BRCGS | Food Safety

LRQA

Audit Report

1. Audit Summary			
Company name	Vion Scherpenzeel B.V.	Site Code	8476525
Site name	Vion Scherpenzeel B.V.		
Scope of audit	Deboning, cutting, slicing, salting, curing, smoking, (vacuum and/or bulk) packing and freezing of pork. Trading of pork products. Including partly outsourced freezing of pork.		
Exclusions from scope	None		
Justification for exclusion	na		
Audit Start Date	2021-11-23	Audit Finish Date	2021-11-25
Re-audit due date	2021-12-11	Head Office	Yes

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

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	A	Previous audit date	2020-12-11		
Certificate issue date	Select a date	Certificate expiry date	Select a date		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0

2. Audit Results

	Minor	9

3.Company Details

Address	't Zwarte land 13, 3925 CK Scherpenzeel		
Country	The Netherlands	Site Telephone Number	+31 (0)33 277 51 51
Commercial representative Name		Email	
Technical representative Name		Email	

4.Company Profile

Plant size (metres square)		No. of employees		No. of HACCP plans	

Shift Pattern	2 shifts 5-6 days a week
Subcontracted processes	Yes
Other certificates held	ISO 9001, IKB (welfare), farming star (welfare), USDA, organic (SKAL), IFS PIA
Regions exported to	Asia North America South America Europe Oceania Africa
Company registration number	NL82EG
Major changes since last BRCGS audit	Since last audit organisation changes and production changes have taken place. This also resulted in an adjusted audit scope. Part of the activities

4 Company Profile

	are moved by March 2021 as they are relocated to Boxtel were HQ and the biggest site of VION. The organisation is still in this transition as some activities are coming back again and others will be added. Activity of bacon production with some 300 of 1200 has stayed in Scherpenzeel. In production several modifications are made, and usage of productions areas are re-organised. This resulted also in some building activities which are still ongoing, adjusted routings are implemented inside and some open areas are not used at the moment. The maintenance department which was located in a hired building at the on the opposite side of the public road, has been moved to the site. Only dry storage is still situated in the hired building, planned to be moved complete to the main site medio January 2022.

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 Europe and Asia (China, Japan, Korea). The site employs approx. people working basically in a 2-shift system from Monday to Friday, occasionally production on Saturdays. ow which own employees and temporary workers (for cleaning, maintenance, production) are contracted by 3 in-house agencies Production capacity.
VION Scherpenzeel BV is specialized in t production of cured and/or smoked bacon by deboning, cutting, slicing, salting, curing, smoking, (vacuum and/or bulk) packing and freezing of pork (mostly middles). 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.
Only B2B delivery; and since more then a year also packing of consumer products. The storage and transport of finished products is partly outsourced (both cooled and frozen) as sister company Distrifresh is now involved in transporting from and to own VION plants. (Not in the scope of this audit). Also outsourced is the deep-freezing of some products to external cold stores. (partly outsourced process in scope) Furthermore, there is onsite cleaning of crates and pallet boxes.
The company is under veterinary control for exporting activities (from cold store), is USA approved and has several client status Official veterinary approval number: NL 82 EG. Packed pork products which are bought from Vion International B.V. (produced by Vion sites, maily Vion Boxtel) are frozen after reception, stored and palletised for export in containers (in scope: Trading of pork products (section 9 added))

Plant size is appr. sqm on ground floor over 2 buildings sqm + 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 is categorised in 2 subcategories: pork meat and meat products as bacon.
The audit was calculated 20 hours onsite. Company Description

5 Product Characteristics

Product categories	03 - Raw prepared products (meat and vegetarian) 09 - Raw cured or fermented meat and fish Category Category

5 Product Characteristics

Finished product safety rationale	Temperature < 4°C (meat preparations), < 7°C or < -18°C (other products), vacuum packaging (bacon), dosage nitrite (> 1 gram/litre brine / > 60 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 justification for area				
Allergens handled on site	none 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	No				
Products in production at the time of the audit	Bacon, legbeds, smoked bacon vacuum packed, sliced pork tenderloin, trimmings 80/20 and other products from pork middles.				

6 Audit Duration Details

On-site duration	22 man hours	Duration of production facility inspection	11 man hours
Reasons for deviation from typical or expected audit duration	No deviations, the audit was calculated on 22 man hours: calculation was 20 hours, 2 hours on site were added because of section 9 was included (traded pork, delivered only from 1 supplier)		
Next audit type selected	Announced		

Audit Duration per day			
Audit Day	Date	Start Time	Finish time
1	2021-11-23	08.30	17.00
2	2021-11-24	07.45	17.45
3	2021-11-25	07.30	12.30

	Auditor number	Name	Role
Auditor Number			Lead Auditor
Second Auditor Number			Witness 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
/ Plant Manager	x		x	x
/ QA Manager	x	x	x	x
/ QA Officer	x		x	x
HR Manager	x			x
Maintenance Manager	x		x	x
Manager Operations	x	x	x	x
manager salting smoking gammon	x	x	x	x
shift leader salting smoking gammon			x	
gammon production			x	
-shift leader slice trimming	x	x	x	x

and cutting line 2				
- shift leader slice			x	
– project preparation maintenance			x	
assistant manager expedition / crate washing area	x		x	
shift leader expedition (CCP)			x	
(Teams) – manager planning	x			
manager packing / coldstorage	x		x	x
hift leader packing/ coldstore			x	
shift leader coldstore			x	
shiht leader coldstore loading			x	
Export documentation coldstore -			x	
(Teams) HR officer	x			
technologist			x	

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced

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	1.1.4	The minutes of meeting were not demonstrably documented. No records of the decisions on the yearly review and actions agreed by the MT on the review process were seen.	Corrective: Minutes of meetings are documented from 1-12-2021 in the BT folder. Additional chapter in MT review is added to MT review. Here the decisions and opinion of the MT are stated. This will be standard applied to the communication/report structure.	These templates are a fill in format. See corrective action which is used from now.	The agenda and resulting actions are documented on the action list and planning of the MT. Not all the details were documented, only the conclusions and actions.	1-12-2021	

Minor							
2	3.4.1	The internal audit schedule did include only 3 different audit dates spread throughout the year, the frequency at which each activity is audited was not demonstrably established risks associated with the activity and/or previous audit performance and les depth was seen.	The pre- and pre-USDA audit have been classified as internal audits in the audit scheme. The audited activities have been made more clear in the audit reports. Other non-conformances cannot be corrected but are included in the preventive actions.	Vion Scherpenzeel will maintain an own audit scheme for 2022 where is specified which audit is classified as internal audit. The internal audit template is issued by QA central. There is an ongoing discussion whether the template needs improvement to make risk based approach more clear and more depth to be shown on reporting.	4 audits have been performed in 2021. There are 2 official internal audit performed each year. This schedule is communicated by QA central in the start of the year. 2 other audits were performed by QA central (pre- and pre-USA. In these audits BRC8 topics have been audited and evaluated. However, this was not specifically stated on the internal audit scheme and documented	10-12-2021 / partly ongoing	

Minor							
					in the audit scheme of Vion Scherpenzeel.		
3	3.11.4	LRQA was not informed about the NVWA regulatory enforcement which was noticed June 2021. Follow up was seen during the audit and it was included in the procedure.	From 30-11-2021, all received definitive fines will be reported towards LRQA . At the moment there is a discussion with LRQA about the frequency.	From 30-11-2021, all received definitive fines will be reported towards LRQA . Also communicated with other Vion locations by QA central and contact with LRQA contact person of Vion Food Group.	The location interpreted 3.11.4 concerning NVWA regulatory enforcement actions different. Therefore NVWA regulatory enforcement were not communicated towards LRQA. All NVWA regulatory enforcement actions which are definitive are already available on the transparancy site of Vion Food Group	10-12-2021	

Minor							
					and are supplemented with a memo with corrective / preventive actions + verification.		
4	4.3.3	During movement of personnel, a piece of meat fell to the floor, the employee did not react as he was trained for, to inform the shift leader. He did pick it up by himself with risk on cross contamination.	Disciplinary action towards the employee have been taken. In addition, the meat was fixed and the employee washed his hands before re-entering the production process.	The department manager of the bacon department has given a re-instruction in the workplace that the workplace should only contain limited meat. When a clean workplace is maintained, the probability of meat falling on the floor is minimal. When there is too much meat, the line should be temporarily stopped to process the meat. In addition, the employees of the curing/smoking department have received workplace instructions that meat cannot be taken from the floor by themselves (similar to individual re-instruction by QA manager).	The meat was dropped on the floor due to a full working table. Working conditions were not following standard working method. As initial response the employee picked up the meat from the floor, causing cross-contamination. This is not following Vion's hygiene regulations.	29-11-2021	

Minor							
5	4.4.1	In the smoking area piece of paint was loose and a rusty fire hose holder on the wall was seen (near the air curtain)	Corrective: Reparation order (028701) send to Technical Services. Repaired on saturday (no production).	Preventive: For a large part of the building, including the curing and smoking area, investments are pending and partly accepted. This includes ceilings, walls, and floors.	The defect should have been observed during SSOP rounds. This can be regarded as a human mistake.	11-12-2021	
6	4.4.2	Damaged floor (hole) seen near the smoking equipment.	Corrective: Reparation order (027102) send to Technical Services. Repaired on saturday (no production).	Preventive: In management meeting of 01-12-2021 the issues regarding reparations have been discussed. This is part of the daily proces control (SSOP) round. By early observation, damaged items can be repaired as soon as possible.	Due to recent changes and in Vion Scherpenzeel: new departments, leaving departments there is a small delay in some reparations due to extra work for technical services. There has been extra personal hired. However, some work	11-12-2021	

Minor							
					can only be performed by specialists. Expected to be improved halfway December. The defect floor was not in an area where open product is present.		
7	4.4.4	Cumulating condense was seen on the ceilings and overheads in the smoking area and near the cold air curtain as this was not working for some time during the audit (segregation between the washing area and the cutting department).	Corrective: Condens was removed upon observation. The air curtain was repaired the same day by techncal services.	Preventive: The bacon department have received re-instruction that when the smoking chambers are opened, someone have to monitor and remove the condensation directly when it forms. During production when the chambers are closed, no condens is accumulated. It is communicated towards technical services when the air curtain is broken, it has to receive priority 1 and fixed immediately. In addition, a new work	1) Smoking area: during opening of the smoking chambers hot air enters the production area. This relative warmer air condensates on the cooler. The current arrangement is that no products are stored below (which was the case	30-11-2021	

Minor							
				instruction have been created and explained towards all concerned employees.	during observation). Condens should be directly removed. 2) Air curtain: On 23-11, the air curtain was defect due to a malfunction. This caused that relative warmer air entered the production area which caused formation of condensation. This condensation was not in contact with products.		
8	4.16.4	The electric trucks were dirty and rusty, seen in deboning area, at reception (unloading) area and at the slicing department. No cleaning/ maintenance schedule could	Corrective: All EPT trucks have been thoroughly cleaned. Both from the inside and the outside, including depth cleaning of the forks.	Preventive: One person have been made responsible for the cleaning of all the EPT / Heftruck trucks (operator). This is the same person who checks	Not clearly defined which specific person is responsible for the cleaning of	30-11-2021	

Minor							
		be shown.		the battery. Each EPT is cleaned from in and outside daily.	ETP trucks. The department is itself was responsible for daily cleaning of ETP trucks after each shift. Due to the fact not a specific person was assigned, nobody felt responsible.		
9	6.4.2	The smoking cabins temperature sensors are calibrated 1 x 2 months by the maintenance department. Seen form P SPC-NL-10065 v. 20 May 2008 deviation of 0,5-1.0°C. Max deviation of 0,2° was allowed. No corrections were demonstrably taken.	Corrective: The temperatures have been measured again and have been recorded on the concerning form (F-SPZ-NL-10042). In case of corrective actions, these are recorded as well.	Preventive: New form (F-SPZ-NL-10042) has been made by the technical services. An extra registration area for corrective and preventive actions are added. There is a maximum of 0,5 °C allowed for surrounding temperatures and 0,2 °C for directly measured temperature. In ultimo, this job is planned every 2 months.	The technician who performed was not aware that the corrective actions should be recorded. Now he received a re-instruction.	8-12-2021	

Minor							

Comments on non-conformities
Comments

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

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

BRCGS | Food Safety

LRQA

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Policy documented in P-SPZ-NL-10158 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 project plan 11-2020 on food safety culture as it is included in the x-matrix with corresponding targets. Examples of these projects are focus on specific training of employees (also temporary employees) and creating more awareness on food safety. Focus on responsibilities on FS not only by QA employees, but specific also by shift leaders, lower in the organisations, more directly on the working floor. Goal is to improve the awareness bottom up.
The whistle blowing policy is imbedded in the VION organisation since several years and the corporate IAD (Internal Audit Department) takes care of verification of effectiveness.

Targets /objectives are included in the X-matrix. Main objectives are focused on the transition of activities of the site, a clear plan seen in overview "Veranderingen en investeringen" Q2 2021 reflecting KPI's in the x-matrix. Special focus on reduction of Listeria positive (< 5% of the samples Listeria m. pos.) (environmental and product analyses) was defined. 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 and production manager were present during opening and closing meeting and discussing the management part during the audit. Formal communication meetings (e.g. daily planning meeting per shift, weekly snapshot and periodical management team meeting) are held within this organisation.

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 including the assessment of the management part of the audit. 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. Q1 2020, Q2 and Q3 2021 and overview Q3 2020-Q2 2021 (MR 06-07-2021) which includes review of HACCP system. Also periodical evaluations until period 10-2021 which covers the required topics as complaints, microbiology and pest management. The minutes of meeting were not demonstrably documented. No records of the decisions on the yearly review and actions agreed by the MT on the review process were seen. **Minor NC 1**

Currently the transition of the operation is still ongoing resulting is several ongoing changes in the organisational structure and production activities. Last change was the re-introduction of the deboning (middels) line 2, started up after being removed for about 6 months, the day before the audit on 22-11-2021. Communication on responsibilities shows clear communication lines. The commitment is also evident in The systematic for continuous improvement (e.g. Multi Moment measurements, 5S, Tier 1 – 3 meetings). The company demonstrated an effective system.

During the past BRC audit in December 2020 6 minor nc's were identified. The minors from previous visit have been closed out and did not re-occur. No logo usage and BRC requirements present onsite.

Site has a list of all relevant legislation laid down in several protocols reflecting the legislations and required documentations of specific countries. No issues were observed during the audit that could be considered as non-compliant with legislative/regulatory requirements. This is kept up to date by QA of HQ Vion Boxtel.
The Senior Management provides enough resources for implementation and development of the FSMS. The site has a genuine, electronic version of the current Standard available and gets the newsletters from BRC Global Standards.

1.2 Organisational structure, responsibilities, and management authority

The senior management has appointed qualified employees for key functions. Responsibilities and competences are laid down in job descriptions. Employees in key functions and the members of the Incident Management Team are announced in the production site. Also, Members of the Food Safety Team are also announced. The organisational structure has been documented in P-SPZ-NL-10092 21-09-2021

In the chart all levels are defined for the departments. Site management team includes site manager, Operations manager, controller, QA manager, HR manager, manager facility and planning.
The QA department responsible for food safety, legality and quality items is reporting within the management team meetings. Clear responsibilities/competences have been documented in competition matrix and document training and development P- SPZ- NL 10079. A key position list is created including arrangements in case of absence of the responsible staff. All staff are aware of their responsibilities and have access to relevant procedures.

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

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-10144) 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-1000, 9 Oct 2020). Local process control plan set-up per site (P-SPZ-NL-10067 30 Sept 2021). 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 Dutch Authorities/NVWA

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-10000 9 Oct. 2020)

Flow diagrams are prepared and available. Flow diagrams seen of all processes 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 ( ). Seen several examples of flowcharts like flowchart Gammon line P-SPZ-NL-10203 4 Nov 2021, Flowchart smoking department Rokerij P-SPZ-NL-10179 8 May 2019, Flowchart brine preparation P-SPZ-NL-10036 8 Aug 2018. No reworking or recycling identified. Freezing (packed in foil/boxes and vacuum or naked product), transport and cold storage (incl. metal detection) are partly done on site and partly 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, radiological 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 and preservatives in the curing department). FTS document is part of the on site assessment, First Time Right is discussed within multi-disciplinary team. Output FTR /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 on several places 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 (33 in total):
- Product contamination (product own / foreign materials – slaughter /handling / lubricants / pest control / personal hygiene / etc.);
- Cross contamination with pathegenes via knife or machines/ equipment
- 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 dosage nitrite as preservative in brine injection (> 60-150 ppm ingoing product);
- Control vacuum packed products (visual inspection);
- Control prepration and injection brine solution (bacon);

- Control cooling down after smoking process (< 5h < 7°C);
- Control temperature during transportation;
- Control metal contamination (knife integrity verifiation, metal detection);
- Control contamination of other foreign materials (X-ray);

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 dd 06-07-2021 is assessed

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

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 (multi 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. All secured kin

3.3 Record completion and maintenance

Most records are handwritten, although a project on housekeeping and inspection currently with digital recordings. Also records from the weighing system Innova 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 2021 against (documented) procedures, carried out by trained auditors (Vion auditor pool of QA Managers). This planning of the subjects of audits was not demonstrably risk based. The production site and involved departments are audited both announced and unannounced by a central Internal auditor organised and scheduled by HQ. In the internal audit planning the internal audit against BRC requirements was only scheduled 2 times in 2021. A third internal audit was performed as pre-audit for . All chapters of the system are audited, not demonstrably established risks associated with the activity and previous audit performance and les depth was seen. No demonstrable fourth audit was planned jet before the end of the year. **Minor NC 2** Internal audits carried out with relevant annexes to guide requirements on schemes (annex 3 on IFS PIA). Procedure 'interne audits' (P-VION-10011). Reports of internal audits reviewed: 04-05-2021 (pre-Tesco incl. BRC req. by HP, 26/27 April announced by ; and unannounced was performed audit 18-19 Nov 2021 (no report available jet). Recording of findings reported on a central list. The conformity is reported.

VOS system audits are performed on weekly basis and on daily basis the so called SSOP assessments are carried out in every production department (digital on tablet). 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 SSOP's related to the vertical traceability test and during the audit days.

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 in 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 materials 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-10190), List of approved transporters (S-MMI-10013) and 'List of approved cold stores in use by VION (S-MMI-10199). Reviewed for . All ok. Last supplier approval 30-09-2020.

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-10030. 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 OPI, BRC Packaging certified. Form in use to identify batches F-SPZ-NKL-10087. Reference procedure: P-Food-1025 25-02-2019 Management of suppliers of raw material and packaging.

A documented intake of raw materials and packaging materials is available at the intake department all directly registered in the digital system. Main issues to check are temperature, damages of packing, volumes/amounts and batch codes. As soon as information is put in the system, the SSSC label is the output to place on the products. Usage of products (incl. raw materials, ingredients and packing materials) is performed by scanning the SSSC label. Order of intake is discussed. Products are stored according requirements. Intake registration is verified during vertical test.

3.5.3 Management of suppliers of services

Reference procedure: P-Food-10032 18-11-2021 management of suppliers of services, managed by HQ.

The approval was shown for all contracted services. Service suppliers (based on risk assessment) are evaluated yearly as input for the MR
Monitoring was shown for contracted services, formal agreements (including food safety and food defence aspects) samples taken, all ok:

-
-
-
-
- Transport and Distrifresh (controlled by Vion HQ Boxtel)
-
-
-
-
-

Catering services are not applicable.

3.5.4 Management of Outsourced processing

This proves handled by HQ. 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, IFS PIA 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.

3.6 Specifications

Specifications of raw materials, packaging and finished product are based on items regarding to suitability for its purpose and (migration) tests/declarations. The specifications are authorised and controlled. 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 in MDM software (Master Data Management). Review every 3 years. Samples of specifications taken at this visit demonstrate control:

- Cleaning agent:
- Raw material Art 50193 sliced neck in MDM and in MDM dd 28-3-2020, Non GMO req. conform EU regulations 1829/2003 and 1830/2003
- Raw material:
- Packaging; il top and down specification incl. DOC 19-7-2021
- Lubricant;
  including declaration on allergens)

3.7 Corrective and preventive actions

Reference procedure: P-Food-10018 9 June 2015 Corrective and preventive actions
Corrections and corrective actions incl verification in seen. This can also be initialized from several sources. This procedure works effectively, this is verified during the audit for non-conformities identified by staff, through complaints, internal audits, third party audits etc.

Seen Excel overview via QA, including code for the cause and RCA if applicable (RCA is only applied under complaints/ NVWA / internal/external audits. Action list SPZ seen, followed actions NC of previous audit: all ok.

Corrective actions and preventive action system is up to date. The handling of these non-conformities is according requirements.

3.8 Control of non-conforming product

Reference procedure: P-SPZ-10176 14 June 2021 Blocking products and non-conforming products.

Raw materials and (semi) finished products are checked on a regular base during the process stages. Products are released by production team leader. Corrective and preventive actions are described in several work instructions. Clear process well understood by staff that was interviewed during the audit.

Non-conforming products are blocked and marked with a red/white chain. QA allowed to unblock/ release. An overall action list (action register) is used to follow actions from internal and hygiene audits. Corrective and preventive actions system is up to date. Blocked 107 order 884422 and product on cooling cell: box 10-11-2021

The handling of non-conforming products is according requirements.

3.9 Traceability

Reference procedure: P-SPZ-NL-10013 Traceability
Traceability system operates through computer system and paperwork enables trace of raw materials and packaging from supplier through processes to packing and dispatch. Planned 1 test a year. Last test performed 01-10-2021 report including mass balance, carried out within

4h. this was the backwards test. The forward test was conducted on 4-05-2021 during the pre audit. With a vertical audit list, during the audit traceability was tested on product art 84430 Back 180-200 pd 23-07-2021, 27-07 transported to produced 3804 kg, BBE 27-08-2021. Fast tracing (forwards/backwards), including packaging was possible in the records/ System.
Seen product specifications of all raw materials and finished product, receipt records, food compliance certificate is verified. Fully traceable one-step-up and one-step-down the system, including packaging. In coming control checks, production checks, calibration and analyses were verified too. Time to perform the test was respected (<4h). Rework was not applicable for this product. During rework traceability is maintained as well via the systems (labelling/scanning etc.).
The company implemented a sufficient traceability system. There were no issues found during the product traceability and all documents showed control over the system for food safety by the organisation. Food contact materials legalization is fully implemented.
Conclusion: traceability system is working properly. Mass Balance is complete. Packaging is also traceable. Verified records of CCP's, CP's and PRP's.

3.10 Complaint-handling

Reference procedure: P-SPZ-NL-10008 Complaint-handling
A trend analysis is available as well as elaborate explanation in the MR. All complaints were settled adequately. Handling thereof was presented thought an excel document. All supplier complaints go back to the suppliers and feed back into the supplier approval. And are taken into the supplier audit when the company visits. Follow up demonstrable no issues. Very extended RCA, and trend analysis verified of the complaints.
Last MR over Q# 2020-Q3 2021,176 complaints were recieved

Segregation of serious complaints (food safety related complains, micro etc), overview was seen:
Seen Excel overview via QA, including code for the cause.
Main issues per product group;

- Foreign body
- Product quality / performance
- Other complaintys like integrity, labelling, transport

Followed customer complaint wk 39 complaint no.9: metal complaint: bearing seems to be damaged: maintenance; replaced: ok.
Followed supplier complaint: wk 31/32: on blue pieces of blue strings in meat received from and

3.11 Management of incidents, product withdrawal and

Reference procedure: (P-VION-10015) Management of incidents, product withdrawal and product recall.

Recall and withdrawal procedures are including the activities, the list of contact persons and the replacement scheme, as well as a checklist, and overview of specialist to consult, and the national recall scheme from the authorities.
Scenarios are discussed in the manual regarding incidents. No withdrawals applicable since the last audit. Permanent contact person is always available in the organisation.
The recall notification letter NVWA has been included in the procedure, stating that the Certification Body will be informed within 3 days of the event of a recall.

Planned 1 tests a year. Latest traceability / recall test seen 01-10-2021 Report including mass balance, carried out within carried out within 4h.
No recalls in 2021 YTD
0 recalls since the previous audit.

LRQA was not informed about the NVWA regulatory enforcement which was noticed June 2021. **Minor NC 3** Follow up was seen during the audit, corrective actions were demonstrably taken, people were trained and special attention was given to this issue.

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

4. Site standards

4.1 External standards

Suitable located building containing enough space. No adverse activities in the surrounding area. Site is suitable maintained and well equipped; makes a logical and safe way of processing possible.

The factory is situated in an industrial area, well maintained external areas. No special risk identified. Total area of the plant is with a fence. There are no potential risks associated with the site that may affect product safety or integrity.

4.2 Site security and food defence

The site is completely closed and access to areas of production, packaging and storage is limited to authorized persons. Electric key control for personnel to gain access to the different departments is implemented. Also e.g. fences and cameras installed inside / outside. The company is always guiding the visitors while visiting the production areas. Security in 2 shifts on site including safety guards

24 h control on movements/ camera system. Bulk storage tank for salt is fenced and locked. Raw materials and packaging materials warehouse are 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 porter's lodge or by intercom).

Staff is trained on the job and this is included in the training program. Meat processing company registered and officially approved by The Food and Consumer Product Safety Authority (NVWA) according to EU legislation. Official approval NL 82 EG. New risk analysis is made on food defence in P-SPZ-NL-10194 (procedure) and 1095 (analysis).

Seen the Food defence Proc P-SPZ-10195 12 Nov 2020, latest update verification plan (TACCP) P-SPZ-10194 12 Nov 2021. The Food Defence plan is suitable for the site. Challenge test (on fishing e mail) seen 15-12-2020.

4.3 Layout, product flow and segregation

The lay out and flow of the processes is based on levels of contamination; manly open products – logic product flow – low risk. Only fresh and vacuum packed products under scope. A lay out with flow of processes and movement of personnel is present, including zoning. Separate rooms are in place between raw material intake, production, packing and storage areas.

During movement of personnel, a piece of meat fell to the floor, the employee did not react as he was trained for, to inform the shift leader. He did pick it up by himself with risk on cross contamination. **Minor NC 4**

Beside enclosed product areas, low risk open product areas are applicable, defined with the decision tree in Appendix 1. Premises allows sufficient working space and capacity to work in a proper way.
Temporary constructions were noticed during this audit, but all well marked and clearly marked with red/white ribbons including measures were taken to avoid contamination risks.

There is a site plan for the plant, routing for employees, raw material, packing, rework, finished products, staff facilities and the removal of waste products is demonstrably stated. Latest version P-SPZ-NL-10159 21-09-2021

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

Suitable flow is implemented. In general a modern building fabric, well maintained through the years. Good facilities. Flat finished walls, in general suitable for processing and packaging activities. In the smoking area piece of paint was loose and a rusty fire hose holder on the wall was seen (near the air curtain) **Minor NC 5** Floors in general are in basic condition. Damaged floor (hole) seen near the smoking equipment. **Minor NC 6**
Cumulating condense was seen on the ceilings and overheads in the smoking area and near the (cold air curtain as this was not working for some time during the audit (segregation between the washing area and the cutting department). **Minor NC 7**. In general well maintained ceilings/constructions with a good access to suspended ceilings. Protected glass, no windows could be opened in the processing areas.
Doors in good condition, external doors are well fitted and kept closed when not in use.
Suitable protected strip lights, including protected electric fly-killer devices.
No temporary fixtures have been noticed. Raw material intake and storage, production, packaging and storage are separate areas. There are no lines present that require equipment to extract dust. All staff has access to all departments via one entrance with brushes for shoes and hand disinfection connected to a gate. This is fully automated. Separate rooms are in place for raw material intake, storage of packaging materials and weigh up area and expedition. No dedicated production lines are applicable. There is one dedicated washing area present separated from production. No high-risk areas applicable only enclosed areas and low risk areas. Sufficient drain points. High level cleaning of ceilings and evaporators arranged including UV in airstreams. External doors are close-fitting. Lighting and windows are protected where they pose a risk to the product. In production areas all LED lightning is installed. 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. Sampling tap points on a quarterly basis as indicated by procedure P-NLFOOD-10032.
Compressed air used for drying of equipment after cleaning. Food grade oil applied on predetermined risk related equipment including compressors. 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 although quality of the filter is not set by HACCP-team. 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.

4.6 Equipment

Equipment installed is suitable and designed for the intended purpose. Equipment is specified, tested and commissioned before commercial use. Equipment which is in direct contact with food is suitable for food contact and meets legal requirements where applicable. Equipment made of stainless steel. 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.

4.7 Maintenance

Maintenance is performed by own resources and some maintenance is outsourced. Maintenance management system based on stem. 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. Maintenance contractor instruction demonstrable, contractors sign for the external hygiene instruction. Greasing plan for food grade and non – food grade grease demonstrable (risk-based approach, frequency depends on type of equipment and usage).
No major breakdowns applicable in last 12 months on machinery that disturbed the delivery to customers, but a lot of work performed because of the re-organisation of the internal processes. Documented hygiene inspections on start-up are completed daily by shift leaders, Pre-SSOP checklists are used to record and confirm maintenance where necessary. Short lines were seen between production and maintenance. Attention for a hygiene clearance to production before starting production full cleaning after maintenance activities is implemented. Seen signing off, of line clearance of 20-11-2021 line 2. Recording of maintenance jobs goes through computerised ;ystem. When the site has new equipment, this is included on the maintenance schedules, this was checked for the new gammon line equipment. Separate engineering workshop: no issue identified. Only entrance to the maintenance workshop using a badge. Only pre-organised maintenance suitcases are allowed to be used inside production and storage facilities. Last external maintenance seen on: Cooling/freezers units by on 23-11-2021, scales by 14-09-2021, x-ray was checked on 08-04-2021by

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. 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 is 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

There is a strict site policy concerning metal control P-SPZ-NL-10023 Suitable knives were used (clicking back in holding system – safety issue). Knives are widely used in production, no cut off blades seen. Daily checks seen for knives and equipment on the SSOP's/daily checklists, seen during the audit of 23 and 24 Nov. 2011 and of the vertical test production date.
Staples, paper clips and drawing pins are not used in open production areas.

Knife checks 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 (>82 °C). 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, 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. No glass complaints were recorded since years.

4.9.4 Products packed into glass or other brittle containers

Products are not packed into glass/brittle containers.

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

De-boxing of plastic bags of pepper is in special cabinets, no further unboxing. In-boxing of plastic bags in carton boxes is also in separated parts from production. Dedicated area for remain of packing material and dedicated equipment material to transport packing material to production. Special metal detectable pens in production areas. Pens used in open production areas are metal detectable

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 and inspection as part of the cleaning program executed by external agency. 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

Detection equipment installed as result of the risk analysis and are controlled as CCP's.
CCP' s which are determined, including critical limits, all checked beginning/end of the day and between breaks;
Metal detectors installed at:

- Packing line 5,0 mm Fe + 6,0 mm non-Fe + 6,35 mm SS (check start-up, every 3 hours and end of production);
- Salting process 1 and 2: 5,0 mm Fe + 6,0 mm non-Fe + 7,94 mm SS (check start-up, every 3 hours and end of production);
- SDP / slice lines: 3,5 mm Fe + 3,0 mm non-Fe + 4,5 mm SS (check start-up, every 3 hours and end of production);

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
Metal detectors installed at:

- Packing line JK / VM12 / VM14 / trimmings / smoking process: 5,0 mm Fe + 6,0 mm non-Fe + 6,35 mm SS (check start-up, every 3 hours and end of production);
- Salting process 1 and 2: 5,0 mm Fe + 6,0 mm non-Fe + 7,94 mm SS (check start-up, every 3 hours and end of production);
- Spare-rib process line: 3,5 mm Fe + 4,5 mm non-Fe + 6,00 mm SS (check start-up, every 3 hours and end of production);
- SDP / slice lines: 3,5 mm Fe + 3,0 mm non-Fe + 4,5 mm SS (check start-up, every 3 hours and end of production);
- DMM process line: 6,00 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 ( ). 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-10052) on registration form F-SPZ-NL-10072.
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:

- 2,381 mm glass;
- 2,381 mm ceramic;
- 1,00 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):

- 0,8 mm SS 316 ball;

- 0,4 mm SS 316 wire;
- 2,0 mm glass;
- 2,0 mm ceramic.

Corrective actions are clearly defined according to the CCP overview. Data of the metal detectors is available in the documentation. E.g. the sensibility of the detector is clear. Automatic rejecting device/belt stop/alarm light goes on.
The CCP was demonstrated, including a right way of recording during the audit. No issues seen. Records of 23-24-25-11-2021 and 23-07-2021 (records for the sample of the vertical traceability test) were verified. In case some metal parts are found this will be given to the technical department to analyse the course of the foreign object. No history of failed (metal) tests.

4.10.4 Magnets

No magnets are used into the process.

4.10.5 Optical sorting equipment

No optical sorting equipment is in use.

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

Cleaning mainly by / own staff according schedules with frequencies and applied agents and procedures and cleaning schedules pdate 16 Nov 2021. Periodic cleaning schedule: check on performance via pre-SSOP and logbook of 2021Cleaning is done as common in the branch: dry cleaning, flushing, foaming, (this includes disinfection), flushing. This is done on a daily base. Seen records of cleaning Pre-SSOP's 23-07-2021 (vert. test) and 23/24-11-2021 for the processing. Daily start-up checks with visual inspections are carried out. Results were (conform Mr) not excellent, yhis way projects to improve were implemented, showing now in general, good results.
Inspection: corrective actions seen cleaning activities 23 nov.2021 daily list to of non-conformities: to correct and verification by employees next morning, Good control was seen.
This cleaning process is monitored by , verified analysis post cleaning 22 Nov 2021, 2 Aug 2021,19 July 2021. Also, residue tests are performed. Last test performed at the same time as the checks. Listeria tests are done on the products as well as on the equipment and floors. Verified the overview of results in the computer and also verified cleaning operations during audit. Several issues were seen. Good RCA and follow up seen including good supporting by management (including contact with meat supplier of which listeria positive meat was supplied on almost weekly basis).At the moment situation is in control. No food safety issues.
Other checks:
Hygiene checks materials 2 x 3 months: 18 Nov. 2021, 2 Sept. 2021 Knifes/ metal gloves, measure equipment, cleaning utensils 1 Sept 2021, hands checks 24 Aug 2021 (1 x Q) on VRBG agar, compressed air 2 Nov. 2021, 31 Aug.2021 (1 x Q)
Emballage 27 Oct.2021 , (min 2 x Q), 30 April 2021, 13 Jan.2021 seen CBL's: pH too high: contacted supplier and washed before usage (good corrective action).
seen in document of all Food grade.
Overview cleaning agents and objects 2021 including what has been done by Vion and what by seen.
CIP is not applicable. Residue tests washed crates on daily basis recorded in SSOP of the internal service department pH 6-8.

4.11.7 Cleaning in place (CIP)

CIP is not applicable.

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 by raw material. Results and trends are plotted in the management review. Actions are taken, short lines in follow up and control were seen.

4.12 Waste

Good control was seen over the collection and disposal of waste. Dispatch of category 2/VO853 and category 3/VO853 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

4.13 Management of surplus food and products for animal feed

Category 2 + category 3 material declared unfit for human consumption, retrieved by which 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

Reference procedure:

The company has a contract with an external pest control service provider
Contract date 11-12-2019 for 2020-2022 (all Vion sites) is available (1 times a year in-dept inspections). Site map is available. Last visit: 17 Nov 2021 Actions are taken and described in the action reports. Once a year pest control survey is performed, verified report of 16-17 Nov 2021.
Specifications of products / MSDS sheets are available online through the digital pest control system of the pest controller. Diploma EVM of the pest controller , available and valid till 5-12-2022. Trend analysis during management review. Layout (with location of bait stations and monitoring stations is available. Baits used are non-toxic, toxic baits are only used in case of infestation. Bait stations are robust, made up of plastic material, secured in place and appropriately located to prevent contamination risk to product. During the site inspection no problems with pests were detected.
Staff (have been trained to identify potential pest activity 25-3-21
17 Nov 2021, 19 Aug. 2021 extra check on rats on maintenance department, good follow up was seen 30 July 2021on traps for cockroaches. Good control was ssen.
During re-organising the plant/ re-building extra visits were performed: in total 29 visits YTD 2021

4.15 Storage facilities

At the production facility limited cold storage is available. Temperatures control system implemented (frozen and cooled) including temperature alarm settings ( ). 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 (< 7°C for fresh and when it is frozen to below -18°C conform 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).
The storage facilities are suitable in relation to the operation. Warehouses are clean, dry, well ventilated spaces protected from dust, condensation, fumes, odors or other sources of contamination. Waste materials and chemicals (cleaning products, lubricants, and pesticides) are stored separately. Good warehouse practice audits are performed.

4.16 Dispatch and transport

Dispatch and release of products is based on temperature verification (CCP). Transport mainly subcontracted to DistriFresh, 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 DistriFresh. Internal transport is performed with electric hand trucks. These were dirty and rusty, seen in deboning area, at reception (unloading) area and at the slicing department. No cleaning/ maintenance schedule could be shown. **Minor NC 8**

Transport: all outsourced. Companies certified against applicable standards (BRC and / or IFS) see 3.5.3.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
4.9.4	Products are not packed into glass/brittle containers.
4.10.4	No magnets are used into the process.
4.10.5	No optical sorting equipment is in use.
4.11.7	CIP is not applicable.

5. Product control

5.1 Product design/development

Reference procedure: P-NL-Food-10190 Product design and development
Product development is normally not applicable except for changes in existing products and introduction of new packaging methods. Past year, new types of salted products were introduced. In all relevant cases when the company changes anything or introduces new methods this is described in detail in a validation report (verified report of legbeds / horse shoe the FTR process which was implemented, seen records / efficiency checks of last tests of 04-08-2021, gammon 31-08-2021). Brine # 37 used 14-06-20218 developed, approval process seen, ok. Factory trials and validation from such trials are documented. Shelf life verification and evaluation details have been verified, see micro testing results.

5.2 Product labelling

Labelling according to legal aspects as required by the company, several checks done during production tour. Raw materials are special labelled in the racks and on the individual product bags. Shown were good results for the product of the vertical traceability test.

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.

No cooking instructions applicable.

5.3 Management of allergens

No allergens on-site.

5.4 Product authenticity, claims and chain of custody

Vulnerability assessment based on central 'procedure product and process integrity' (P-FOOD-10049) and complies with IFS PIA certification, GGN4056186517845. 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-10174 with high risk appraisal. Also listing of countries to supply to is available in F-SPZ-NL-10095. 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 IFS PIA by LRQA. All products are produced based on EG 82 NL approval number, incl. regular meat (called ST "standard"). 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.
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 (NVWA) 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 (products from).

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 NVWA) laid down in procedure P-FOOD-10008 (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.
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 ( ). Results of 2020 and 2021 ytd

demonstrate compliance with the defined specifications. Each month a comprehensive report is created also to be presented to authorities.
Physical / chemical product monitoring as part of process control, for example meat part size and fat content for SDP.

5.6.2 Laboratory testing

Reference procedure: Product sampling and assurance & Contamination control Procedure P-FOOD-10008

The company has a full updated product sampling and assurance program available to verify that products are in accordance with buying specifications and legal requirements. CoA's are supplied by the suppliers. The QA reviews these results and if they are approved. The products are all low risk and the suppliers are GFSI certified.

Analyses are done on both products and surfaces in relation to cleaning. Clear overviews are available. In the management review an overview is taken as well.
No laboratory present on the site.
External analysis via
Verified several analyses performed throughout the year, Shelf life is determined. Annual CoA from suppliers. The products are all low risk and the suppliers are certified and most of them also supplier belonging to the Vion orgnisation.

- THT schedule, micro schedule 2021 per Q:
- Slice product 6-10-2021 28 dagen ok (production 06-10-2021)
- Hors shoe, pd 17-08-2021 THT 42 days
- Brine grondstoffen 12-10-21 Tari: all ok
- Raw material meat: P0 31-06-2021
- Paks, USA req. 15-11-2021 8/10 /2021 1 x mnd sulfit reduce anaerobe bact (vacpacked smoked cured bacon)
- STEC 9/11/2021 17/9/2021
- Vion breed pathogenen onderzoek 18-10-2021 gist schim lactobacillen Coag pos staph coccen ok
- PAK s; 2 x year 28-09-2021
- Water , checks plus own water 4x year schedule: tappoint 20-09-2021 all checked following the sampling plan 11-03-2021 micro and chemcical/ orgnoleptical, 8-6 21 water: ok
- Listeria 1x week swaps production and periodic evaporators (all ok): wk 43 and 44 positive Rm supplied by #Em, wk 29-wk 42 neg, ok (also belts production), so improving, good follow up and closely control was seen.
- Evaporatrs ok From wk 25 better results… from then re organisation (middle productie naar Boxtel)

5.7 Product release

Finished product is fit for delivery unless it is in blockade, these products are released after the QA department.

5.8 Pet Food

The site does not produce pet food.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.3	No allergens on-site.
5.8	The site does not produce pet food.

6. Process control

6.1 Control of operations

The site 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 according Lean management is 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. Also consumer packing ((B to B), a system is developed with controls and instructions. Several types of products are identified, and pre-printed labels applied. Packs are labelled with more than one label per pack on customer request.
Label checks are implemented per batch. Verified records of these checks of slice 25-11-2021 label check of raw material and verification with final product label. In ˆ (with Ipad/ photo/digital system, good control was seen Dutch pork tenderloin chinks 300 g ΓHT 28-05-2023. These checks are done at the end of all batches and the beginning of a new batch. Not sliced: conventional paper check Label 15-11 check bacon smoked box
Product changeover is witnessed during the audit and sufficient controls to prevent mislabeling are in place. Procedure P-SPZ-NIL 10197 7-12- 2020

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, tarres are

implemented. Consumer packing are all weight, minimum weight is applicable. The devices are tested internally by means of standard weights. Weighing equipment is calibrated 1x/y and tested daily in Pre-SSOP. Checks are performed at start and at the end of the run. Verified records of these checks of slice article 50201 25-11-2021, ok. The scales for intake and dispatch are connected to the computer system.

6.4 Calibration and control of measuring and monitoring devices

Calibration procedures (with use of maintenance software) 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 e.g.;

- Incubator rodac 16-01-2021 (1x year)
- No. 9 thermometer exp fresh FP CCP T meter: 1x 2 mnd)(CCP T meter) 29-09-2021, "mother" thermometer meter 1 x year 25 17-11-2021
- Exp bacon 8e: 13-10-21, reception of middels CCP
- Scale floor exp. T62, 13-09-2021, scale slice 14-09-2021
- Xray 08-04-2021
- Metal detectors 03-09-2021
- The smoking cabins temperature sensors are calibrated 1 x 2 months by the maintenance department: Seen form P SPC-NL-10065 v. 20 May 2008 deviation of 0,5-1.0°C. Max deviation of 0,2° was allowed. No corrections were demonstrably taken. **Minor NC 9**

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
NA	

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 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. Seen induction training of started dd 16-11-2021 and seen the HACCP general training incl. health declaration, also seen of 17-11-2021, # Seen CCP training of 08-11-2021. Trainings on CCP and other controls guided by form F-SPZ-NL-10128. All version of training content, trainers and durations is to be filed and is filled in.

As the NVWA did not approve the way of working (an official regulatory enforcement notice (a fine) was received of the NVWA), a special training was given on how to handle situation in case of meat has fallen on the floor on 15-07-2021. This training was a classical training with a translator to make this clear to all

employees. (seen attention list 15-07-2021 and presentation slides of the training according WI P-\SPZ-NL-10067 and 10010, pres. V2019-09)
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, plasters are tested for each batch. The wearing of any jewellery is not allowed. Policy on phones is under construction.
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. Visitors get hairnet, astrocap, head cap, coat, trousers, shoes. 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.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
NA	

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
Not applicable
8.2 Building fabric in high-risk and high-care zones
Not applicable
8.3 Maintenance in high-risk and high-care zones
Not applicable
8.4 Staff facilities for high-risk and high-care zones
Not applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not applicable
8.7 Protective clothing in the high-risk high-care zones
Not applicable

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

9 - Traded Products

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

All packed and labelled products received to be frozen and stored before dispatch are produced at Vion own production location, most of the products are produced in Boxtel (packed cut chilled meat products, directly from the deboning area of the slaughterhouse in Boxtel (Netherlands). The Vion Boxtel company is an approved GFSI certified supplier (as all Vion production sites are GFSI approved).

All handlings of products on the cold store area are performed under direct supervision of the NVWA employee, always on-site during reception and dispatch of goods (they have to approve and sign for the specific forms to approve the requirements for export).

Records of reception of goods are maintained, including the check on approved manufacturer's processes. Internal audits are conducted by HQ Vion including traceably checks, audit reports are verified, certificates confirming the product safety status of the manufacturing and packing sites supplying the products which are traded.

The complaint procedure is applicable for these supplied products, but no complaints were recorded.
Product testing is performed by the producers Vion Boxtel, in case needed analytical reports can be added to the product forms and official papers before dispatch.
The countries of destination can have their own requirements (like USA / Canada, Korea, Japan, China).
Dutch authorities (NVWA) issues health certificates on batch level following third countries export protocols.

9.2 Specifications

The specifications are authorised and controlled.
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 in MDM software (Master Data Management). Review every 3 years.
If applicable customer-specified requirements are met.

9.3 Product inspection and laboratory testing

As the products are bought from Vion production sites only, label check and logistic forms are checked during receiving products.
Metal detection is performed after freezing the products (frozen storage), before loading containers. Metal detector functioning is checked using certified sample sticks. Both belt stop systems with and light and/or rejection devices used depending on the packaging size. Procedure metal detection documented (P-SPZ-NL-10052) on registration form F-SPZ-NL-10072. (Fe2.5 mm, NFe 3.5 mm and SS 3.5 mm)

No laboratory testing by Vion Scherpenzeel. If analyses are required by the country of destination, or the customer, analyses are conducted and approved by the producer (e.g.Vion Boxtel), proof is available at the office, making up the official documents for dispatch.

9.4 Product legality

The legality checked at reception by checking the label information, compliance with relevant legal compositional requirements including quantity/ volume of the batch.

9.5 Traceability

Reference procedure: P-SPZ-NL-10013 Traceability
Trace test was performed specially focused on the cold store/ trading part on annual basis
Last test was conducted during a pre TFS audit by HQ Vion (HP), the trace test was successfully conducted < 4h on 04-05-2021, back to the last manufacturer and forward.

Module 11: Meat supply chain assurance

Scope	Click or tap here to enter text.

11.1 Traceability

Click or tap here to enter text.

11.2 Approval of meat supply chain

Click or tap here to enter text.

11.3 Raw material receipt and inspection

Click or tap here to enter text.

11.4 Management of cross-contamination between species

Click or tap here to enter text.

11.5 Product testing

Click or tap here to enter text.

11.6 Training

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Module 12: AOECS Gluten-free Foods

Scope	Click or tap here to enter text.

12.1 Senior management
Click or tap here to enter text.
12.2 Management of suppliers of raw materials and packaging
Click or tap here to enter text.
12.3 Outsourced production
Click or tap here to enter text.
12.4 Specifications
Click or tap here to enter text.
12.5 Management of gluten cross-contamination
Click or tap here to enter text.
12.6 Management of incidents, product withdrawal and product recall
Click or tap here to enter text.
12.7 Labelling
Click or tap here to enter text.
12.8 Product inspection and laboratory testing
Click or tap here to enter text.

Additional Specifier requirements

14.1 Traceability
Click or tap here to enter text.
14.2 Finished goods microbial test and hold program

Click or tap here to enter text.
14.3 Gloves
Click or tap here to enter text.

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018			
Clause	Module Item	Conforms Y/N	Comments
13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
13.1.4	Ice used in contact with food must be manufactured in		

	accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • *Economic* adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		
13.1.7	All identified known or		

	reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).		
13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • 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		
13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.		
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).		
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.		
13.1.13	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.		
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		
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		
13.1.16	Devices used to verify preventive controls must be calibrated.		
13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
13.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of		

	individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.		
13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		
13.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-		

	chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. *Verification activities* must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		
13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.		
13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, *including the following:* - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that		

	identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and 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.		
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		
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.		
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.		
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.		
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		
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		
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		
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		
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.		
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.		
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.		
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.		
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.		
13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.		
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.		
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		
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		
13.4.8	The site shall keep all	NA	

	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.		
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.	NA	
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	NA	
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	NA	

	hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment		
13.5.3	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.	NA	
13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.	NA	
13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.	NA	

13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.	NA	
13.5.7	Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.	NA	
13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.	NA	
13.5.9	Where agricultural water does not meet	NA	

	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.		
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),	NA	

	EPA–821–R–09–007)," December, 2009 or equivalent method.		
13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.	NA	
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.	NA	
13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food	NA	

	contact surfaces.		
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	NA	
13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.	NA	
13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.	NA	
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	NA	

	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).		
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	NA	

	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		