Audit Report

Global Standard for Food Safety Issue 8: August 2018

1. Audit Summary			
Company name	Vion Scherpenzeel B.V.	Site Code	8476525
Site name	Vion Scherpenzeel B.V.		
Scope of audit	Deboning, cutting to specification, slicing, packing in bulk and consumer packaging (modified atmosphere, chilled) and freezing of pork. Production and packing in bulk packaging of cured and/or smoked bacon, meat preparations and mechanically separated meat, including Good Farming®-meat.		
Exclusions from scope	None		
Justification for exclusion	n/a		
Audit Finish Date	2019-10-31		
Re-audit due date	2020-10-31		

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

Head Office	Yes

2. Audit Results					
Audit result	Certificated	Audit grade	AA	Audit type	Announced
Previous audit grade	A	Previous audit date	2018-10-24		
Certificate issue date	2019-12-02	Certificate expiry date	2020-12-12		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	5

3. Company Details

Lloyds Register 1 Trinity Park, Bickenhill Lane, Birmingham, B377ES			
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Address	't Zwarte land 13, 3925 CK Scherpenzeel		
Country	The Netherlands	Site Telephone Number	+31 0 33 277 51 51
Commercial representative Name		Email	vionfood.com
Technical representative Name		Email	ionfood.com

4.Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	501-1500	No. of HACCP plans	1-3

Shift Pattern	2cshifts, 5 days/week
Subcontracted processes	No
Other certificates held	ISO 9001, IKB (welfare), farming star (welfare), USDA, organic (SKAL), Chain of Custody
Regions exported to	Asia North America South America Europe Oceania Africa
Company registration number	NL 82 EG
Major changes since last BRC audit	Announcement that part of the site will be closed by March 2021 as activities are shifted to Boxtel. Some 300 of 1200 fte will stay in Scherpenzeel. New site manager as within the VION organisation several site managers have shifted (new manager not new to the company). Also HR manager is shifted to Boxtel and an ad interim is currently in place. In production several modifications in air quality to reduce condensation and another mixing machine is installed.

Company Description

Vion Scherpenzeel BV belongs to the VION Food Group which produces pork and beef. VION Group is one of the biggest meat processing and selling companies in Western Europe and sales is worldwide with a focus on Asia (China, Japan, Korea). This site focusses on Great Britain with of its capacity appr 60% is bacon production. The site employs approx. 1200 people working basically in a 2-shift system from Monday to Friday, occasionally production on Saturdays. The main shift includes approximately 575 people: 30 administrative staff and 200 people in production employed by Vion. About 900 temporary workers are contracted by an 2 in-house agencies. Production capacity: approximately 55.000 middles a day. VION Scherpenzeel BV is specialized in the deboning, cutting to specification, slicing, seasoning, blending, packing and cooling or freezing of pork (mostly middles), production of cured and/or smoked bacon and the production of mechanical separated meat, so called desinewed minced meat (DMM). Only pork meat is processed and final products are based on welfare and good farming breed programmes of the pigs (EKO, GB, GF, QS, standard and FS (farming star). The raw materials come from own slaughterhouses, which are part of the VION Group in the Europe (Netherlands, Germany) and from some other non-Vion slaughterhouses in France. The company is under veterinary control for exporting activities, is USA approved and has several client status (e Approved), . Official veterinary approval number: NL 82 EG. Only B2B delivery; and since past summer also packing of consumer products. The storage and transport of finished products is partly outsourced (both cooled and frozen) as sister company is now involved in transporting from and to own VION plants. Also outsourced is the deep-freezing of some products (like DMM and other products) to external cold stores

Furthermore there is internal cleaning of crates and pallet boxes and partly outsourced cleaning of crates. Plant size is appr. 9500 sqm on ground floor over 2 buildings (8500 sqm + 1000 sqm). Dry storage of non-meat raw materials and packaging materials in a separate building away from meat processing (together with maintenance department on the opposite side of the public road).
The HACCP-study may be categorised in 3 subcategories: pork meat, pork meat preparations (incl. separated meat) and meat products as bacon.
The audit was calculated 20 hours and due to planning constraints, it was executed in 2x10 hours.
The auditor also visited the company twice this year for CoC audits

5.Product Characteristics

Product categories	03 - Raw prepared products (meat and vegetarian) 09 - Raw cured or fermented meat and fish Category Category				
Finished product safety rationale	Temperature < 2°C / -18°C (DMM), < 4°C (meat preparations), < 7°C or < -18°C (other products), vacuum packaging (bacon), MAP packing (< % O2 / > % CO2), dosage nitrite (gram/litre brine / > ppm on ingoing product). All to be heated prior to consumption.				
High care	No	High risk	No	Ambient high care	No
Justification for area	Appendix 2 applied. All products have to undergo full cooking step prior to consumption. Smoking process step is not considered as a sufficient heating step.				

Allergens handled on site	None Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	IKB: FS (farming star / "beter leven") and GB (= GF + welfare) and GF (good farming) + Qualität und Sicherheit (QS) + Organic (SKAL)
Product recalls in last 12 Months	Yes
Products in production at the time of the audit	Bacon, mechanically separated meat (type 3), DMM (desinewed minced meat), seasoned diced pork, sliced pork backs, tenderloins, trimmings 80/20 and other products from pork middles.

6.Audit Duration Details

On-site duration	20 man hours	Duration of production facility inspection	10 man hours
Reasons for deviation from typical or expected audit duration	Due to planning constraints the audit was executed in 2x10 pattern instead of 2,5 x 8. Audit was taken over last term and this option was only available		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-10-30	7.00	17.30
2	2019-10-31	7.00	16.45

	Auditor (s) number	Name	Role
Auditor Number			Lead Auditor

Second Auditor Number	N/A		Please select

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
'lant Manager	X		X	X
QA Manager	X	X	X	X
/ QA Assistant	X	X	X	X
/ HR Manager ai	X		X	X
/ Maintenance Manager	X	X	X	X
/ Controller				X
/ Manager Operations	X			
/ Department manager MMC		X	X	
/ Department manager Salting/Smoking/SDP		X		
/ Planning engineer		X		
employee Receipt and dispatch		X		
assistant manager of packaging material/internal services		X		
/ Employee meat reception department		X		
Shift leader MM department		X		
/ Department manager+VOS lean coordinator		X		
/ shift leader SDP		X		
/ shift leader Slicing		X		
/ employee Salting department		X		

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Non-Conformity Summary Sheet

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

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

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

		be held annually. No planning or checking available. New forms introduced this year without clear protocol on functioning as shown protocol belongs to past (still valid) forms.	The renewing of the procedure on Functioning is put on the action-list of Central HR. **CLOSED TO BE VERIFIED**	employee of HR was replaced and this was not proceeded by unknown reason. Central HR is responsible for updating the form, because of no changes were made. They did not think of this.	given without the names from the employee, because of privacy regulation.		
5	7.2.4	Plaster not thrown out by metal detector. Batch not checked and wrong plasters accepted.	Monday (25th of November) the new procedure is finished so this will not happen again. No more one person job. **FULLY CLOSED**	Root cause: With the new interim HR manager the wrong plasters were ordered and the batch not checked	Seen: Recording of the batch received 26-11-2019 on checking with detection on F-SPZ-NL.	2019-11-25	

Comments on non-conformities

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	3.5.1.1	Criteria on acceptance of non cooled goods raw material as pepper, sugar and salt not defined. Goods are accepted as packing materials.	Intake form warehouse is adjusted and ingredients are checked at intake. **FULLY CLOSED**	Root cause: This was seen as an incoming packing product with less criteria.	Seen v2 of F-SPZ-NL	2019-11-25	
2	5.1.2	Validation on another mixing/dicing machine not available. (No new process is introduced so no validation necessary according own procedure). No positive release on hygienic design and correct grease is demonstrable.	The mixing/dixing machine is seen as the same machine only with a newer look. Cleaning was discussed with only not registered the way it used to be. For the new machine were middle are thrown on the belt is the validation now started up. Example is seen in evidence. **CLOSED TO BE VERIFIED**	Root cause: Only new machines/techniques go through the first time right procedure and validation.	Seen: Start Validation on ARBO/Safety on Menger wolf mm centrale	2019-11-26	
3	6.2.3	Labelling instructions of clients not visible in production department. Information is available in Master Data Management but not put to use for production.	On the specifications where needed is the client label added. **CLOSED TO BE VERIFIED**	Root cause: By discussing it at the audit we were aware of the incompleteness. New way of working identified.	Seen: Specification on 50145	2019-11-25	
4	7.1.7	Appraisal and performance interviews are protocolised to	The old list of 2017 is filled in again.	Root cause: The list was kept till 2017,	Seen: An example is	2019-11-25	

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Additional Modules / Head Office Non-Conformity Summary Sheet

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

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

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

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Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Policy documented in P-SPZ-NL- and signed off by the Site Manager and complete MT. Policy deployment using the X-matrix specifying the interaction between strategic / plant objectives, responsibilities and key performance indicators.
There is made a plan on food safety culture as it is included in the x-matrix with corresponding targets.
The wistle blowing policy is introduced in the VION organisation since several years and the corporate IAD (Internal Audit Department) takes care of verification of effectiveness.
Evaluation of objectives on a weekly basis. SMART objectives (about safety & people, quality (e.g. complaint reduction), delivery / performance, cost, sales / production) and improvement projects (Vion Operating System/VOS) defined. Focus on reduction of foreign material contamination risks. Clear targets are set per department and results monitored and discussed on a weekly / periodical basis during management team meetings (Tier 2). The management team showed commitment to the quality management system (QMS) during the evaluation interviews as the site manager was present during opening and closing meeting. Formal communication meetings (e.g. daily planning meeting per shift, weekly snapshot and periodical management team meeting) are held within this organisation.
Communication is also organised through white boards, TV-screens and the Vion App. The quarterly management review is after the second quarter of the year combined with HACCP system verification. Seen Q3, Q$, Q1 and Q2 2019 review. Also periodical evaluations untill period 09-2019 which covers the required topics as complaints, microbiology and pest management. Currently an issue is the prevention and eradication of Listeria. Microbiologic monitoring program shows incidents and trends.
The commitment is also evident in the systematic for continuous improvement (e.g. Multi Moment measurements, 5S, Tier 1 – 3 meetings) as past week the silver status is gained in lean management. The company demonstrated an effective system.
Non-conformities (8 minors) identified at the previous audit are effectively actioned: 4 minors were already fully closed during follow-up. The other 4 minors from previous visit have been closed out and did not re-occur.

1.2 Organisational structure, responsibilities and management authority

There is a norganisational structure (P-SPZ-NL- /ith the necessary links in between each other and a document included to guide on deputation. The various production departments directly report to the Manager Operations and he for his part reports to the Site Manager. The responsibilities, authorities and reporting relationships of all staff members are described in the job descriptions. General duties described in procedures and further details in work instructions. Performance of processes and personnel is monitored day to day with a formal review during the appraisal system (see minor in 7.1).

2 The Food Safety Plan – HACCP

The company's food safety control system is based on the Codex Alimentarius HACCP principles. The HACCP system is implemented and maintained and lead by Head Quarter procedures. The HACCP system has full management commitment and is an integral part of the company's Quality Management System (QMS). Multi-disciplinary HACCP-team (P-SPZ-NL-· consists of Site Manager (team leader), QA Manager, Manager Operations supported by Maintenance Manager, Manager F&A and HR Manager where necessary (Tier 2). Competent team of people working for many years in the meat

processing industry.
Prerequisite program assessed. Setup of PRP program centrally by HQ Vion Boxtel within 'Procedure Prerequisite requirements and additional CCP's, CP's' (P-FOOD Local process control plan set-up per site (P-SPZ-NL). Production specification information used as input for the hazard identification / risk assessment. Due to the range of countries supplied to several protocols are available on management of requirements per country, closely guided by , officers.
Full product description including microbiological limits and shelf life is in place. The intended use of the product by the customer has been clearly defined and never is ready to eat. Product suitable for delivery B2B and consumption by general consumer groups but also vulnerable consumer groups. No claims made regarding food safety aspects. Documented within central 'Procedure Hazard analysis' (P-VION- and 'Procedure HACCP manual' (P-VION-
Flow diagrams are prepared and available. Flow diagrams seen and annual verification of flow charts as reported in the combined HACCP-system verification / management review. Verification details of flowcharts are recorded in the document control system ( ). No reworking or recycling identified. Freezing (packed in foil/boxes and vacuum or naked product), transport and cold storage (incl. metal detection) are subcontracted and outsourced processes, decided by HQ.
Hazard identification / risk assessment setup centrally by HQ Vion Boxtel. The HACCP plan includes a review of potential physical, chemical and microbiological hazards. Each identified hazard was reviewed and given a risk rating to define the severity and likeliness of a hazard occurring. The risks have been defined from the hazards (occurrence x severity) with the adoption a decision tree. Risk calculation based on 3 x 3 matrix which has to be adapted by the production locations like Vion Scherpenzeel BV. This generic risk assessment has to be adapted to the local processes and buildings. No allergens on site (only raw materials are sugar, salt in the curing department and pepper in the seasoning department). Output risk assessment will lead to CCP, CP (PRP control measure) depending on the risk score.
The company has defined one Critical Control Point (CCP) relating to product safety and the scope of the BRC audit: Core temperature of the incoming pork meat (including returns) and the outgoing fresh meat . Critical limits have been defined for this CCP and are related to the legal temperature requirements for raw red meat and corporate engagements: Core temperature < 7°C (legal limit), < 6°C (for raw materials transferred within Vion plants). When core temperature is between action limit and critical limit it is allowed to receive the batch but it must be quarantined (QA / management must be informed). Above the critical limit the batch actioning is obligate. Due to supply chain management, trailers with meat from sister companies are parked onsite and of loading of trailers is decided by planning. Records of CCP monitoring and verification show measurements are carried out by authorised persons as planned. The procedure for CCP 1 identifies the corrective action to be taken when the limits are exceeded. Records are kept of adjustments made and any actions taken.
CP's (food safety control measures at PRP-level) identified amongst several others (more than 30 in total): – Product contamination (product own / foreign materials – slaughter /handling / lubricants / pest control / personal hygiene / etc.); – Control contamination with condensed water from cooling systems; – Temperature control during processing (trimmings: < 6°C); – Hygiene recipients (crates, pallet boxes, etc.); – Procurement of raw materials according to specification (incl. additives); – Control product age (< 5 days after slaugter); – Control printing shelf life date;

- Control MAP packing process (< O2);
- Control dosage nitrite as preservative in brine injection (> ppm ingoing product);
- Control vacuum packed products (visual inspection);
- Control prepration and injection brine solution (bacon);
- Control cooling down after smoking process (< 24 hours, < 7°C);
- Control temperature during transportation;
- Control metal contamination (knife integrity verifiation, metal detection);
- Control contamination of other foreign materials (X-ray);
- Control temperature at load-out (< 2°C DMM, < 4°C meat preparations, < -18°C frozen products).

Each department has Pre-SSOP forms and SSOP forms to record findings and actions. Good management seen.

The HACCP system is verified through daily checks and daily verification of all forms, internal audits, check of all CCP's + CP's + PRP's during the yearly system verification. Report of HACCP Reassessment (assessed.

3. Food safety and quality management system

3.1 Food safety and quality manual

The company has a quality manual which states the company's commitment to quality and food safety. The quality manual is the total of all quality documents: system procedures, working procedures, work instructions, registration forms. Furthermore the VOS system is applied with MMM (muliti moment measuring). IT-system used for document control (HR and VOS have its own document control management system). The quality manual is available on the computer for all key functions (password protected).

3.2 Document Control

Authorisation of documents based on system functionality. Some documents available in relevant languages as several employees of different origin are working for the company.

3.3 Record completion and maintenance

Most records are hand written. Also records from the weighing system to guide traceability. And records on external pest contractor and external lab are available in their applications. More and more digitalisation. Company uses lean drivers in excel sheets to record production efficiency (stops, changeovers, brake downs, etc). Records are archived for 5 years according to procedure. Maximum product shelf-life applied is 2 years. All electronic data are secured by daily back-ups, arranged by HQ.

3.4 Internal audits

Audit management by the Vion ' system. There is a schedule of internal audits in 2019 against documented procedures, carried out by trained auditors (Vion auditor pool of QA Managers). More than 4x/y the production site and involved departments are audited, both announced and unannounced. internal audits carried out with relevant annexes to guide requirements on schemes (annex 3 on CoC). Procedure 'interne audits' (P-VION . Reports of internal audits reviewed: Pre USA audit by and dd 22-03-2019, pre USA audit on documents on 03-05-2019 by Pre SSOP audit on 28-03-2019 by ; Internal audit on 4/5-06-2019 by and latest internal audit on VOS by on 28-10-2019. Recording of findings reported on a central list. Also conformity is reported.
On a daily basis so called pre-SSOP assessments are carried out in every production department. These assessments are used to identify and solve any non-conformity related to hygiene and/or state of repair of processing equipment, processing / storage areas and buildings. Reviewed examples of pre-SSOP's related to the vertical traceability test.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

Risk identification / risk assessment related to raw materials setup centrally by HQ Vion Boxtel resulting in product specifications specifying relevant aspects to quality and food safety (CP). Approval of suppliers based on GFSI-certification. All suppliers of packaging have to be approved by the central Vion office entered into the system) before they are allowed to deliver. Supplier questionnaires used too. Some additives from the brine delivered by trading companies. List suppliers additives Vion Food NL (S-MMI-), List of 'HACCP-transporteurs 2017' (S-MMI- and 'Lijst toegelaten vrieshuizen' (S-MMI-) assessed. Reviewed for pepper supplier. All suppliers have to be GFSI-certified.

Minor 1 Criteria on acceptance of non cooled raw material as pepper, sugar and salt not defined. Goods are accepted as packing materials..

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

The risk assessment depends on the kind of material according to procedure P-SPZ-NL·
Temperature control of incoming meat (pork middles, other pork meat) is CCP. Identification of IP-status of pork middles by means of coloured labelling (organic = green, farming star = orange, GB/GF/QS = blue). Also slaughterhouse specification by coloured labelling (determining further processing according to costumer specification). Verification of slaughter date and origin at reception of meat batches. Meat guiding documents are verified by the gate keeper and must be approved before trucks are unloaded. Document must show the official approval for export countries. Overview available showing which slaughterhouse is approved to supply meat for export countries. Ingredients and packaging materials are received at the dry warehouse in a separate building and undergo visual inspection. Seen supplier of foil as primary packaging BRC Packaging certified.

3.5.3 Management of suppliers of services

Service suppliers identified: cleaning pest control , laundry maintenance (several contractors involved), transport (mainly , controlled by Vion HQ Boxtel), cold stores (for final products), laboratory services, catering, crate washing , waste.

Overview available of approved external cold stores specifying their legal approval (EU-number and scope) and applicable GFSI-certificates. Cold stores involved in freezing (both naked products and packed products) but also metal detection. GFSI-certification and CoC-certification (Chain of Custody) required for cold stores. Based on the risk profile the cold stores are audited by Vion HQ periodically. Contracts refer to relevant Vion procedures.

3.5.4 Management of Out sourced processing

NA -no out sourced product

3.6 Specifications

Specifications of raw materials, packaging materials, cleaning agents and finished products are available and managed by the involved departments. Raw material specifications are documented and include microbiological criteria. Specifications concerning packaging and cleaning products issued by suppliers are used. Vion HQ Boxtel is responsible for formal agreement of specifications. Specifications are reviewed internally to ensure they are correct and up to date. Finished product specifications kept up to date. Review every 3 years. Samples of specifications taken at this visit demonstrate control:
– Middle zwart links art
– Seasoned Diced Pork F ar dd 24-04-2019
– er white from ar CoA dd 28-04-2019, spec dd 07-0 nd spec d

04-2015
- Bag - SDP 38x88cm blue105mu art ; spec dd 21-6-2018 and on polyolefinen folie gekleurd dd 14-03-2018
- bxJ bottom 59x33x11 art 100(spec dd 31-10-2019 and of 05-2017 from
- bxJ lid FF 59 art 10 Spec dd 31-10-2019 from BRC Packaging certified.
- chain oil spray 1500 SA – H1– including declaration on allergens)

All specifications were present in the actual version. The specifications were available for relevant staff and found unambiguous, complete and compliant with legal requirements.

3.7 Corrective and preventive actions

Corrective / preventive actions will be taken in case of a non-conformity. This can be initialized from several sources: (internal) audits, complaints, product analyses, product controls and hygienic controls. Different documents and systems are used, no central recording of PDCA-cycle concerning deviations / non-conformances. Corrective action was seen to take place in a timely manner. Deadline depends on the type of corrective action.

3.8 Control of non-conforming product

Non-conforming products / products on hold are physically identified as such with a red label / banner. There is a documented procedure for the identification and disposal of non-conforming product (P-SPZ-NL- . This procedure defines how non-conforming product is identified, quarantined and disposed of. Production supervisor and Manager operations are responsible for release or disposal of concerning products. Furthermore there is procedure on fallen meat / dropped down (P-SPZ-NL-

3.9 Traceability

Traceability system is well developed. It covers raw materials through work in progress to finished product including packaging materials and distribution. The system is based on documents and records, bar code reading and the + Software according to procedure P-SPZ-NL-1
Identification of raw materials rder number, date of slaughter, slaughterhouse, origin); Cutting line + salting department: batch number; Salting: tank number + brine lot number; Finished products traced as day lot or cutting / salting batch or specified code on the packing label (slicing); Scanning of batch code at weighing stations; Additives and primary packaging materials are traced on the date of delivery / breaking into new batches.
Traceability test performed on 05-09-2019 with evaluation written. Mass balance / quantity check included. During the audit traceability was checked forward and backwards on production batch SPD on 29-05-2019. Traceability was found adequate. Information was available within 4 hours. No rework operations take place. When products are repacked, only in the same batch, traceability is maintained.
Mass balance check is carried out on a daily basis to demonstrate the segregation of IP-product. These mass-balance checks are carried out at process level. Last integral mass-balance check over all processes within the plant carried out as part of the CoC-audit. More than 99% accuracy reported.

3.10 Complaint handling

Complaints are received via Sales departments in different countries of sale via mail and also complaints are gathered via software. All complaints which are considered to be attributable to the site are communicated and investigated. All complaints are trended and reviewed by the site management team and discussed frequently in tier 1 meetings. Food safety related complaints get extra focus from the organisation. They concern shelf life, too old / not fresh, too high temperature, glass / hard plastic and dirt. Food safety complaint level on foreign bodies is stable (target on fb, metal, plastic, other). Investments to reduce product contamination with foreign materials carried out are X-ray, visual final inspection (cutting line), visual inspection of raw materials (SDP), use of astro caps. The procedure for complaint handling (P-SPZ-NL-1 defines types of complaints and addresses requirements in terms of incident reporting as these are escalated to relevant personnel for review and action (corrective / preventive) as appropriate. No

complaints from the authorities. Microbiologic monitoring program shows incidents and trend. There have been no recalls because of complaints.

3.11 Management of incidents, product withdrawal and product recall

There is a company's crisis and recall management procedure (P-VION- which covers the process which is applicable for all Vion sites. The local procedure product recall (P-SPZ-NL-1) defines the recall team and complies with this requirement. List of telephone numbers for the benefit of recall available. Business continuity guaranteed by central procedures and emergency coordination protocol. Two recalls past year on salmonella. Since the a negative release procedure is installed and applied. Recall was reported to CI and Authorities and followed up.

4. Site standards

4.1 External standards

The site has been designed and constructed for its activities at an industrial area. There are no local activities that are expected to have an adverse effect on the activities under scope. The maintenance department and storage of ambient raw materials and packaging materials is located in a separate building across the street. Other company also are in this building. Site area is fully paved.

4.2 Site security and food defence

Site fully fenced and 24 hour security in place. Site area is shared with another company. Entrance to the building using badges. Verification of issue and return of badges, especially for temporary workers. Not returned or missing badges will be blocked to prevent uncontrolled access to the production and storage facilities. Laser detection system with camera support installed around the main production building to warn production management in case of unexpected activity around the building. Bulk storage tank for salt and CO2 is fenced and locked. Raw materials and packaging materials warehouse has to be locked manually. Porter present at entrance point of trucks. Visitor reporting system implemented in the office building. Site entrance close to the office building is closed outside office hours (only entrance to the site after reporting at the porters lodge).
Meat processing company registered and officially approved by The Food and Consumer Product Safety Authority ( ) according to EU legislation. Official approval NL 82 EG.

4.3 Layout, product flow and segregation

The production and storage zones have been defined and based on a risk assessment: all zones are categorized as low risk areas. There are no high care or high risk areas. All products have to undergo a full cooking step prior to consumption. Site map demonstrable specifying routing of personnel, materials, etc. (P-SPZ-NL-). No specific risks identified due to product flow across the building. The slicing department near the SDP processing line is properly segregated from other production areas. Bin and crate washing near expedition area but strictly segregated. Production lines are located in fully or semi-separated rooms (cutting/deboning, DMM, SDP, slicing, bacon, spare-ribs, trimmings). Separate maintenance workshop. Truck drivers have to report at the porter lodge and in the expedition area afterwards (hygiene lock is available). Visitors and contractors are instructed prior to entering production and storage facilities.

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

Walls, floors and ceilings are finished and suitable. All maintained and some aging seen. All areas are "low risk areas". Usage of process water (brine) and manual cleaning. Sufficient drain points. High level cleaning of ceilings and evaporators arranged. External doors are close-fitting. Lighting and windows are protected where they pose a risk to the product. Past year in several production areas a shift to LED

lightning is made. Pre-SSOP inspections prior to production include checks on status of breakable items.

4.5 Utilities – water, ice, air and other gases

All utilities for water, cooling water and compressed air are covered by the maintenance system. Both water from the mains and well water (one source) are used. Water streams are mixed up, break tanks applied. Well water filter installed which is inspected every week as part of the maintenance program. Water used for brine is only from the mains (no well water applied). Well water quality is monitored as required by law (4x/y). A water distribution plan is available seen version dated 3-2-2017. Sampling tap points on a quarterly basis as indicated by procedure P-NLFOOD.
Compressed air used for drying of equipment after cleaning. Food grade oil applied. Maintenance of cooling equipment outsourced and overview on screens in maintenance office. Monitoring of the air compressors is also part of the maintenance program (water / oil separation, drying, etc.). Filters installed in the air supply and maintained. Daily inspection of any oil leakage in the compressed air as part of the pre-SSOP inspections (CP). Also, inspection and maintenance (incl. cleaning and anti-fungal treatment of the evaporators) is a CP.
CO2 used for MAP-packing and cooling (direct injection) is suitable for food use. Steam and ice from water are not in use.

4.6 Equipment

The used equipment is suitable for its purpose. Mainly stainless steel equipment. Use of well-known brands of equipment for food applications (e.g. slice line). New equipment is purchased as required and specified. Conveyor belts of the cutting department supplied with confirmation of approval for food use. (Minor on validation of the new mixer in 5.1.)

4.7 Maintenance

Maintenance management system based on system. If possible any maintenance activities are clustered and executed every week on Saturday outside production hours. Communication to production and cleaning is done prior start-up in order to prevent contamination. Pre-SSOP checklist are used to record and confirm cleaning where necessary. Maintenance contractor instruction demonstrable, contractors sign for the external hygiene instruction. Second maintenance workshop also inside the production building. Maintenance activities causing contamination risks carried out only at the first floor. Separate storage room for lubricants. Only green labelled lubricants are food grade and suitable for food safety critical applications. Only entrance to the maintenance workshop using a badge. Only pre-organised maintenance suitcases are allowed to be used inside production and storage facilities.

4.8 Staff facilities

Central suitable staff facilities for both own employees and temporary workers. The surface of storage facilities (staff lockers) is in line with the number of employees. Vulnerability assessment has been conducted and reviewed annually, Based upon a risk assessment all zones are "low risk areas". Lockers available for private clothing and personal items. No storage of protective clothing in the lockers except for protective shoes. Central issue of protective clothing. Boot wash installed at the entrance to production facilities. Direct access to production facilities. Also personally issued body protection (worn underneath the clean protective clothing) may be stored in the locker. Hygiene lock at the entrance of the production facilities. Toilets are located near the changing facilities. Closed smoking room in the canteen area. Catering provided to the personnel. Facilities created to store own food in canteen including fridges.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas
4.9.1 Chemical control
Within the company there is a place where the working stock for the external cleaning company is stored. Control over cleaning chemicals on site was demonstrated. MSDS available and specifications confirm suitability for use in food processing industries. Polish for knife sharpening has specification available. Different mechanisms are in place: - glass: evidence seen of a glass breakage procedure. Also, a glass register which is checked as well as infrastructure everyday (Pre-SSOP) and quarterly. - equipment: there is a check of the physical integrity of the equipment every day, before start-up. - wood: the use is prohibited excepting at the smoking cabinets (beech wood chips).
4.9.2 Metal control
Foreign bodies are an integral part of the hazard analysis and this hazard is checked at several places. Different mechanisms are in place: - staples etc. are prohibited. - metal detection applied for packed finished products (bacon, SDP, sliced product). Two X-ray detectors in place at SDP department. - metal hazard / sharp implements: there is a knife register with knife checks daily, ingenious system applied to count and control handknifes. This starts at sharpening department and ends there too. Knifes are issued to employees by numbered sets and changed every break for cleaning. Colour codes knifes in knife assembly baskets are in place and assessed was the sharpening and cleaning of the knifes in a special area with two sharpeners, two whetting machines and a dish washer with calibrated chemical dosing equipment and checks on rinsing water temperature (>82oC). Integrity check of knives carried out. Knives which not return every break are covered by daily (pre-)SSOP inspections. Inspections of cutting blades and needles carried out during breaks (e.g. SDP department). Breakage of injection needles in bacon processing department is considered very unlikely.
4.9.3 Glass, brittle plastic, ceramics and similar materials
Quarterly glass audits are carried out, seen results of Q2 by and Missing or broken items are reported and directly linked to a maintenance task. Periodic verification of maintenance program. Daily verification of breakable items during pre-SSOP inspections. Procedure management of broken items complies with requirements.
4.9.4 Products packed into glass or other brittle containers
No glass packaging activities in place.
4.9.5 Wood
No wood is allowed in the production departments, except the wood chips for smoking bacon. These are stored and used separately.
4.9.6 Other physical contaminants
Special metal detectable pens in production areas.
4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of foreign-body detection and removal equipment

Metal detection (products), sieves (brine injector, water) and X-ray (products) applied. Vision camera system not validated to remove foreign materials (control of quality aspects). Also during visual inspection at specific lines (for example SDP) foreign materials found are collected and evaluated. Both foreign bodies and product own materials (like bone residues due to improper cutting) are presented to supplier when necessary. Testing metal detection and X-ray detection using methods and samples compliant with commercial specification as verified during the audit.

4.10.2 Filters and sieves

Filters used to control the hygiene of the brine to prevent any obstruction of the injection needles (with the risk of insufficient injection at certain areas of the meat pieces). Cleaning as part of the cleaning program executed by . Assembling of the micro-sieve of the injection equipment by the team leader after hygiene inspection as recorded on the pre-SSOP-list as reviewed during the audit. Well water filter installed is inspected every week as part of the maintenance program.

4.10.3 Metal detectors and X-ray equipment

Metal detectors installed at:

- Packing line JK / VM12 / VM14 / trimmings / smoking process: nm Fe + mm non-Fe + mm SS (check start-up, every 3 hours and end of production);
- Salting process 1 and 2: mm Fe + mm non-Fe + mm SS (check start-up, every 3 hours and end of production);
- Spare-rib process line mm Fe + mm non-Fe mm SS (check start-up, every 3 hours and end of production);
- SDP / slice lines: mm Fe + mm non-Fe + mm SS (check start-up, every 3 hours and end of production);
- DMM process line mm SS (check start-up, every 3 hours and end of production). Metal detector used to protect processing equipment.

Also metal detection applied by contractor (frozen storage). Metal detector functioning is checked using certified sample sticks. Both belt stop systems with noise and/or light and/or rejection devices used depending on the packaging size. Procedure metal detection documented (P-SPZ-NL- n registration form F-SPZ-NL·

X-ray systems installed at the same SDP packing line (incl. rejection valve system). Verification of proper functioning of the equipment by testing samples at start-up, every 3 hours and at the end of production:

- m glass;
- mm ceramic;
- mm metal.

Verification of proper functioning of recently installed X-ray system using specified sample sizes. Test strips contain different sample sizes. Therefore the X-ray detector has to detect at least 4 objects on each strip (which is equal to the minimum samples specified below):

- nm SS 316 ball;
- mm SS 316 wire;
- mm glass;
- mm ceramic.

4.10.4 Magnets

No magnets applied.

4.10.5 Optical sorting equipment

camera system installed at spare-rib packing line. System used for monitoring quality aspects (size), not for controlling foreign materials. System settings are controlled by recipes which correspond to the customer specific requirements.

4.10.6 Container cleanliness – glass jars, cans and other rigid containers
No packaging in glass jars, cans and other rigid containers.
4.11 Housekeeping and hygiene
Both equipment and facility cleaning is subcontracted t Cleaning program demonstrable including working instructions for specific equipment. Monitoring of hygiene status by pre-SSOP-inspection every day at every department carried out by team leaders. The effectiveness of the cleaning and disinfection process is followed by daily visual inspections, hygienograms by means of agar (TPC – 2 sets of contact points) + Listeria swabs and microbiological analysis of finished products. Records of checks are maintained and were sampled during the audit. Chemical residue testing using pH-strips. After a period of time again repetitive positive results of Listeria swabs found causing extra cleaning. The site organized an additional full cleaning on particular places and belts. It has the attention of HQ and site management and resources are made available to eliminate the cause. Also, microbiological monitoring of crate cleaning process performed. Calibration of chemical dosage equipment is done on a quarterly basis. Reports from assessed. Cleaning materials are also part of the cleaning program.
4.11.7 Cleaning in place (CIP)
CIP is not applied.
4.11.8 Environmental monitoring
Agar, swabs and residual tests are performed weekly as indicated by the risk-based environment monitoring program. Currently an extensive cleaning and monitoring plan on Listeria is executed as the bacteria comes in occasionally eg by raw material. Results and trends are plotted in the management review.
4.12 Waste
Good control was seen over the collection and disposal of waste. Dispatch of category 2 and category 3 materials to authorized processing companies Other by-product (like bones) supplied to authorized processing companies for human consumption . Other waste stored on-site and collected separately by var
4.13 Management of surplus food and products for animal feed
Category 2 + category 3 material declared unfit for human consumption, retrieved by c is specialised in the destruction of this type of animal by-products. Trade documents according to Regulation 1069/2009/EC. A register is kept and legal requirements are met, e.g. separate refrigerated storage and clear identification.
4.14 Pest management
An external pest control contractor is used. VION has a corporate contract with on pest control of rodents (rats and mice), cockroaches, crawling insects and flying insects. The frequency of control is 12x/y. Maintenance of EFK is 1x/y and determination/counting 4x/y. All documentation is present in the digital web portal. The pest control file does detail the baits/pesticides used with material safety data sheets (MSDS) being available. Application of non-tox detection equipment inside and outside the

production and storage facilities as well. Up to date site plan is available to show the location of rodent baits, mouse traps, crawling and flying insect control units. An activity trend log is provided by the pest control contractor. In-dept pest control survey (1x/y) dd 28-08-2018 seen, next visit planned for 06-11-2019. In case of infestation an emergency call is raised to the pest control company and necessary corrective actions are taken. Emergency treatments provided in the contract and an effective pest control system is seen in place. No issues reported in 2018 and 2019 ytd. Proper follow-up of recommendations by the pest controller as demonstrable by dashboard on the website.

4.15 Storage facilities

At the production facility limited cold storage is available. Temperatures control system implemented (frozen and cooled) including temperature alarm settings ('). System linked to contractor alarm desk forwarding alarms to Vion officers when necessary. No storage under controlled atmosphere applicable.
External contracted storage is applied for almost all goods. All transported at appropriate temperature (< 2°C for DMM and is then frozen to below -18°C by an external cold store according to legislative requirements). A separate building is applied for the storage of packaging and other raw materials. No return of partly used packaging materials to this warehouse. No outside storage, except for dirty crates. Warehouse / cold store contractors are approved. In a separate part of the production facility, the packaging is unpacked so packing material not transported into production areas (like foils and strips).

4.16 Dispatch and transport

Dispatch and release of products is based on temperature verification (CCP). Transport mainly subcontracted to , a Vion transport company, which is BRC Storage & Distribution certified. Other approved logistic partners are listed. Contracts managed by the logistic / supply chain department at the corporate VION organisation covering the requirements of the BRC Food standard related to transport. Transport is organised and scheduled by the Service desk. They are only using approved transport and storage contractors. Trucks and reefer containers are inspected for hygiene and temperature before loading. Results of this inspection are recorded at the CP control forms. Trailers may be pre-loaded and parked on the Vion Scherpenzeel site area. Remote monitoring of cooling equipment by logistic contractor

5. Product control

5.1 Product design/development

Product development takes place at HQ by introduction of new machines, new processes, new customers or new packaging and product cuts. The product development process is managed centrally within the Vion Food organisation according to Procedure "Product Ontwikkeling Convenience" (P-NLFOOD .
Any new process validation is carried out by Vion HQ Boxtel as part of the project management process. Local HACCP team is involved in case of new product introductions or new or changed processes, but no new introductions past year. In the procedure is a trial period with extra checks on the quality of the product. Microbiological testing is done at end of shelf life. Results of shelf-life tests assessed, as seen results trace test. Site Vion Scherpenzeel BV is an allergen-free site.

Minor 2: Validation on another mixing/dicing machine not available. (No new process is introduced so no validation necessary according own procedure). No positive release on hygienic design and correct grease is demonstrable.

5.2 Product labelling

Verification of shelf life date recorded on labelling controlled as CP. No full automatic labelling of packed product installed. Slicing is packed for of consumer products this line is automated with automatic labelling and verification procedure applied, rest is B2B. Pre-printed labels used, up to 6 different types. Product labels are printed based on article numbers and have to be printed per packed unit. No functional product claims made. No allergens identified on-site. Labelling product for EU-market following EU-legislation and any additional customer requirement. Following Vion central procedure labelling for markets outside EU approved by sales (HQ Vion) after evaluation by the customer. In storage no none-labelled goods allowed.

5.3 Management of allergens

No allergens on-site. Verification of specifications of non-meat raw materials is part of the supplier approval process.

5.4 Product authenticity, claims and chain of custody

Vulnerability assessment based on central 'procedure product and process integrity' (P-FOOD-1(and complies with CoC/GlobalGap certification, . Local assessment must be carried out on the basis of this procedure and is translated in Procedure 'Risicomanagement-beheersplan Product-procesintegriteit derde landen" P-SPZ-NL-1 with high risk appraisal. Also listing of countries to supply to is available in F-SPZ-NL-1 Basically, the local vulnerability assessment is based on the evaluation of raw material characteristics, supplier evaluation and logistic services. Raw material risks are considered low as products can be easily recognised as pork meat parts. Product mainly supplied by Vion sister companies. Procurement of meat parts from external companies and external logistic services (especially when products are unpacked, e.g. freezing) are considered high risks. Chain of Custody audit program implemented for logistic service providers depending on the company risk profile. Logistic service providers have to be GFSI-certified and CoC-certified as well. Segregation and correct identification is established for several animal welfare categories (so called quality lines):

- Organic pork (SKAL certified): identification by green label, last number of article number = 7 not in production at the time of the audit;
- Farming star ("beter leven"): identification by orange label, last number of article number = 5;
- GB (good farming including welfare requirements for UK clients): identification by blue label, last number of article number = 6;
- GF (IKB certified): identification by blue label, last number of article number = 3;
- QS (Qualität und Sicherheit for German market): identification by blue label, last number of article number = 4 or 8.

Certification of GF, GB by certification bodies i and st; FS/CoC by . All products are produced based on EG 82 approval number, incl. regular meat (called ST "standard"). Vion Scherpenzeel BV is certified according to the CoC scheme (Chain of Custody) by dd 05-10-2019. Risk assessment and execution of mass balance exercises are scheme requirements. Daily verification of mass balance FS at process level is accepted by the certification body (FS scheme requires full daily mass balance test). Mass balances are made on a daily basis for all quality lines. During the audit it is checked how the status of quality lines is verified and segregated at the intake department and several production departments (cutting / deboning, DMM, SDP, etc.) like the labelling of meat hooks, the identification of product lines, the production sequence (starting with high quality lines followed by lower quality lines), colour coding of recipients (coloured liners) to prevent exchange of meat categorised in different quality lines.
Procedures are implemented concerning the verification of the quality line and how to downgrade the quality lines as generally the demand of certain quality lines is lower than the availability of meat categorized in higher quality lines. Downgrading quality lines is the responsibility of trained and qualified personnel. The downgrading is allowed following the sequence: FS -> GB -> GF -> QS -> ST. BIO-> GB. At the DMM department also organic and FS categorised meat can be downgraded.
Vulnerability assessment for non-meat raw materials covered by the procedures and risk calculation based on a few factors like product characteristics, packaging materials, origin, product availability. No high-risk raw materials identified.
Also countries of destination can have their own requirements (like USA / Canada, Korea, Japan, China).

Dutch authorities) issue health certificates on batch level following third countries export protocols.

5.5 Product packaging

A system of coloured jumbo bin liners is in use for some clients / products (purple for Japan, orange for FS). For others mostly blue liners are used. Packaging materials are unpacked in a separate cell next to production are (re-)stored separately from production materials. Partly used packaging is covered prior to returning to the storage area. Partly unpacked does not return to the second building. Packaging materials have to comply with Regulation 1935/2004/EC (specification review / approval process) and 10/2011. Foils assessed during the tracetest.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Product monitoring based on Regulation 2073/2005/EU and interpretation guideline ('Infoblad 85' issued by the Dutch authorities laid down in procedure P-FOOD- (from 13-02-2017). Both food safety criteria and process hygiene criteria set by legislation are translated to the monitoring program as reviewed based on sampling.
Listeria positive swabs found during monitoring of production areas (internal requirement). All products produced by Vion Scherpenzeel BV have to be fully heated prior to consumption. Comprehensive action plan on cleaning is observed.
Mechanically separated meat type 3/type 4 (according to Regulation 853/2004/EU) to be used for meat product must be heated prior to consumption. Positive release on Salmonella only required when requested by customer to be able to use the DMM for other products. Also calcium monitoring for DMM demonstrable.
A microbiological monitoring program: bacon (TPC, entero's, Salmonella, Listeria), SDP (TPC, E. Coli, Salmonella, Listeria), DMM (TPC, E. Coli, S. aureus, Salmonella, Listeria) and shelf life testing program is in place. Results are analysed and reported (Quality Trends – Oracle). Results of 2018 and 2019 ytd demonstrate compliance with the defined specifications. Two recalls past year on salmonella. Since the a negative release procedure is installed and applied. Recall was reported to CI and Authorities and followed up.
Physical / chemical product monitoring as part of process control, for example meat part size and fat content for SDP.

5.6.2 Laboratory testing

No internal lab. All analyses (excepting hygienograms) are subcontracted to an accredited laboratory operating in accordance with ISO 17025 (accreditation number RVA L-' .

5.7 Product release

Finished product is fit for delivery unless it is in blockade. Positive release on Salmonella only required when requested by customer to be able to use the DMM as raw material in meat preparations.

5.8 Pet Food

NA

6. Process control

6.1 Control of operations

The site clearly demonstrated a good control of operations. Process conditions and methods are well looked at and revalidated. Systematic monitoring is demonstrated. Maintenance of the cold chain is of prime importance including prevention of condensation. Continuous real-time temperature-recording equipment, linked to an automatic alarm system is in place. Alarms are set according HACCP team instructions and the maintenance service is notified of any alarm. The system is tested regularly. All processes are validated with records maintained, to demonstrate that the process is capable of producing safe, legal and quality products. Process control is based upon the HACCP study, legal and customer requirements. Documented start up checks (pre-SSOP) are applied. Multi moment measurement (MMM) system implemented. Team leaders take a predefined number of samples during their shift and compare the processed product to reference pictures to verify compliance to customer or internal specifications. Results are reported on white boards. In case of scores exceeding predefined limits containment actions and where necessary corrective actions have to be taken. Communication structure at different levels. Daily tier 1 production meeting covering quality performance.

6.2 Labelling and pack control

Packing takes place in line with production planning and customer requirements. Tests of product labelling, traceability code and shelf life carried out in accordance with specifications. New to the organisation is packing consumer packaging and a system is developed with controls and instructions. Several types of products are identified and preprinted labels applied. Packs are labelled with more then one label per pack on customer request.

Minor 3: Labelling instructions of clients not visible in production department. Information is available in Master Data Management but not put to use for production.

6.3 Quantity, weight, volume and number control

The company has implemented a quantity control system. All products are sold by weight. Metrology controls the balances for commercial purpose. Calibration of the scales is demonstrable. The devices are tested internally by means of standard weights. Weighing equipment is calibrated 1x/y and tested daily in Pre-SSOP.

6.4 Calibration and control of measuring and monitoring devices

Calibration procedures (with use of) ensure relevant equipment is identified and regularly calibrated. Critical measuring equipment are thermometers (hand held and PT 100 in refrigerators). Internal calibration with 2-monthly frequency (thermometers CCP), 6-monthly frequency (thermometers CP) and yearly frequency (PT 100) or external calibration with yearly frequency (weighing scales, reference thermometer '25') is adequate according to the calibration records. No adjustments are made by the company. Several calibration reports seen eg for the reference thermometer, the CCP related equipment, weighing scales, x-ray and metal-detection equipment have been reviewed during the audit.

7. Personnel

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

There is evidence of introduction training for new starters, temporary workers (by

and both in-house) and contractors. All new personnel have to watch a video on rules and instructions and pass an exam. Refresher training is carried out and documented within 'logboek intake'. Especially for workers from Poland, Slovakia, Romania, Hungary a translation of the hygiene and HACCP instruction is present in their own language. As past year there was a minor on registration, the system is updated and improved. Seen the CCP training on JN dd 12-02-2019. Trainings on CCP and other controls guided by form F-10128. All version of training content, trainers and durations is to be filed.

Minor 4: Appraisal and performance interviews are protocolised to be held annually. No planning or checking available. New forms introduced this year without clear protocol on functioning as shown protocol belongs to past (still valid) forms.

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

The standards for personal hygiene, dress code, medicines, jewellery and medical screening have been defined and communicated to all personnel (including temporary personnel, visitors and contractors) prior to commencing work. Compliance is checked during the internal audits and daily inspections by production supervisor and QA. These hygiene rules are enforced. Hand-washing facilities are available in the staff facilities and at the transfer point from staff facilities to production. A hand disinfection station has been installed. A sole brush is installed at the entrance to production. Blue coloured, metalized plasters are in use together with gloves. The wearing of any jewellery is not allowed. Policy on phones is under construction.

Minor 5: Plaster not thrown out by metal detector. Batch not checked and wrong plasters accepted

7.3 Medical screening

Visitors and contractors have to complete a health questionnaire prior to entry to any production areas. Medical screening of internal / external employees implemented. Procedures are established for personnel to notify management of infectious conditions they may be suffering from or been in contact with. The site makes all visitors, new starters and contractors aware of the need to report infectious disease during the intake by the porter before entering the site. In case of a disease the company is consulting a specialised company doctor. Persons who are suffering from relevant infectious diseases are not allowed to enter the production facilities.

7.4 Protective clothing: employees or visitors to production areas

Company issued protective clothing (inclusive work shoes) is given to all staff and visitors. The laundering of protective clothing is outsourced to a contracted and specialised laundry ( ). The wearing of sleeves, aprons and work coats isn't allowed during breaks, eating, smoking and using the toilets. White protective shoes are worn and washed by sole washer (before entering production) and by manual cleaning (after leaving production). Disposable hair nets, beard snoods and astro caps are in use. Cleaning facilities are provided. Knifes and metal gloves are washed internally following a manual cleaning procedure incl. disinfection.

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

NA

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

Details of non-applicable clauses with justification	
Clause/section reference	**Justification**
4.3.9	No temporary structures.
4.10.4	No magnets applied to control / prevent product contamination. Method not suitable for this sector.
4.10.6	No packaging in glass jars, cans and other rigid containers.
4.11.7	No CIP cleaning applied. Brine storage tanks are cleaned using manual flushing programs.

4.13.1	No customer-branded surplus food.
5.2.3	No claims made.
5.3.2 to 5.3.8	No allergens on site.
5.6.2.2	No laboratory on site.
5.6.2.4	No laboratory on site.

9 - Traded Products
9.1 Approval and performance monitoring of manufacturers/packers of traded food products
9.2 Specifications
9.3 Product inspection and laboratory testing
9.4 Product legality
9.5 Traceability

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

11.5 Product testing
11.6 Training

Module 12: AOECS Gluten-free Foods	
Scope	
12.1 Senior management	
12.2 Management of suppliers of raw materials and packaging	
12.3 Outsourced production	
12.4 Specifications	
12.5 Management of gluten cross-contamination	
12.6 Management of incidents, product withdrawal and product recall	
12.7 Labelling	
12.8 Product inspection and laboratory testing	

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018				
Item no.	Clause	Module item	Conforms (Y/N) or Not Applicable (NA)	Comments
1	13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
2	13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
3	13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
4	13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
5	13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
6	13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		
7	13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).		
8	13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed,		

		packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
9	13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		
10	13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.		
11	13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRC sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).		
12	13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.		
13	13.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
14	13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		

15	13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
16	13.1.16	Devices used to verify preventive controls must be calibrated.		
17	13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
18	13.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
19	13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.		
20	13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		
21	13.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
22	13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		
23	13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically		

		thereafter at an adequate frequency.		
24	13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
25	13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.		
26	13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant vulnerabilities and actionable process steps • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
27	13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum): • Scale and severity of threat if a contaminant is added to product • Degree of physical access to the product • Ability of an attacker to successfully contaminate product—including consideration of an inside attacker A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.		
28	13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the		

		strategy significantly minimizes or prevents the vulnerability.		
29	13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.		
30	13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions		
31	13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation strategies. Verification procedures shall include: • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities		
32	13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence		
33	13.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
34	13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.		

35	13.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.		
36	13.4.1	Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used. A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.		
37	13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.		
38	13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.		
39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.		
40	13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.		
41	13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment		

		• Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper		
42	13.4.7	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems • Responsibilities of the carrier		
43	13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.		
44	13.4.9	The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.		
45	13.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following: • Principles of food hygiene and food safety Produce safety standards applicable to an individual's job		
46	13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment		
47	13.5.3	One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.		
48	13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.		
49	13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and		

		protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.		
50	13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.		
51	13.5.7	Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.		
52	13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.		
53	13.5.9	Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria. Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.		
54	13.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007)," December, 2009 or equivalent method.		
55	13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of		

		pathogens into produce.		
56	13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.		
57	13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.		
58	13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.		
59	13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.		
60	13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
61	13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts. Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria: • Target test (i.e., Listeria spp. or L. mono) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) The plan shall describe aseptic methods for sample collection and testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent).		
62	13.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts. The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono. If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process: • Resample positive surfaces and the surrounding area to determine the extent of contamination • Clean and sanitize the affected and surrounding areas		

		• Resample and re-test to confirm the elimination of Listeria spp. or L. mono • Conduct finished product testing as appropriate • Take additional action to prevent recurrence and to prevent adulterated food from entering commerce		