Control of operations

Dosing process:
Big and small balances verified, bailers for flours.
Seen raw materials and finished product warehouse
Cleaning schedule before and after the production process seen.
Production area cleaning seen.
Correct labeling process in place.

6.2 Labelling and pack control

Adherence to packaging allocation procedure was observed during product changeover ensuring pack clearance before start up and documented label and packaging checks.

6.3 Quantity, weight, volume and number control

The frequency of quantity checking are respected on refer Italian legislative requirements DPR 690/78 (every pack was weighted with automatic reject for non conforming products).
Every batch of production is weighted.
The quantity checking was recorded systematically.

6.4 Calibration and control of measuring and monitoring devices

All critical measuring equipment has been calibrated to a National Standard according to Quality System procedure defined in Quality Manual chapter 7.6.
Instrument are calibrated with relation to international certify sample.
All identified measuring devices, including new equipment, shall be checked and where necessary adjusted
Appropriate records referred to a series of instruments seen.
Evidence of calibration seen e.g.

- 2015.12.14 on balances by Gulminelli Bilance
- 2015-01-30 primary certificate LAT 134 25-2015.

7. Personnel

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

Procedure P06.01 for personnel training.
The company has a comprehensive training programme for staff on induction, after three months and annual programme of assessment and refreshment as appropriate.
The site is training personnel to maintain product safety, legality and quality.
Training is provided to the staff in accordance with procedure According to Quality Manual. The training is assessed ad refreshment consequently planned on hygiene, allergens, cleaning and GMP. Seen relevant records on form.
Detailed training records were maintained for individuals.
Competency review are carried out after training.
Seen training dated:

- 2015-10-01 by external consultant Ferruzzi Fabio on HACCP, prerequisite and GMP to all personnel.

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

Procedure P0602 “Igiene del personale” issue 2 dated 2015-02-01.
The site has a suitable personal hygiene policy in place that covers all areas of production and personnel, which has been adopted by all members of staff including agency staff.
Procedures for hand cleaning; management of first aid; storage of personal medicines are all in place and being effectively controlled.

7.3 Medical screening

Procedure P0602 “Igiene del personale” issue 2 dated 2015-02-01.
Medical screening according to Italian law requirements.
Medical questionnaires were completed by new employees, visitors and contractors.
Illness reporting requirements were suitably detailed and included procedure for action to be taken in event of employers reporting/suffering from infectious disease
Procedures in place whereby staff (or visitors) that are returning to work after illness that maybe/are infectious to prevent them contaminating product.

7.4 Protective clothing: employees or visitors to production areas

Suitable protective clothing was provided for production and visitors: disposable gloves, cap and clothing is used by operators.
Blue metal detectable disposable gloves were available for product handling duties and were controlled appropriately.
In storage area, where products are packed and protected, operators wear clothes provided by the Company.
For each operator, the company provides 3 sets of trousers, polo and coat.
Laundering at home.
Swabs properly carried out on clothes and hand dated December 2015: confirming results.

Traded Goods Module

Scope

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

Defined procedure P07.02 “GESTIONE DEL SERVIZIO”.
Suppliers evaluate on GFSI certifications and audits results.
Seen suppliers:

- D., BRC certification verified
- B., BRC certification verified.

Seen contract completely documented.

8.2 Specifications

Specification for every raw material are well managed for each supplier.
Specification are updated at least every 3 years.
Actually, no specific request by clients.
See specification of “L….” by supplier B. dated September 2013.

8.3 Product inspection and laboratory testing

Analysis plan defined on HACCP plan.
In acceptance there are visual check on packaging, identification of the products.
Depending on the typology of the product, Natural World srl asks to the supplier a documentation with laboratory analysis and conformity to Specification.
Seen analysis carried out on 2015-12-16 by Neotron (Accredia 0026) on product Y.E. lot. 339S for Cloramfenicolum absence verification: no Cloramfenicolum found.

8.4 Product legality

Label approved following procedure “ Istruzione di lavoro per la etichettatura”.
Weight check carried out systematically during acceptance phase.

8.5 Traceability

Traceability system operates through paperwork enables trace of raw materials and packaging from supplier through storage and dispatch; a SW computer data system implemented for storage and dispatch of finished products.
Last traceability test dated 2015-09-21 with mass balance verified.