Audit Report

1.Audit Summary			
Company name	TS Food Packaging	Site Code	10002296
Site name	TS Food Packaging – Burlington		
Scope of audit	Packing of various seeds, beans, yeast flakes, granola, salt, ingredient powder mixes, sugar, candy, popcorn kernels and flours into pouches and PET containers, various types of collagens into pouches and PET containers. Mixing of oatmeal packed into 25-lb bags and bulk.		
Exclusions from scope	None		
Justification for exclusion	Not Applicable		
Audit Start Date	2021-08-24	Audit Finish Date	2021-08-26
Re-audit due date	2022-08-24	Head Office	No

Additional modules included			
Modules	Result	Scope	Exclusions from Scope

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	N/A	Previous audit date	N/A		
Certificate issue date	2021-09-17	Certificate expiry date	2022-10-05		
Number of non-conformities		Fundamental	0		
		Critical	0		
		Major	0		
		Minor	8		

3.Company Details	
Address	701 Blackhawk, Suite b, c and d Burlington, Wisconsin 53150

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3.Company Details

Country	United States of America	Site Telephone Number	1 262 763 9434
Commercial representative Name	Gail Koss	Email	gail@tsfoodpackaging.com
Technical representative Name	Gail Koss	Email	gail@tsfoodpacking.com

4.Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	51-500	No. of HACCP plans	1-3

Shift Pattern	1st shift starts 7:30 am to 3:00 pm, then second shift 3:00 to 11:00. The first shift is the largest with 35 employees
Subcontracted processes	No
Other certificates held	Kosher, Organic, Gluten Free
Regions exported to	None
Company registration number	Confidential
Major changes since last BRCGS audit	This was the facility's first audit.

Company Description

The facility is in rural Industrial Park in the City of Burlington, WI. TS Packaging was founded in 1982 and is privately owned. The operations moved to this location in May and started production in June 2021. TS Food Packaging primary business is packaging of food products – ready to eat and flour baking mixes. The company also does mixing/blending of baking flour products. TS Food Packaging does all private label, we do not produce any type of product under its name. They specialize in pre-packaged popcorn packets with oil and seasoning, Variety of Pumpkin Organic Sprouted Seeds, Variety of Collagen Powder for Human Consumption, Variety of Baking Mixes and Hard Candy. There is no actual processing on site, just repackaging of existing product per customer order. The site has about 55 employees. The operation has 2 five dayshift a week.

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5. Product Characteristics

Product categories	15 - Dried food and ingredients 17 - Cereals and snacks				
Finished product safety rationale	Water activity less than 0.85. All products dried shelf stable.				
High care	No	High risk	No	Ambient high care	No
Justification for area	As per Appendix 2 of the BRCGS standard (decision tree) The production area is low risk, maintenance, breakroom, office are non-production areas and warehouse, are enclosed areas.				
Allergens handled on site	Milk Soya Nuts Egg Cereals containing gluten				
Product claims made e.g. IP, organic	Kosher, Organic, Gluten free				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	Pumpkin seeds, oatmeal maple brown sugar and apple cinnamon oatmeal				

6. Audit Duration Details

On-site duration	20 man hours	Duration of production facility inspection	7 man hours
Reasons for deviation from typical or expected audit duration	The facility is small and did not require half of the audit time for the site inspection.		
Next audit type selected	Announced		

Audit Duration per day

Audit Day	Date	Start Time	Finish Time
1	2021-08-24	08:00	17:00
2	2021-08-25	07:00	16:00
3	2021-08-26	07:00	09:00

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	Auditor number	Name	Role
Auditor Number	21322	Elysee Saint-Elie	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 1.1.11)

Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Robin Vos / President				X
Matt Cialdini / Production Manager	X	X		X
Gail Koss / Compliance Manager	X	X	X	X
Amber Powell / Quality Manager	X	X	X	X
Beth Bourne / HR Manager	X			X
Angel Free / Production Planner	X			X
Kristin Connelly / QA Tech	X			X
Eddie Lopez / Logistics Manager				X

GFSI Audit History

Date	Scheme/Standard	Announced/Unannounced

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Non-Conformity Summary Sheet

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

Critical			
No.	Clause	Detail	Ant. Re-audit date

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

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	2.6.1	The onsite challenge of the flow diagram for	Document reviewed, dated and time of the	Added to the HACCP Plan/Pre-Requisite Programs	During the review of the Process Flow Diagrams for	2021-09-16	Elysee Saint-Elie

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Minor							
		the Viking Powder Line was not available for review as requested by the BRCGS standard	review by Gail Koss, Compliance Manager	Annual Review SOP all reviewed, and signed documents must be reviewed by another member of the team to ensure documents are completed before filing.	701 Black Hawk, one of the Flow Diagrams was not signed, dated and time of review. This was an oversight on the Food Safety Team Member doing the review. Will add a line on the SOP for Annual reviews that another team member must review to ensure it is completed before filing.		
2	3.2.1	The restroom inspection and cleaning log did not have a document number and was not listed on the document register.	Added Form Number to cleaning log.	Before any new forms or documents are released to departments for use, it must be approved by the HACCP Coordinator.	Reviewing the reason for this document not to be controlled, it was found that the new Sanitation Manger was unaware of the requirements that all forms used in his/her department must have document/form numbers before releasing.	2021-09-16	Elysee Saint-Elie
3	4.1.2	Cigarette butts, debris, paper, dead leaves, pieces of wood and plastic bottle were observed in the docking area	Production Manager assigned 2 workers from 2nd shift to clean up debris.	Production Manager will have 2nd Shift Supervisor assign 2 employees once a week to pick up any debris that is in the docking.	No one was ever assigned the job to make sure that the dock area was cleaned up weekly.	2021-09-16	Elysee Saint-Elie

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Minor							
4	4.4.8	A gap was observed at the bottom of the overhead dock door #4.	Contracted Overhead Company came the day after our walk through and repaired the overhead doors	Review of the overhead doors in on the TS Food Packaging Monthly Hygiene Audit	The doors were noted during the July Monthly Housekeeping Hygiene Audit and appropriate steps were in place to have them repaired.	2021-09-16	Elysee Saint-Elie
5	4.7.6	In the maintenance shop there was no control in place to prevent transfer of engineering debris to the production areas	Placed a mat in front of the door until a new one could be ordered	New Mat was ordered for the maintenance shop to be placed at the entrance of the shop doors	When the shop was moved into our facility, the maintenance mat was never brought with the other supplies. Maintenance did not place an order for a new one. Was not on Monthly Housekeeping Hygiene Audit to check for mat placement.	2021-09-16	Elysee Saint-Elie
6	4.8.4	The handwashing station in the cup filler production area did not have advisory signs to prompt handwashing such as pictorial instructions	Put up new signs that has pictorial handwashing instructions	Added new verbiage to the Monthly Housekeeping and Hygiene Audit to inspect for both handwashing signs and pictorial handwashing signs at each handwashing station	Food Safety Team was not aware that the pictorial handwashing sink was missing the pictorial handwashing instructions. This was missed during the July Monthly Housekeeping Audit.	2021-09-16	Elysee Saint-Elie
7	4.11.6	The 3-compartment sink in the sanitation area was not labeled to identify the intended use of each compartment	Put up new signs immediately	Added to Monthly Housekeeping and Hygiene Audit – inspect for proper signage placement.	New sink & wall was installed. There was not follow up to make sure the signs were placed back properly. The Monthly Housekeeping and Hygiene	2021-09-16	Elysee Saint-Elie

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Minor							
					Audit as part of the inspection		
8	4.16.2	During the review of the shipping documentation for the product used for the traceability exercise, the record for the condition of the vehicle was not available.	Talked to the MH Manager and Supervisor regarding the importance of documenting all inbound and outbound shipments and completing the documentation every day.	Training documentation for new employees was implemented as part of our new employee onboarding and annual review	Both the MH Supervisor and Manager were not present the day the shipment was received. Both material handlers present were new and not trained yet to receive shipments	2021-09-16	Elysee Saint-Elie

Comments on non-conformities
No Comments

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Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit due date

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

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

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Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The company has a documented food safety and quality policy “Food Safety and Quality Policy” signed by the President dated 2021-05-17. It is communicated to the staff by posting at the employee lunchroom at visitor sign in and reviewed during annual GMP training.
There are documented objectives for: obtaining BRCGS certification, 10 customer complaints, completing scheduled internal audits. Objectives are measurable and include targets. These are communicated to staff during the monthly manager meetings and emails.

Management review meetings are held monthly. The last review was 2021-07-30 and was attended by the President, Compliance Manager, Quality Manager, Inventory Manager. The minute records of the management review were available and included decisions and actions which are communicated to appropriate staff and completed within timescale.

There is adequate resource to maintain compliance to the Standard.

There are also regular meetings including: monthly quality meetings, weekly operations meetings food safety meetings.

The company ensure that they are kept informed of scientific and technical developments, industry code of practices as applicable as well as new risks to authenticity of raw materials and relevant legislation by review and monitoring of: BRCGS Participate, AIB newsletter, SAI Global and FDA, OCIA, Gluten Free.

Food safety culture is the responsibility of the Quality Manager and Compliance Manager who discussed these matters with the auditor. Reduce customer complaints through root cause analysis, open communication with management regarding food safety. Employee training on quality and food safety.

Work so far includes- Employee Questionnaires for food safety, locked box for anonymous suggestions for food safety. Effectiveness will be measured through the quiz results. Facility issues gift certificate to the employee who has the most correct answers. The quiz result is used to evaluate the knowledge of employees and to focus on what needs to be reinforced.

Interviews with employees confirmed that they were aware that non-conforming product issues could be reported to Quality or any facility Manager for action.

The company has a confidential reporting system which works in the following manner: locked box in the breakroom for anonymous food safety concerns.

A genuine printed copy of BRCGS standard was available. The organization had access to BRCGS participate to be updated on changes to the standard.

The BRCGS logo was not used.

The company has ensured certification is maintained, with audit due date 2021-08-24.

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The Production Manager attended both the opening and closing meeting.

This is the facility first audit and there was no non-conformity.

1.2 Organisational structure, responsibilities and management authority

The company has a clear organizational structure in place issued 2021-06-30. The person responsible for food safety, legality and quality is Compliance Manager who reports directly to the President.

Deputization is documented in the Cover Personnel document dated 2021-06-30. The organization ensures that employees are aware of their responsibilities through job descriptions, training, Work Instructions and SOP's. Interviewed staff appeared to be aware of their responsibilities and documented work instructions are in place.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
1.1.13	The logo is not currently being used.

2 The Food Safety Plan – HACCP

The plan has been developed and maintained by a multidisciplinary team including:

Job Title	Experience	Qualifications / Training
Compliance Manager / team leader	17 yrs. Food Safety Experience	HACCP 2019-11-29, PCQI 2016-11-03
QC technician	2 yrs. Food Safety Experience	In house Annual HACCP training 2021-08-23
Production Manager	20 yrs. plus Food Safety Experience	In house Annual HACCP training 2021-08-23
QA Manager	1 yr. Food Safety Experience	In house Annual HACCP training 2021-08-23

The company has a fully implemented and effective food safety plan based on Codex Alimentarius HACCP principles. There was one HACCP study which included all products packed in this facility.

Each group of products includes a full description which includes all relevant information on food safety. The intended use of the product is identified as ready to eat and not intended for those that suffer from food allergies and there are no alternative uses.

Pre-requisites are documented within the HACCP Plan and included the following: GMP, Allergen Program, Training, Sanitation, Foreign Material, Pest Control, Complaints, Preventative Maintenance,

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Traceability and Recall, Shipping, Approved Supplier, and Receiving. The pre-requisites are reviewed as part of the HACCP review.

Flow diagram	Issue date	Verification Method
Mixing	2021-08-10	Visual walk through by HACCP Team
Viking Powder line	2021-08-10	Visual walk through by HACCP Team
Bosh line	2021-08-10	Visual walk through by HACCP Team
Cup Filling Machine	2021-08-10	Visual walk through by HACCP Team
Stick Pack	2021-08-10	Visual walk through by HACCP Team
Stand Up Pouch Line 1	2021-08-10	Visual walk through by HACCP Team
Spee-Dee Servo Rotary	2021-08-10	Visual walk through by HACCP Team
Stand Up Pouch Line 2	2021-08-10	Visual walk through by HACCP Team

Minor Non-conformance 2.6.1: The onsite challenge of the flow diagram for the Viking Powder Line was not available for review as requested by the BRCGS standard.

Relevant information has been used to conduct the hazard analysis including codes of practice on third party HACCP training materials, sanitation course, Codex and FDA compliance.
Flow diagrams are in place covering relevant inputs and outputs. The following is a list of existing diagrams: Mixing, Viking line, bosh line, cup filling machine, stick pack, stand up pouch line 1, Rotary stand up pouch line 2.

Process steps summary: Receiving, Processing and Packaging, Finished Products Storage, and transferred to the facility warehouse which is BRCGS certified.

The HACCP team have identified and recorded potential hazards that are reasonably expected to occur at each step of the process, and this includes raw materials. Identified hazards were determined for microbiological (salmonella, E-Coli), chemical (sanitation, machinery lubricant), physical (foreign materials), allergens and malicious contamination and fraud. Auditor verified that the risk assessment was done in compliance with the standard.

Hazard Category	Specific Hazard	Risk Determination
Biological	Salmonella, E-Coli, listeria	Low
Physical	Metal, wood, plastic	Low
Chemical	Cleaning chemicals, Machinery chemicals	Low

A hazard analysis has been conducted based on likelihood and severity. Control measures have been identified and documented within the HACCP plan.

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Critical control points have been determined by using a risk matrix/codex decision tree

Critical control points identified are:

CCP	Process Step	Critical Limit	Monitoring
1	Rotary line	1.5 mm Fe, 2.5 mm Non-Fe, 3.0 mm Stainless Steel	Start of the shift, middle and end of the shift and change over
	Stand up line	1.5 mm Fe, 2.0 mm Non-Fe, 2.4 mm Stainless Steel	Start of the shift, middle and end of the shift and change over
	Stand up 2	1.2 mm Fe, 1.2 mm Non-Fe, 1.5 mm Stainless Steel	Start of the shift, middle and end of the shift and change over
	Viking Line	1.5 mm Fe, 2.5 mm Non-Fe, 3.0 mm Stainless Steel	Start of the shift, middle and end of the shift and change over

Documented procedures define corrective actions expected to be implemented if critical limits are exceeded.
CCPs were validated as follows:

CCP	Means of Validation	Date of Last Validation
1	Deviation report reviews, complaints, and calibration of the metal detector by a 3rd party company	2021-06-08

CCP records are signed by QC technicians and verified by the QA Manager.

Verification of the HACCP plan is achieved by HACCP Team including internal audits, review of customer complaints and withdrawals or recalls. This is done as part of the Annual HACCP Review Program. The annual validation is conducted on products, process formula, process flow, equipment, process history repeats, CCP deviations, similar industry recalls, new hazards by FDA, and confirmed food safety consumer complaints. This information is made available to the HACCP food safety team.
During the audit multiple records were sampled and considered to be properly documentation and kept.

The last HACCP review was conducted on 2021-07-30.

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

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3. Food safety and quality management system

3.1 Food safety and quality manual

The company demonstrated a documented quality system manual based on the BRCGS requirements. The manual or their parts are made available as needed to the staff by electronically in the shared drive and hard copy in QA office.

Verified procedures and work instructions were clearly legible and available in English. During interviews and auditor observations these were properly understood by relevant staff.

3.2 Document Control

There is a “Document Control” procedure in place dated 2021-05-01 revised. Documents are controlled by the Compliance Manager. A record of the reason for change is retained. A list with all controlled documents were provided and verified during the audit. Computer data is backed up daily.

Minor Non-conformance 3.2.1: The restroom inspection and cleaning log did not have a document number and was not in listed on the document register.

3.3 Record completion and maintenance

Records reviewed were legible and easily retrievable and are retained for 6 years which properly covers the maximum product shelf life of 5 years plus one year. No issues were seen for the reviewed records during the audit.

3.4 Internal audits

There is a planned program of internal audits based upon risk for which the organization considers the following criteria: BRCGS standard. Procedure states that internal audits are conducted a minimum of 4 times per year. Maintenance, Receiving, Shipping, traceability, food safety complaints etc. Schedule issued 2021-06-01 demonstrates that all system requirements are covered throughout the year and that all activities are covered at least annually.

Currently there are 3 available auditors to cover all aspects of the organization and ensure independence. Auditors were demonstrably competent and evidence for this included training records from International Food Safety and Quality Networks.

Audit reports include objective evidence of conformity as well as non-conformity and are reported to personnel responsible for the activity audited. Corrective actions and timescales are agreed, and completion of corrective actions are verified by Quality Assurance and Compliance team.

During the audit the results of the following audit activities conducted throughout the year were reviewed:

Date	Area / Requirement	No. NCs	Action plans Y/N	Implemented Y/N	Verified Y/N
2021-07-12	Complaints	0	N	N	N
2021-07-12	Control of non-conforming	0	N	N	N
2021-07-12	Recall	0	N	N	N
2021-08-10	Pest control	2	Y	Y	Y
2021-08-12	Management of allergens	2	Y	Y	Y

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In addition to the internal audit program there is a program of planned inspections for hygiene and housekeeping as well as fabrication. Inspections are conducted monthly. Records were seen for the month of June and July by the auditor. Deviations identified are reported on non-compliance and corrective action log and implemented actions are verified by Quality Manager.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

There is a documented supplier approval and monitoring system “Supplier and Raw Material Approval and Performance Monitoring” in place dated 2021-05-10. This requires that the organization performs a risk assessment of each raw material/group of raw materials to identify potential risks to product safety, legality and quality including allergen contamination, foreign body risks, micro contamination, chemical contamination and substitution or fraud

Existing methods to accept raw materials are consistent with the reviewed risk assessment which includes the following means of control: visit of supplier facility, supplier questionnaire, GFSI benchmark audit.

During the audit a sample of supplier assurance records was conducted:

Item	Risk Rating	Method of Assessment	Valid Until
Organic Pumpkin Seeds	Low	BRC	2022-08-14
Confectionery hard candies	Low	SQF	2022-03-02
Pouches	Low	SQF	2022-01-04

Evidence of raw material changes being communicated to goods was provided via customer provided specifications to Compliance Manager.

Exceptions to the supplier approval process were allowed; emergency suppliers required initial review. None had been used in the past year.

Materials purchased via agents/brokers are assessed in the same manner as direct suppliers through customer supplying information.

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3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Documented procedure Supplier and Raw Material Approval and Performance Monitoring" dated 2021-05-10 describes controls for acceptance of raw materials and packaging materials. A list of raw materials and requirements to be met for acceptance was available and observed to be followed. During the audit were sampled materials to ensure compliance with the defined requirements the results of the sample were as follows:

Material Description	Defined Means of Control	Evidence Provided	Comments
Pumpkin Seed	COA and Physical inspections	Trailer inspection	None
Confectionery hard candies	COA and physical inspections	Trailer inspections	None
Pouches	COA letter of guarantee	Trailer inspection	None

Claims of authenticity are currently identified for organic and gluten free.

3.5.3 Management of suppliers of services

Procedure "Food Packaging Management of Supplier of Services describes the means to approve and monitor service suppliers which includes review of contract and service. Contract reviewed during the audit included pest control, Uniform Company, Waste Company and Pest Control. This includes service expectations.

3.5.4 Management of Out sourced processing

Section considered not applicable.

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3.6 Specifications

Specifications are in place for raw materials including packaging and finished product. When required specifications are formally agreed with customers/suppliers. Procedure includes the requirement to review specifications when product/materials change or at least every 3 years.
Sampling of specifications was conducted as part of site inspection and traceability with following results:

Type of Specification	Description	Specification	Last Review Date	Comments
Final Product	Organic Pumpkin seeds	Specification provided by customer	2019-02-28	Up to date
Raw material	Confectionary hard candies	Specification provided by customer	2019-09-19	Up to date
Packaging material	Pouches	Specification provided by customer	2021-04-19	Up to date

3.7 Corrective and preventive actions

The organization provided evidence of documented procedure Non-Conformance Corrective Action Procedure dated 2021-06-01. The company demonstrated that they use information from identified failures in the food safety, legality, or quality of the products to make necessary corrections and prevent recurrence. The organization manages existing corrective and preventive actions via Corrective action form.
Example seen during audit was for prepopulating times not real time for internal audit. This resulted in retraining for employee which showed that root cause analysis was effective.

There was no trend.

3.8 Control of non-conforming product

A non-conforming product procedure is in place Non-conformance Corrective Action Procedure dated 2021-06-01 which includes controls and responsibilities for out-of-specification products/materials to avoid /prevent unauthorized release.
Non-conforming materials/products are identified by direct labelling and blocked in IT-systems (taped off and segregated) and placed on hold to avoid accidental release. There was non-conforming item during the audit.

3.9 Traceability

A system is in place which allows the organization to trace all raw material product lots including primary packaging from their suppliers through all stages of their process until one step out of their responsibility and vice versa. The procedure dated 2021-06-01 describes how items may be traced.

The organization provided evidence of internal traceability exercises across a range of products which included a review of the pertinent documentation and records as follows:

	Product	Date of Production	Amount Produced	Amount Traced	Time Required / Comments

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Forward Trace 2021-08-19	Beef gelatin	Received 12000 lbs, 2021-06-02	Used 9200 lbs and 2800 lbs in inventory	.100%	1 hour 10 minutes
Backward trace 2021-07-02	Dill Pickle seasoning	2021-06-10	600 lbs	98.45%	1 hour

An onsite traceability test was successfully conducted on:

	Product	Date Produced	BB Date	Mass Balance	Time Required
Backward Trace From Finished Product	Organic Pumpkin Seeds	2021-06-15	2021-06-15	98.8%	1 hour 55 minutes
Forward Trace From Raw Material	Pumpkin seeds	40478 lbs received 2021-06-15	Use 40005	98.8%	99.9% in two hours

The facility does not use rework

3.10 Complaint-handling

There is a fully documented complaint handling procedure “Customer Complaint Procedure” dated 2021-05-10. All complaints are recorded and tracked. An investigation is conducted by QA in the appropriate areas. The organization demonstrates the means to analyze and trend complaints and in case of significant increase or serious complaint root cause is determined as part of the action plan.
Main cause of complaints was: light printing of lot code and sealing of packages.

During this year, 2 complaints have been reported and there were no trends.

Customer complaints were discussed at the monthly meetings.

During the audit were reviewed records of existing complaints which demonstrates a proper documented and implemented system.

3.11 Management of incidents, product withdrawal and product recall

There is a documented crisis management procedure called Emergency Response and business continuity Plan dated 2021-08-15 and Product Identification, Trace, Withdrawal and Recall procedure dated 2021-07-01.
The crisis management team includes Logistics Manager, Quality Manager, Maintenance Manager, Production Manager, Compliance Manager, Inventory Manager and HR Manager.

The recall procedure is tested at least annually to ensure effective operation at both facility and company level. The test showed that the site’s responsibilities were properly understood and capable of being promptly enacted.

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Date	Product	Batch Traceability	Key Timings	Corrective Actions
2021-06-04	Go Raw Sea Salt and Cracked Pepper	2000 lbs recovered	3 hours 45 minutes 100%	None

The company has confidence in its out of hours protocol as evidenced by 24-hour phone contact list.

There have been no withdrawals / recalls in the last 12 months however the procedure states that in the event of a product recall the certification body should be informed within 3 working days of the decision to issue a recall.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.2.3	There is no reception of alive animal
3.5.4	There is no outsourced processing
3.9.4	Rework is not used in the facility

4. Site standards

4.1 External standards

The organization moved in this facility in June. The production site is situated in a light industrial section of Burlington, WI. A plant tour around the perimeter was conducted and no activities were observed which may have an adverse impact on product.
Minor Non-Conformance 4.1.2: Cigarette butts, debris, paper, dead leaves, pieces of wood and a plastic bottle were observed in the docking area

All areas around the building were observed with enough clear areas to discourage rodent burrowing. Roads around the plant were observed to be paved and in good condition. Waste containers are maintained far from plant entrance and kept closed to prevent pest harborage.

Building fabric was in good condition. Docking doors were observed to close properly and without evidence of bird roosting sites. Walls and floors were in good condition; pipes, vents etc. were adequately proofed

4.2 Site security and food defence

Security systems are in place. A documented risk assessment was conducted 2021-08-18 including both internal and external threats. The system requires annual review. No changes were needed based on the risk assessment.
There is no identified risk to raw materials and the products

Visitor reporting system is in place.

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There was not any outside storage or outside ports.

The site is registered with FDA, registration number is confidential and with an expiration date 2022-12-31.

Security procedures are part of the training program and personnel interviewed explained their responsibilities in that respect.

4.3 Layout, product flow and segregation

The factory layout, process flow and movement of personnel appeared acceptable. Contractors and visitors are made aware of company procedures by reading and signing GMP Guidelines for Visitors and Contractors.

Contractors are under the supervision of the host manager.

The site tour demonstrated that the plant has sufficient workspace and storage capacity to enable proper hygienic conditions.

Temporary structures are managed by the maintenance manager. There was no temporary structure during the site tour.

Map provided by the plant and assessed by the auditor demonstrate the following areas:

Areas	Location	Level of control
Low-risk	All processing and Packing areas	GMPs, hairnets, beard nets, lab coats
Enclosed product	Warehouse (Storage)	GMPs, hairnets, beard nets, lab coats
Non-product	Employee's facility and maintenance shop, breakroom.	GMPs, hairnets, beard nets, lab coats

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

Fabrication of site, buildings and facilities observed to be suitable for intended purpose:

Walls	Observed to be overall in good conditions, no accumulation of dirt, condensation or mold. Walls are included in the cleaning program. The walls in this facility are made of concrete cement.
Floors	The floors are made of cement and were in good conditions, without cracks or evidence that does not resist process needs and observed in good cleaning conditions.
Drainage	Included in the cleaning program, The drains are clean weekly and is part of the Master Sanitation Schedule and properly covered to avoid pest entrance. Back flow prevention devices are installed in the hoses and reported to be in good condition. The city stated that the building does not need a back flow.
Ceilings and overheads	Ceilings are made with metal of metal roof and maintained in good condition, included in the cleaning program. There is no suspended ceiling and elevated walkway in this facility.

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Windows, roof glazing and ventilation	Observed to be in good condition. Windows which open to the outside are properly screened to prevent the ingress of pests. Glass near production areas was observed to be protected against breakage natural /mechanical ventilation system were installed. No condensation or excessive dust observed.
Doors	Provide evidence that plants are properly sealed, no gaps between walls and/or floor. Minor Non-conformance 4.4.8: A gap was observed at the bottom of the overhead dock door #4.
Lights	Light seems to be adequate for process needs. Where located in process areas were observed properly protected and shatter proofed. Inspection areas observed with adequate light for proper performance of their operations.

4.5 Utilities – water, ice, air and other gases

The water distribution schematic diagram dated 2021-06-02 was used as a basis for water sampling. All water is potable and provided by City of Burlington, WI. Testing sample schedule was in place and requires yearly microbiological (E coli, HPC, coliforms) and chemical quality tests conducted by Matrix Sciences, an accredited laboratory. Satisfactory results for E coli and Coliforms dated 2021-07-13 were seen. Water was not used as an ingredient.
Non-potable water is not used.

Compressed air is generated by oil free compressors. The organization has identified the steps in the process were compressed air is in contact with the primary packaging (pouches). The air is filtered at point with the first stage filter is 5.0 microns and the second stage filter is 0.01 micron which is replaced by maintenance annually.

The organization does not use CO2 / N2 for their production process.
No Steam is used.

4.6 Equipment

Food processing equipment was observed to be industry standard. Key pieces of equipment include supersack dumpers, conveyors, scales and packaging equipment. Equipment selection is based on type of equipment specific to this product type and is in compliance with FDA requirement. Equipment in direct contact with food including dumpers is food grade.

4.7 Maintenance

The organization plans, tracks and records their maintenance program based on paper files. System has controls in place to provide corrective/preventive/deductive maintenance based on defined routines.
There was no temporary repair during the site tour. Procedure is in place and dated 2021-08-15.

Maintenance work is followed by documented hygiene clearance procedure accountability of tools and parts. A hand over process to Quality, then to production is in place, evidence of compliance was seen with work order review.
There are 4 maintenance team members supported by contractors as appropriate.
Start-up checks are completed by the QA. Records for the 2021-06-16 and 2021-08-23 were reviewed

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Food grade lubricants including allergen status were listed on allergen certificate on file in SDS. Location, identification and clear determination on where permissible for use were evaluated and considered to be satisfactory.

Engineering workshop is situated away from the production area.

Minor Non-conformance 4.7.6: In the maintenance shop, there was no control in place to prevent transfer of engineering debris to the production areas

During the audit were assessed maintenance routines for the following equipment:

Equipment	Routines verified	Period Reviewed	Comments
Viking Line	Monthly	June and August	Completed according to defined routines and properly documented including details of who performed the routine
All Fill	Bi-weekly	June and August	Completed according to defined routines and properly documented including details of who performed the routine
Capper	Monthly	July and August	Completed according to defined routines and properly documented including details of who performed the routine
Conveyor	Weekly	July and August	Completed according to defined routines and properly documented including details of who performed the routine

4.8 Staff facilities

Suitable staff facilities are provided. Based on risk assessment changing rooms were not required as company shirts were provided, and employees could wear them into work. The facility was low risk. Lockers allow for the segregation of personal items and production clothing. Clean and dirty production clothing are properly segregated.
Suitable handwashing facilities in place.

Minor Non-conformance 4.8.4: The handwashing station in the cup filler production area did not have advisory signs to prompt handwashing such as pictorial instructions.

Toilets are segregated. Adequate smoking facilities provided externally and include policies with respect to the use of electronic cigarettes.
Catering facilities were not provided. Vending machines are provided on the premises and were suitably controlled to prevent contamination of products.
A break room is provided with appropriate stored and hygienic conditions including a fridge.

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

4.9.1 Chemical control

Cleaning chemicals and lubricants are properly identified in the existing list of approved chemicals, properly contained and segregated with non-food grade chemicals in specified lockers located in maintenance shop and designated areas of production wash bay area, maintenance lubricants.
Confirmation of suitability is conducted by Compliance Manager.
When in use chemicals are properly identified and employees are aware and trained on their proper use.
Safety Data Sheets are made available and used as part of existing training programs.
When strongly scented or taint forming materials are used, procedures are in place to reduce risk of contamination.

4.9.2 Metal control

Sharp metal implements are controlled according to Sharp Metal Policy dated 2021-06-05. This requires that they be inspected monthly by Quality. Records from June and August were seen. Snap-off-blade knives were not observed and reported to be forbidden.
The policy also confirms that packaging/ingredients which use staples is not permitted. Policies are in place to avoid the use of staples, paper clips etc.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Glass breakage procedure with the reviewed 2021-08-16 is in place. Instructions for staff clothing were included and breakages are recorded on the incident report form 4.9.3.2.

Glass and other transparent brittle materials have been excluded wherever possible from open product areas.

The glass and hard plastic register was up to date. Checks are conducted on a monthly frequency and records for the check conducted on 2021-06-22 and 2021-08-23 were reviewed.

4.9.4 Products packed into glass or other brittle containers

The organization does not pack products in glass or brittle containers.

4.9.5 Wood

Wood use was in pallets only and these were controlled by limiting their use to the ends of lines only and receiving. Wooden pallets were checked for structural integrity upon receipt and through the use in production and within the warehouse. Wood within the site included pallets only. They were noted to be in good condition during the site tour.

4.9.6 Other physical contaminants

When unpacking raw materials / ingredients care is taken to prevent cross contamination via Other Physical Contaminants policy
Writing implements comply with the standard – pens are metal detectable.

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4.10 Foreign-body detection and removal equipment

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

A documented assessment dated 2021-06-10 has been carried out to identify the potential use of equipment to detect or remove foreign body contamination.

4.10.2 Filters and sieves

The facility does not use filters or sieves

4.10.3 Metal detectors and X-ray equipment

Metal detectors include a stop to the entire system with an alarm. Contaminated products are removed by the line operators and placed in the containers away from the production line.
Documented procedure Metal Detector Procedure and Training Document dated 2021-08-02 details controls for testing of the equipment including responsibilities, operating conditions including sensitivity; methods and frequency of checks and requirement to document the obtained results. Frequencies included at start-up, middle and end of production and change over.
Metal detectors are CCPs
Test observed during site tour and conducted correctly.

4.10.4 Magnets

Magnets are used and are located in the cup filler line before the packaging. Inspection of the magnets is conducted by QC weekly. Records reviewed on site provided details of test results. Records of pull strength testing were on file.

4.10.5 Optical sorting equipment

Optical sorting equipment is not used

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

Not in use at this facility.

4.11 Housekeeping and hygiene

Production employees clean the facility during and after production. Master Sanitation Program “Operational Cleaning Procedure” dated 2021-08-15 was in place.
Prestart checks and equipment cleanliness were verified during the audit. Site was maintained in appropriate level of cleanliness.
Written cleaning methods are in place, those for Viking line and Stick Pack line were checked during the audit.
Cleaning records are analyzed, and trend analysis are available to instigate improvements where required.
Minor Non-conformance 4.11.6 The 3-compartment sink in the sanitation area was not labeled to identify the intended use of each compartment
Cleaning programs were validated and verified via ATP swabs and pre-start visual inspections. Records for 2021-06-16 and 2021-08-23 were reviewed. Out of specification results have been defined and the corrective action is described in the procedure.

4.11.7 Cleaning in place (CIP)

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There is no CIP is used

4.11.8 Environmental monitoring

The facility has developed a program which requires Listeria, E-Coli and Salmonella, EB, yeast and mold monthly. Auditor reviewed the records for the months of July and August.
Acceptable limits have been defined for the different pathogens in the procedure dated 2021-03-17 requires that the following actions be taken when these limits are exceeded, the area will be re-cleaned sanitized and re-tested.
The last review of the programme was triggered by the QA Manager.

4.12 Waste

Waste was observed to be well managed. All waste is removed from production on a regular basis.

External waste collection containers are well managed. Containers are properly covered.

Waste is removed by licensed contractor. Unsafe product or trademarked waste is disposed of by ASDA a license contractor and records retained.

4.13 Management of surplus food and products for animal feed

The company does not give any products to organization or employee.
Surplus items were not used for animal feed.

4.14 Pest management

The organization has a preventive control program in place to minimize risk of infestation which includes external service provided by Wil-Kil Pest Control.

The following is a description of the existing program:

Contract or document that describe service	2021-06-01
License or permit	Expiration date 2021-12-31 issued by the Wisconsin Department of Agriculture.
Pest covered	rodents, crawling and flying insects
No. of routine visits	Bi-weekly
Station map	2021-06-22 which matches with existing numbered pest control devices.
Type of used pest control devices	Exterior baits and tin trap, ILT, pheromone, noise alarms as bird deterrent
In-depth pest control surveys	Survey will be done quarterly. The facility contracted the Pest control company in June. There is no survey done.
Controls in case of infestation	In the event of an infestation, the plant activates an action plan, and the Food Safety Team meets along with IPM personnel to initiate additional sanitation procedures and increase pest control service.

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The organization has a list of approved pest control products used including MSDS. Bait stations are robust and secured in place. Toxic rodent baits are not used in open product areas. EFKs and pheromone traps are correctly sited.

Inspection reports provide details of the inspections conducted, if any activity is reported inside or outside the facility, recommendations are provided, and actions are taken over such recommendations.

Reports will be assessed every quarter for trending which includes catch analysis existing information provide evidence to support that in the last 12 months there has not been infestation.

Interviewed employees understand the signs of pest activity and are aware of the steps to be followed to inform of pest activity to designated functions.

4.15 Storage facilities

Storage facilities observed to be satisfactory. Allergens segregated by category.
There is no cold storage on site.
Controlled atmosphere storage is not applicable.
Outside storage is not conducted.
Stock rotation is controlled by FIFO. Program was observed properly followed.

4.16 Dispatch and transport

Dispatch observed to be satisfactory. Loads are inspected prior to dispatch which includes documented verification of seals, odors, visual conditions, debris, container conditions, and compatible materials

Minor Non-conformance 4.16.2. During the review of the shipping documentation for the product used for the traceability exercise, the record for the condition of the vehicle was not available.
Traceability is ensured through BOL and Planning System. Records were available for traceability exercise.
Vehicles are provided by third-party contractors and was arranged by customers.
Containers are not required to control temperature.

The documented procedures for transportation include restrictions in the loads, security measures during transit, and instructions on case of breakdowns or accidents.

Approved third party contractors are BRCGS S&D / GFSI certified or meet requirements which are described in contracts

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.2.2	There is no identified risk to raw materials and the products
4.3.5	There are no temporary structures present.

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4.4.5	There were no suspended ceilings.
4.4.6	There were no elevated walkways in the facility
4.9.4.1 - 4.9.4.3	No products were packaged into glass or other brittle containers.
4.10.2	The facility does not use filters
4.10.5.1	Optical sorters were not used.
4.10.6.1, 4-10-6.2	Container cleaning devices were not used
4.11.7	There is no CIP in use.
4.13.1	There are no customer branded products
4.13.2	The plant does not sell products to staff and does not donate products to charitable organizations.
4.13.3	There are no products intended for animal feed.
4.14.3	The site does not undertake its own pest control.
4.15.3	Cold storage was not used on site.
4.15.4	No controlled atmosphere storage.
4.15.5	There was no outside storage.
4.16.3	There is no temperature control required for transport.

5. Product control

5.1 Product design/development

Product development and design procedure called Product Design and Development dated 2021-06-01 is in place. Procedure is applicable for new and modified products and includes HACCP review, samples, approvals, label design, and production trials. Shelf-life tests are managed by the QA and are conducted following documented protocols which demonstrate compliance with relevant microbiological, chemical and organoleptic criteria.

The site does not conduct any product development as all products are packaged per customer request.

5.2 Product labelling

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The company ensures that labels are legal for the country of use by information from the customers. The customers owned the brands and were responsible for label development according to Product Labeling dated 2019-02-11.
The site would assist with labelling and use third party for nutritional evaluation and labelling if the customer requested.
Where claims are made these are verified through testing and verification by Kosher and Organic inspections.
No cooking instructions were provided for products from this plant.
Evidence seen during the audit included label for pouches of pumpkin seeds used for trace exercise.

5.3 Management of allergens

The company has an allergen control procedure in place called Management of Allergens dated 2021-05-28 which includes assessment of raw materials to establish the presence and likelihood of contamination by allergens.
A list of allergens containing raw materials, processing aids, intermediate and finished products was held on file and dated 2021-07-01

Allergens on site are dairy, soy, tree nuts, egg, gluten
A risk assessment dated 2021-06-01 has been conducted to identify routes of contamination.
No Allergen rework.
Warnings are in place on labelling as appropriate.
Claims made regarding suitability of a food for allergy or food sensitivity sufferers is fully validated.

Allergen	Protein Specific Swab / Finished Product Testing etc	Date
Dairy	Neogen Swabs	2021-06-16
Soy	Neogen Swabs	2021-06-16
Gluten	EZ Gluten	2021-06-16

Line start-up checks are in place for product change over and changes in batches of packaging to ensure labels applied are correct for products packed. Records for 2021-06-24 and 2021-07-14 were reviewed.

5.4 Product authenticity, claims and chain of custody

Company has access information on risks of adulteration or substitution of raw materials via trade associations / government sources/ private resource centers.
A vulnerability risk assessment dated 2021-06-30 was made available to assess the potential of adulteration or substitution. Due to the assessment the organization did not identify any raw materials as being affected.
Product claims are in place. The status of each batch of raw materials is verified by inspections and records maintained. Evidence of Kosher and Organic were demonstrated. Certificates valid for Kosher expiry 2022-06-30 Gluten free expiry date 2021-10-30-and Organic expiry date of 2022-07-13.
The organization provided copy of the documented process flow for production of products with claims which identify potential areas for contamination or loss of identity identified and controls established.
These claims are labelled onto finished products: Kosher Gluten Free and Organic. The facility has not conducted the traceability exercise to confirm this status. The organization moved in the current location in May.

5.5 Product packaging

Purchasing of food contact packaging includes the need to provide characteristics of the food to ensure the provided material is suitable for the intended use. Evidence seen during the audit included letters of guarantee for pouches and PET containers.

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Liners were not used.
Storage Facilities procedures dated 2021-06-30 outlined the destruction of obsolete packaging materials using a written X on the film. Obsolete materials were sent back to the customers.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Test critical to confirm product safety, legality and quality are performed by external laboratories.

Tests include listeria, E-Coli, salmonella. The regime does not properly consider risk. Results are recorded and reviewed regularly to identify trends.

Test results are compared against product specifications or acceptability criteria to identify compliance and relevance of reported determinations, when deviations are identified the organization treat product as non-conformity/re-evaluate test results before actions are taken.

Results for 2021-07-13 for pumpkin seed tested for listeria, E-coli and salmonella were seen during audit.

5.6.2 Laboratory testing

Laboratory testing is carried out by external accredited laboratory Matrix Sciences for which the scope of services matches the tests conducted.

The reliability of in-house laboratory results includes recognized documented test methods, qualification of laboratory staff, and implementation of ring/proficiency tests, inclusion of laboratory equipment in calibration and maintenance programs.

A schedule of testing is in place, satisfactory results were seen for:

Test	Frequency
Listeria	Monthly
Salmonella	Monthly
EB	Monthly
Water	Annually

5.7 Product release

Some products require positive release based on the customer.

Product is released based on packaging requirement which demonstrate criteria have been met. Product release is conducted by QA team.

5.8 Pet Food

The factory does not make pet food.

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Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.2.5	There is no cooking instruction
5.3.5	The facility does not use rework
5.4.3	No raw material was identified as being in a particular of adulteration or subtitition
5.5.2	Liners were not used.
5.6.2.2, 5.6.2.4	There were not any in house physical, chemical, or micro labs.
5.7.1	The facility did not have a positive release program for the low-risk items.
5.8	The facility does not make pet food

6. Process control

6.1 Control of operations

Process observed to be well controlled.
Documented process specifications / work instructions are available for key processes in production.
Process specifications were assessed during the audit as well as part of the traceability study. Documents reviewed demonstrated that process specifications meet final product specifications.
Process conditions are not linked to critical safety or quality parameters of the product.
Equipment failure is covered by non-conformance procedure.
Access to key pieces of equipment such as metal detector, X-Ray is controlled by maintenance.

6.2 Labelling and pack control

The company ensures that the correct labelling / packaging is available online by keeping only the current pouches, bags, film at the line. Product Labeling procedure stated that labels is checked at start-up, end of run and changeover.
Documented checks are conducted at the beginning of each production shift or product type and end of product type. Records for 2021-06-16 and 2021-08-23 were seen during the audit for Pumpkin Seeds.

Online vision systems or verification equipment were not used.

Due to production runs / scheduling no change over observed during the audit.

6.3 Quantity, weight, volume and number control

Products are checked for weight control. Checks are completed on four packages every hour. Minimum label weight method was used for all items. Selected method meets legal/customer requirements.
All items were packaged by weight. Checkweighers were not used.

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6.4 Calibration and control of measuring and monitoring devices

A list of equipment requiring calibration is held QA.
Equipment used to monitor CCPs, product safety or legality includes:

Item	Frequency	Valid until
Scale	Daily	In house by QA
Weights	Annually	2021-11-06
Metal detector	Annually	2022-03-09

Reference equipment is stored in the maintenance office.

Procedures for control of out of specification equipment are available which include documentation of actions taken.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
6.1.2	Process conditions are not linked to critical safety or quality parameters.
6.1.3	Process monitoring are not linked to critical safety or quality parameters of the product.
6.1.4	No in-line monitoring of process parameter
6.2.4	No on-line verification equipment for label checks
6.3.2	No bulk-quantity products were produced.
6.3.3	This site does not use online check weigher equipment.

7. Personnel

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

Relevant personnel, including agency-supplied staff, temporary staff and contractors are trained prior to commencing work. New employees are supervised for thirty days to evaluate adherence and compliance to defined rules.

Employees engaged in activities relating to critical control points are assessed for competency and training requirements. Records for mixer, allergens, line operator, metal detector and shipping employees were seen. Labelling controls are trained by QA.

Training records assessed provide the name of the trainer, confirmation of attendance, date and duration, title of the course, results of training effectiveness. Training is provided in a language that is understood by employees English.

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During the audit the training and competency requirements were assessed for CCPs operators, Shipping positions which demonstrate compliance with the program requirements and expectations.

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

Personal hygiene rules are documented in the GMP and compliance is checked by supervisor, and management team. During the audit these were observed to be properly followed.

Hand cleaning observed to be performed appropriately.
Blue metal detectable plasters are used; a sample of each batch of plasters is checked through metal detectors recorded on the metal detector sheet for Band-Aid. Ear Plugs and Pens. Where appropriate in addition to the plaster, a glove is worn.

Use and storage of medicines are described in GMP procedures and employee handbook. Employees can store their medicines in their personal lockers.

7.3 Medical screening

Employees are made aware of and know who to notify in the case of symptoms of infection, disease or condition which would prevent a person working with open food by reading the GMP, Employee Handbook, trainings and orientation before hiring.

Visitors and contractors are aware of conditions that prevents visiting areas with open food through the GMP Guidelines for Visitors and Contractors and require them to inform the organization if suffers of any identified conditions.
Employee Handbook, GMP policy and Personal Practice Procedure describe actions to be taken in case of been in contact with an infectious disease

7.4 Protective clothing: employees or visitors to production areas

The use of protective clothing is defined and documented in the GMP procedure dated 2021-07-30.

Protective clothing includes hair net, beard net and lab coats.

Laundering is by Aramark.

Gloves are controlled by line operators.

There is no PPE not suitable for laundering.

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

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7.4.6	There is no PPE not suitable for laundering

Template control	Food	**Version**	1.0

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
N/A
8.2 Building fabric in high-risk and high-care zones
N/A
8.3 Maintenance in high-risk and high-care zones
N/A
8.4 Staff facilities for high-risk and high-care zones
N/A
8.5 Housekeeping and hygiene in the high-risk high-care zones
N/A
8.6 Waste/Waste disposal in high risk, high care zones
N/A
8.7 Protective clothing in the high-risk high-care zones
N/A

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
All section 8	N/A

9 - Traded Products

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

Not applicable

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9.2 Specifications
Not applicable
9.3 Product inspection and laboratory testing
Not applicable
9.4 Product legality
Not applicable
9.5 Traceability
Not applicable

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