Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	Vion Boxtel BV	Site Code	17768974
Site name	Vion Boxtel BV		
Scope of audit	The slaughtering of pigs, the deboning and cutting to specification and packing in bulk, bag in box, vacuum packaging and consumer packaging of pork.		
Exclusions from scope	The intestinal washing process		
Justification for exclusion	Segregated process with clearly differentiated products		
Audit Finish Date	2019-06-26		
Re-audit due date	2020-06-28		

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

Head Office	Yes

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	A	Previous audit date	2018-06-20		
Certificate issue date	Select a date	Certificate expiry date	Select a date		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	8

3.Company Details

Address	Boseind 10 5528 RM Boxtel		
Country	The Netherlands	Site Telephone Number	+31 (0) 658196411
Commercial representative Name		Email	vionfood.com
Technical representative Name		Email	onfood.com

4.Company Profile

Plant size (metres square)	10-25K sq.m	No. of employees	501-1500	No. of HACCP plans	1-3

Shift Pattern	2 shifts from Monday until Friday
Subcontracted processes	No
Other certificates held	ISO9001, IKB, approved, SQMS, QS, Better life 1 star, Chain of Custody
Regions exported to	Asia Oceania Europe Choose a region Choose a region Choose a region
Company registration number	EG 61 NL
Major changes since last BRC audit	Implementation of new ERP system for labelling in cutting- and expedition department (Innova), commissioning of mild chill, new plant manager, only slaughtering of pigs reared in the Netherlands, because of the swine fever in Belgium. Preparation of investment project to enlarge the plant with the processing of the pork middles.

4.Company Profile

Company Description

Vion Boxtel BV is the biggest processing plant of pigs to pork meat in the Netherlands. The company is part of the Vion Food group. The company is slaughtering about 19.500 pigs per day in 2 shifts. Main customers are industrial meat processing companies in Europe, Asia and Australia. Snit ham are particularly produced for Spain and Italy. All pigs are bred by Dutch farmers and reared conform the Good Farming principles (IKB); a part of them are also reared regarding special Welfare demands (Good farming *). The company has a approved system to comply with dedicated welfare demands. The company has own employees and emporary workers (hired via contracted agencies). There's a 2-shift pattern. Most of the temporary workers are from East European countries such as Poland, Romania and Bulgaria. There are interpreters in the company for communication purposes.
The company is certificated for ISO 9001 as part of a multi-site ISO system. Vion Boxtel is approved by authorities for export of pork meat to several third countries (e.g. Japan, Korea, Russia, Canada, Africa, China, Australia) The surface is 18.0 K sq. metres. The used quality system is based on one HACCP-principles. The pork is packed at semi-bulk level and there are some vacuum-packed consumer goods for the Greek market. EG number is NL61 EG. Website: www.Vionfoodgroup.com. The site is audited against the requirements of BRC food 8; additional modules are not a part of the audit.

5.Product Characteristics

Product categories	01 - Raw red meat Category Category Category
Finished product safety rationale	Chilled red meat, short shelf life 5-8 days and chilled red meat vacuum packed, short shelf life 14-21 days

High care	No	High risk	No	Ambient high care	No

Justification for area	No high risk or high care production assigned on site. All products undergo full cooking prior to consumption
Allergens handled on site	None Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen

5.Product Characteristics	
Product claims made e.g. IP, organic	Welfare (GB = Good Farming Bacon) and BLK 1star (FS = Good Farming Star
Product recalls in last 12 Months	No
Products in production at the time of the audit	Pork products in several cuts: ham products, shoulder, necks, front pieces, middles, organs

6.Audit Duration Details

On-site duration	24 man hours	Duration of production facility inspection	16 man hours
Reasons for deviation from typical or expected audit duration	No		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-06-24	09.00	17.00
2	2019-06-25	09.00	17.00
3	2019-06-26	09.00	17.00

	Auditor (s) number	Name	Role
Auditor Number			Lead Auditor
Second Auditor Number	N/A		Please select

Present at audit

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
. Plant manager (via skype)	x			
. Controller	x			x
. Manager planning	x	x		x
production manager slaughtering/processing	x			x
manager cuttinng department	x	x		

Present at audit				
manager QA and facilities	x	x	x	x
HR manager	x	x		x
coordinator storage packaging materials		x		x
QA employee			x	
manager slaughtering department		x	x	
manager internal logistics		x		x
manager facility management		x	x	
Several employees and teamleaders		x	x	

Non-Conformity Summary Sheet

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

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

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

Minor							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
01	1.1.2.	The X-matrix contains several objectives and improvement projects related to food safety culture, for example the objective about the training of the assistant line supervisors and objective related to the communication process	NA Minor NC is closed and fully implementation will be verified next BRC audit	Root cause analysis: Several trainings and checks and projects are in place and linked to food safety culture aspects. However, this was not combined in a	New X-matrix 2019 is seen	2019-07-16	

		between maintenance and slaughtering department to reduce breakdowns, but there's no overall food safety culture plan. Also, the aspect food safety culture isn't integrated in the Q-report template.		plan and part of the X-Matrix. Corrective measurement: Food safety culture is added to the X-matrix and will be monitored and reported as a separate item in the Q-report and management review process.			
02	2.2.1.	CP 32 wasn't fully in control during the site audit: at the cutting department the overflow of necks at the packaging line and backlog in packaging of China claws wasn't under control and the requirement of < 1-hour residence time wasn't met.	The products stored in the bin where downgraded to Cat. 3. Also a new storage is constructed at the overflow. The claws which could be longer than 1 hour at the production where downgraded to Cat. 3. Minor NC is fully closed	**Root Cause:** The packing of the necks was briefly adjusted, in a way that the boxes are folded in the corridor. The overflow was not yet adapted. The staff member could not process the amount off claws which were sorted out.	2 digital photos of the new situation at the shop floor	2019-07-16	-

				Action: A new storage is constructed in a way a crate will be used and this will be reworked within every hour. An additional staff member is added to process the claws faster and to solve the bottle neck in this process.			
03	2.10.2.	CCP 7 and 8 are related to the intake of returned goods from customers at dock 15. During the audit at 25th of June a returned batch was seen, containing organ and pork meat. CCP 7 (temperature or organs) wasn't controlled demonstrably.	The temperature of the organs is checked and recorded. The concerning staff is reinstructed directly, to check and record all returned organs and meat. Minor NC is fully closed	**Root Cause:** The instruction of the handling of returned goods was not clearly understood. It was clearly mentioned in the procedure, but not in the additional instruction. **Action:** The instruction is clarified, and the concerning staff will be reinstructed this	Updated instruction and records of received instructions.	2019-07-16	

				instruction. Also several questions are added to this instruction, to check if the instructions are understood			
04	3.8.1.	The company has a product flow with potential non-conforming products, which are send back by customers. Procedure P-BXT-NL-10105 describes how registration and release of returned batches is organized. Results of these process need to be recorded at F-NL-FOOD-10002. The records of May-June 2019 are seen, appr 80% of the records isn't complete: the records of the intake and release are missing. The release and re-use of the products is recorded in another database, controlled by the QA department.	The concerning staff is reinstructed to fill out the form completely. This will be random checked at the QA department. Minor NC is fully closed	**Root Cause:** The instruction of the handling of returned goods was not clearly understood. It was clearly mentioned in the procedure. But not in the additional instruction. **Action:** The instruction is clarified, and the concerning staff will be reinstructed this instruction. Via questions is verified to check if the instructions are understood.	Updated instruction and records of received instructions.	2019-07-16	
05	4.6.1.	At the workplace "positioning middles" in the cutting department a bunch		**Root Cause:**			

		of cables is found below the conveyor belt. This is related to the implementation and final release of the project. The current situation is hard to clean.	We discussed the installation of the cables for ' ; scales with the eam to improve the finish of the installation. The remaining cables are removed till the exact location is known. Minor NC is closed and fully implementation will be verified next BRC audit	There was no agreement with the supplier regarding the installing of the cables and the position of the scales. Action: We have made an agreement for this installation. The new agreement is including a clearance of the responsible shift manager for the final installation.	Mail of 12.07.2019 from the project manager related to the new agreement about the clearance of installation of cables / scales.	2019-07-16	
06	4.9.2.1.	The company has a 2 color knife system operating as part of CP2: reduction of cross contamination with meat by the use of knifes or equipment. During the site audit it was noticed the practical method at the cutting line of front pieces wasn't in line with the knife procedure: employees shall use 1 color knife and attending knife holder during the production run	The 3 concerning new staff members are directly reinstructed to take only one knife set. Minor NC is fully closed	**Cause:** The staff members thought it would be easier to take their two knives sets to their working space. Our staff responsible for the SSOP checks did not noticed this action. Action:	Digital photo of current situation	2019-07-16	

		between 2 breaks. At the front pieces lines the employees were using both knife holders.		This new fact is discussed with the staff member who checks the Ssop and they are aware to check if only one knives set is in use. This is no longer observed.			
07	4.11.3.	In the storage of primary packaging materials several hoses were found, stored at the floor below the storage racks. Wooden pallets are in use in the racks. The hoses are used for the cleaning of the chilling areas.	The hoses are removed cleaned and stored on to the racks Minor NC is fully closed	Root Cause: Because several times these hoses where used by other staff members which did not put them back to the place, the hoses where missing when needed. For that reason the hoses where stored under the racks and the maintenance was requested to put some holders to the racks to store the hoses. Actions: The maintenance fixed some holders to	Digital photo of new situation with the holders	2019-07-16	

				the racks and the clean hoses are stored on the racks			
08	4.11.5.	The agar checks of a wizard knife and SS frame in the cutting department in week 22 has resulted in score 4 for both items. The results of the recheck are not demonstrably.	The rechecks are added to the digital list. The staff is reinstructed to add al rechecks in the digital list Minor NC is fully closed	RootCause: The rechecks were performed and recorded on the form. However, forgotten to add to the digital list. It was not clearly visible that these rechecks should be added. Actions: We altered the digital list in a way that rechecks are easy noticed visual if the rechecks are added	New excel list for recording agar results	2019-07-16	

Comments on non-conformities

Additional Modules / Head Office Non-Conformity Summary Sheet

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

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

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

BRCGS Food Safety

Lloyd's Register LRQA

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The company is working with the VOS systematic of communication, measuring results and management of improvement. VOS is based at the lean management principles. The communication levels are described in P-BXT-10028 and is based at a cascading model, based at 2-4/day team huddles, daily tier 1 meeting and weekly tier 2 meetings. Objectives are documented in the X-matrix and are demonstrably linked to the vision and mission of the Vion group. Focus areas/objectives for 2019 are for example the implementation of 5S, (labelling system), improvement of shelf life/microbiological aspects, reduction of complaints and training of supervisors.

Clearly defined Food safety and quality policy 2019 seen in which the intention of the site to produce and deliver safe, good, reliable and sustainable products is described; signed by the site manager.

The progress of realisation of objectives are monitored via the Q-based Q-report. (seen report Q1-2019). Reviewed aspects in the Q-report are animal welfare, EKS, complaints, food safety, suppliers, training. Yearly management review process covering the period July – June. The management review report July 2017 – June 2018, report date 30.08.2018 is seen; corrective actions are clearly defined and added to the X-matrix of the current year. Q-reports and management review are demonstrably discussed during tier 1 meetings.

Vion has a general whistle blower procedure for all employees, based at the possibility to report via telephone anonymous concerns. There have been no notifications in 2018 for Vion Boxtel.

Although there are clear objectives related to food safety culture improvement, an overall food safety culture plan couldn't be shown. This has resulted in a minor NC.

The audit is scheduled before the due date. The plant manager was on holiday but has joined the opening meeting via skype. The NC's from the previous audit were fully closed and not reoccurring.

1.2 Organisational structure, responsibilities and management authority

The organ chart is documented in P-BXT-10028; version 21 and is up to date. Replacement of key staff is documented in P-BXT-NL-10247. Access to work instructions is digital and with hard printed documents at the shop floor.
There is a matrix in place for the production personnel to cover their experience and responsibilities. This will be extended in the next years.
Performance of personnel is monitored day to day with a formal review during the appraisal system (POP process).

2 The Food Safety Plan – HACCP

The company's food safety control system is based on the Codex Alimentarius HACCP principles: an assessment is made of microbiological, chemical and physical risks for all steps in the production process,

packaging material and general elements. The HACCP analysis is carried out by the group QA department of the Vion Group and the results are locally translated to the process control plan for the plant Vion Boxtel BV. In this way the site is informed and updated with legal, product & technology information. Additional assessments are performed for food defense (P-FOOD-10051) and food fraud (process integrity control plan P-NL-FOOD-10211). The local process control plan is documented as P-BXT-NL-100116. The site has 8 CCP's and 38 control points (CP's).

The QA manager is the food safety team leader; he`s sufficient educated and well experienced. The Food safety team exist of the MT of the site. Quality and food safety are fixed agenda topics of the weekly tier 1 meetings. Formal HACCP team meetings are kept at a quarterly base; report last meeting at 16.04.2019 is seen.

The prerequisite programme is part of the QMS system and is based at EG 853 and EG 854 requirements. Verification by the daily pre-SSOP and SSOP checks.

Flow diagrams are seen and is verified for the cutting department; no deviations found.

Different product groups are distinguished (Procedure Products Boxtel P-BXT-NL-10.170):

- Fresh pork meat (Dutch and Belgium);
- By-products (category 3);
- Destruction material (category 2);
- Partially chilled pork meat (50% / 70%).

The intended use of the product by the customer has been clearly defined. No specific groups are applicable. The intended use is business to business pork meat and a few vacuumed consumer products (Greece)

The company has defined 8 Critical Control Points (CCP's):

1. Faecal contamination of carcasses (Zero tolerance for visible faecal contamination);
2. Temperature control of animal by-products at dispatch <= 3°C vacuum <=2 °C;
3. Temperature control of fresh / vacuum packed pork meat at dispatch <= 7°C vacuum <=6 °C, organs <2 °C);
4. Temperature control of partially chilled pork meat (6-hour transport) at dispatch, surface <= 7,0 °C
5. Temperature control of partially chilled pork meat (30 hours transport) at dispatch surface <= 7,0 °C, temperature <= 15,0 °C .
6. Temperature control of fresh pork meat at reception <= 7°C
7. Temperature control of returned animal by-products at reception <= 3°C;
8. Temperature control of returned fresh pork meat at reception <= 7°C.

Clear instructions about control procedures, critical limits and corrective measurements are seen.

There's a yearly verification of the HACCP system, the report of the last reassessment (30.08.2018) is seen.

Changes in process and products are validated by the food safety team. The last validation was done at the mild chill process. Validation report 05.02.2019 is seen; is at 16.04.2019 authorised by the Food safety team.

2 minor NC's are reported for this chapter:

- CP32: residence time at cutting line was partly not under control during the site audit
- Check of CCP 8 wasn't demonstrable for a received batch of organs

3. Food safety and quality management system

3.1 Food safety and quality manual

The company has a digital Quality Manual, complying with ISO 9001: 2015 and BRC 8 requirements,. The quality manual is the total of all quality documents, including procedures, work instructions, HACCP analysis and registration forms.

3.2 Document Control

An electronic quality manual named ' ' is in place. Changes in old versions of documents are maintained and checked during the audit. Is verified for F-BXT-10024; control of CCP 1 version 01.11.2014 and this document is the actual version.

3.3 Record completion and maintenance

Records of the following controls are verified: SSOP, pre-SSOP's, CCP checks, the new CP checks (including metal detection). Records are retained for at least 2 years at the site. Records are verified of 16.03.2019 and 19.03.2019 as a part of the vertical test. All records were traceable.

3.4 Internal audits

The internal audit plan 2019 is seen. 6 internal audits are scheduled throughout the year. The last internal audit report is kept 1+2 April 2019; 1 major and 9 minor NC's are reported and follow up is demonstrably. Internal audit is kept by his qualification is based at a Lead assessor training (certificate 22.12.2015 is seen).

Hygiene and fabrication inspections are kept at a daily base (pre-SSOP and SSOP checks). On top of that there's a quarterly based in depth inspection of the architectural aspects. The results are shared with the maintenance department and follow up is demonstrably; seen for inspection Q1 2019 for cutting department (vertical test).

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

The management of suppliers is a corporate responsibility within the Vion Group.
Vion Farming is taken care for the suppliers of livestock (pigs and cattle) documented in P-NL-Food 10157 and verified for pork, canalisation GB delivered (trace test and during the audit) at 16.03.2019: f These pig manures are demonstrably GB approved.

Purchasing processes of raw materials (ingredients) and packaging materials are centrally managed via approval procedures and contracts. The Vion plants are only authorised to order products or services from approved suppliers:

- Procedure supplier's audit' (P-FOOD-10023);
- Procedure food supplier assessment' (P-FOOD-10025)
- Procedure requirements products and services' (P-FOOD-10026).

There's an audit plan for external suppliers, based on risk management. Site Vion Boxtel BV has no external suppliers of pork meat, except incidental ham products from the Vion site in Apeldoorn (also BRC certificated).

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Livestock deliveries are checked at their requirements by an administrative check of the delivery documents before slaughtering. A veterinarian check at animal welfare and health aspects is carried out by the local veterinarian (employed by the Dutch government / nVWA).
Vion Boxtel BV is incidentally processing meat, delivered by the Vion plant in Apeldoorn (Dutch hams). The temperature of incoming meat is CCP6.

Packaging materials are inspected visual during delivery.

3.5.3 Management of suppliers of services

Purchasing processes of transport, storage and services are partly centrally managed via approval procedures and contracts and partly by the site for local deliveries.
The Vion plants are only authorised to order products or services from approved suppliers: Procedure requirements products and services' (P-FOOD-10026).
Yearly monitoring of suppliers is executed and seen from 12-2018. 2 suppliers of services get a lower rating: (cleaning agents) and (laundry). The lower rating was caused by logistic aspects; corrective action is.

Assessment of suppliers of transport companies by transport audits: Audit report of transport company ' transport number 57071 is seen: the agar score was good and the temperature process was under control.

3.5.4 Management of Out sourced processing

No outsourced processing.

3.6 Specifications

Specifications are managed by the HQ department master data management.

The following specifications are sampled as a part of the vertifcal audit:

- Jowl steak art 53773
- ‹ top and bottom foil
- Shoulder ham 4D

Specifications were available in an up-to-date version.

3.7 Corrective and preventive actions

Process of corrective and preventive actions is related to VOS for the operational processes. Corrective actions related to complaints are communicated via the tier 1 structure. Corrective actions related to pest control, pre SSOP, SSOP are recorded and demonstrable. In case of unfavourable trends an A3 improvement process is starting to investigate the root cause and identify measurements to improve. The current A3 process for reduction of contamination risks in the slaughtering department is seen.

3.8 Control of non-conforming product

Clear procedures for control of non-conforming products (e.g. fallen meat, blockades) are in place: P-BXT-NL10131. Products on hold are physically identified as such (red label/tape).

The procedure for non-conforming product defines how non-conforming product is identified, quarantined and disposed of. Only authorised personnel (QA Manager or department manager) is allowed to release products
The process of acceptance, release and recording of returned goods from customers is verified during the site. The current procedures are not followed structural, this has resulted in a minor NC.

3.9 Traceability

Traceability system is well developed. It covers raw materials through work in progress to finished product including packaging materials and distribution according to 'procedure traceerbaarheid' (P-P-Food-10015). This system is fully based on written documents, batch codes and bar codes:

- Porks bear an earmark (+ accompanied by track record and VKI)
- Half carcasses get an EG-mark + serial number (together with date of slaughter + slaughter line number + origin)
- Technical parts (own production + additional purchase) get a batch code (EG-mark + date of production + origin)
- By-products get a batch code (date of slaughter / production)
- Finished product is traced depending on the date of production + calculation number + serial number of EG-mark (weighing label is scanned at dispatch)
- Primary packaging materials are traced on the date of receipt / breaking into new batches
- Returned product + NAR (destination form)

Traceability tests including mass balance are kept at least 2x/year. The reports of the traceability tests of 20.11.2018 and 13.02.2019 are seen.

During the audit a vertical test is kept for the product Jowl steak, article 53773, order 444213 160 kg, produced at 19.03.2019. The test was performed well within 3 hours, showing a good grasp of tracking and tracing of product and corresponding documentation.
Documents showed during the test: End product specification, CCP training documents, Control on cleaning (Agar and residues), Trend analyse agar control, Distribution documents, Weight lists, Label check, Traceability to slaughter house number, specifications of packaging material, trace on packaging material, monthly trend micro results, SSOP list, PRE SSOP, Verification list CCPs, Monitoring list CCPs, Pre-shipment control list.
The production process has no rework flows.

3.10 Complaint-handling

Complaints are received by the sales organisation and send to the complaint inbox email address of Vion Boxtel. Complaint handling is performed at a daily base within the prescribed timelines. Process is verified for complaint 13062019: temperature and the complaints in week 12 (vertical test). Good organised process with in depth analyses for food safety complaints and link to the VOS system. There's a weekly complaint analysis report for the MT, which is discussed in the tier 1 meetings.

3.11 Management of incidents, product withdrawal and product recall

There is a company's crisis and recall management procedure P-VION-10015 which covers the process which is applicable for all Vion sites. The procedure for non-conforming product defines 'incidents' and addresses requirements in terms of incident reporting as these are escalated to relevant personnel for review and action as appropriate. Business continuity guaranteed by central procedures and emergency coordination protocol. The local procedure Product recall P-BXT-NL-10024 defines the composition of the recall team and complies with these requirements.

The recall procedure is tested 1x / year. Last mock up recall was 23.05.2019; report is verified – learning point is the early warning of Sr management in case of a potential recall situation, this is communicated to relevant staff.
No recalls since last BRC audit.

4. Site standards

4.1 External standards

Site is located in Boxtel, which is in the south of the Netherlands. At the same address the meat processing plant of Vion is located. At the opposite of the street the HQ of the Vion Food group is located. Site boundaries are clearly marked and fenced. Separate storage takes place for cleaning chemicals, lubricants and waste. The site is registered by The Food and Consumer Product Safety Authority (official approval EG 61). At the moment building works have started related to the project to extent the site in Boxtel with the processing of middles.

4.2 Site security and food defence

24h site security during production days from 06:00 till 22:00 by own trained staff the rest is covered by There is a system in place with badge control for employees and identification and badge control for visitors and contractors on all potential entry points to the plant. Reassessment Food defence executed 30-08-2018 including verification of the food defence plan. Actual site diagrams are seen

4.3 Layout, product flow and segregation

The slaughtering, processing and packaging areas of the production are well designed and maintained to prevent risk of contamination. Premises are suitable for the intended purpose. Process flow is designed to minimise/prevent contamination and agreed with the Food and Consumer Product Safety Authority. Personnel-, material-, air-, water, waste-, services flows are designed and equipment placed in such a manner as to minimise the risk of product contamination.
No high risk or high care production assigned on site. In the low-risk areas, effective procedures are in place to minimise the risk of the contamination.
Actual site map dated 12.12.2018 is seen and contains the flows as described in 4.3.1.

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

The internal condition of the site is suitable and satisfactory for the process. Walls, ceilings and floors were suitable in general. Floors are coated or granite and in good condition. Continuous attention is given to the condition of the floors. This was verified for the floor in the direct neighbourhood of the entrance of the mill chill. The repair of this floor is scheduled by the maintenance department next Saturday. False ceilings are in place in manufacturing area, which are full closed. In case of glass windows, these are protected by foil. Suitable ventilation and cooling throughout the factory.

Daily check of the condition by the SSOP checks and in depth by the quarterly inspection of fabrication and hygiene aspects.

4.5 Utilities – water, ice, air and other gases

The water used for cleaning and process purposes is water from the main supply. Testing of water (chemical/microbiological) is part of the microbiological monitoring plan P-BXT-NL-10009 and P-NL-Food-10.196C. The samples are analysed by which is an ISO 17025 accredited laboratory (. Water quality is defined as a CP. Sampling frequency is 4 times a year, last tests assessed from 12-03-2019, generic germ count above the limit (300 counted; limit is < 100), resampling has taken place and recount was within the standard.

Air flow is regulated; airflow directly in contact with meat (at cutting department) is filtered. These filters are controlled and changed each 2000 hours. Filter is an EAKC 14 filter with an active coal filter, designed to filter particles to a high level. Specification and replacement of filter is demonstrably performed.

4.6 Equipment

Equipment was suitably designed and used to minimise potential contamination. The used equipment is suitable for its purpose. New equipment is purchased as required and specified, validation report mild chill is assessed. The food approved of the conveyor belts in the organ packaging department is verified: food approved statement is clear.

1 minor NC is reported for this chapter: a bunch of cables was found below a work station in the cutting department.

4.7 Maintenance

Equipment is maintained using the maintenance system ( ). This will be replaced by in the future. Maintenance consists of ca. 30 employees; break down mechanics, project management, work preparation and management. Maintenance is also outsourced to dedicated companies within the food and meat business. Registrations to confirm that the preventive maintenance or preventive controls have been carried out as planned are in place. New machines are directly incorporated in the system. Maintenance and activities for disturbances/failures are typically and preferably planned and carried out after production hours or in the weekend. Release of equipment after repairs and/or maintenance are signed off via the (pre)SSOP forms. Repairs/maintenance are communicated with team leaders and other relevant people, as well as the cleaning company, to keep focus on hygiene.

All used lubricants are food grade with a FDA H1 status (food grade). Automatic lubricant system in use for the main process like transport chains.

Maintenance people are trained on hygiene and contamination prevention. A sole washer is present at the entrance of the clean slaughtering department. Main Maintenance Department is located in a separated building from the production.

4.8 Staff facilities

Canteen and changing rooms (production and dirty slaughter house) were assessed. Facilities are designed to a good level. Cleaning and maintenance are in good order, to prevent contamination or food safety risks. Outdoor clothing and shoes are stored separately from work wear.

Hand-washing facilities (with hand-free soap tap operation and air blade dryer / single use paper towels) were provided in toilets and at entry points to production areas. Before entering the production areas boot washing and hand disinfecting equipment is installed including a tourniquet.

Rest room and catering facilities are provided for staff . . . A HACCP plan is applicable. Smoking is only allowed in a separated area of the canteen. No evidence of smoking was seen during the site evaluation. Proper storage areas and fridge were observed for brought food stuffs.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas
4.9.1 Chemical control
Chemicals/cleaning agents are stored separately and away from production. Authorised access by cleaning company and production department. MSDS available and specifications confirm suitability for use in food processing industries.
4.9.2 Metal control
The HACCP study has determined that metal detection is not necessary as CCP, but as CP. Registration and corrective actions could be demonstrated. A knife handling policy is in place. During the site audit it was noticed that the knife handling at the front pieces line wasn't in conformity with the knife handling policy. This has resulted in a minor NC.
4.9.3 Glass, brittle plastic, ceramics and similar materials
A glass / hard plastic register is in place and records the location and condition of glass / hard plastic. Glass / hard plastic audits are regularly carried out by production department (daily pre-SSOP and SSOP). Besides daily check, 1 x / 3 months audits are executed by the verification of the glass register, which is documented as a map of the specific department. Verified for the glass audit in March 2019 for the cutting department (vertical audit).
4.9.4 Products packed into glass or other brittle containers
No products packed into glass or other brittle containers
4.9.5 Wood
Wooden pallets are not permitted in production of pork meat (only non-food area; storage of packing materials).
4.9.6 Other physical contaminants
No other physical contaminants applicable
4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of foreign-body detection and removal equipment
The HACCP study determined the metal detection step as a CP, not a CCP. Checks are performed every hour. Employees for monitoring are trained by an instruction. During the audit the use and control of the metal detection equipment was assessed at the packing area (vacuum products) and "mager met" packaging line. Method and recording in line with the procedures.
4.10.2 Filters and sieves
Sieves and filters are not in use for product checks.
4.10.3 Metal detectors and X-ray equipment
Metal detection devices are used to check for unpacked products and vacuum-packed products. Appropriate foreign body detection equipment (metal detectors) is in place, calibration of equipment is

demonstrable. Metal detector check is performed correctly, as well as registration of results and, in case of non-conformance, corrective measures.

4.10.4 Magnets

Magnets are not in use for product checks.

4.10.5 Optical sorting equipment

No optical sorting equipment.

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

No glass jars, cans and other rigid containers in use

4.11 Housekeeping and hygiene

Cleaning is subcontracted and performed by in the evening/ at night after production. Cleaning of equipment is carried out according to documented and detailed cleaning schedules.

Specific or dedicated equipment, such as whizard knifes and balances are cleaned by own employees

The effectiveness of the cleaning and disinfection process is followed by hygiene audits (pre-SSOP), agars and swabs for pathogens (e.g. Listeria). Records of checks are maintained and were sampled during the audit, both of as the pre-SSOP lists. Cleaning schedules of are available and cover equipment, plant, buildings and services (with daily / weekly / monthly cleaning frequencies). Low frequent cleaning schedule (ceilings, walls above 2,5m, evaporators) are scheduled via the overview of periodic cleaning tasks. Is verified for the periodic cleaning of buffer cell 5 (chilled area) and records were demonstrably. Pre-SSOP registrations are carried out correctly, deviations from schedule are followed up properly.

Specifications of the cleaning agents delivered by (consisting of MSDS and food grade certificate) are present eg.

Daily verification of the disinfection process by agar and pH tests. Results are verified; noticed was that the resampling of 2 poor disinfection results in week 22 2019 was not demonstrably; a minor NC is raised for that.

During the site audit it was noticed that hoses in use for the cleaning for the chilled areas and mild chill were stored in an unsuitable area (storage of primary packaging materials), this has resulted in a minor NC.

4.11.7 Cleaning in place (CIP)

A cleaning in place system is used for the cleaning of the blood vessels and tank and the cleaning of knifes and crates. Temperature is monitored in and check on residue was performed during the audit. Cleaned crates are visual and microbiological checked.

4.11.8 Environmental monitoring

Environmental monitoring is taken place with Listeria swabs with a frequency of 4x/year. Results of 2018-2019 are seen. No Listeria has been found.

4.12 Waste

The site has several types of waste materials. The removal of waste is done by contracted and licensed waste removal companies.

Cat 2/3 is removed by Other types of waste are paper, carton, plastic, metal, wood, chemicals and residual waste. Company is contracted for the removal of these types of wastes.

4.13 Management of surplus food and products for animal feed

All waste material based at pork is unpacked before removal. No waste material for animal feed products.

4.14 Pest management

Pest control is outsourced to a contracted pest control agency Contract management by Vion HQ. Contract is covering the pest control of rodents, insects and mots. Control frequency 8x/year and yearly in-depth inspection.

Competences of pestcontrol inspector is verified (EVM recognised until 14-12-2022) and (EVM recognised until 13-04-2022).

Bait is seen during the site audit, this bait is found at the plan at the actual location. Report of the inspections at 23.01.2019 and 07.05.2019 is seen. Due to a cockroach infestation in January extra inspections were done to solve the issue, which was finalised in March 2019.

Measures for bird protection by the use of bird pens.

Follow up of recommendations of the pest control agency is timely; during the audit only 4 recommendations were in process. The in depth inspection was kept at 23.11.2018; follow up actions is finalised.

The trend analysis of the pest control activities is part of the reassessment process.

4.15 Storage facilities

The company is producing fresh pork meat.. Carcasses are stored 1 dav before they are cutted to specification. Storage temperatures are controlled automatically via the system. Used temperature standards are in conformity with the legislative demands about temperature. Production and expedition processes are organised based at the FIFO principle. Part of the production output is distributed to contracted frozen storage locations.

4.16 Dispatch and transport

Temperature during dispatch of the product is a CCP. Records of the CCP check and the preshipment process were verified during the audit and as a part of the vertical test. (19.03.2019) Transport is organised and scheduled by the Service desk. They are only scheduling approved transport companies. Trucks are inspected for hygiene and temperature prior to loading. Results of these inspections are recorded on the CCP control forms F-BXT-NL-10045. There's a schedule for audits of the transport companies and a verification of the cleaning by agar samples, see chapter 5.4.3

5. Product control

5.1 Product design/development

The product development process is centrally organised within the Vion Food. There are no product development activities at the Boxtel site (changes are mostly changes in snit). New processes are validated before implementation. Verified for the mild chill; validation report 05.02.2019 is seen.

Shelf life / best before date trials are coordinated by the central QA department of Vion Food, except for shelf life trials on customer demand. Shelf life trial samples are taken in conformance of the central shelf life trial plan and seen during the audit, for different temperatures and shelf life (stored at 0-2 and 4 degrees). The current used shelf life terms are in line with the shelf life test results.

5.2 Product labelling

Bulk products are delivered with product specifications based on customer requirements and legislation aspects. Labelling text is based at product description, production date, shelf life term, country of origin and storage conditions. There are 2 vacuum packed consumer products. Ingredients are mentioned at the labelling text. Label Jowl steak verified (vertical test): no remarks.

5.3 Management of allergens

No allergens on site under current scope, only production and handling of fresh meat.
The risk of allergens via employees / food stuff is part of the risk assessment. This is controlled with the following measurements: it's not allowed to wear the work coat in the canteen and all employees need to wash and disinfect their hands before they are entering the production facilities and the wearing of gloves. Allergen management is part of the refresher training for employees and introduction training for new starters.

5.4 Product authenticity, claims and chain of custody

The vulnerability assessment is documented as Process integrity control plan P-NL-FOOD-10211, dated 01.04.2016. Aspects like replacements and substitution are part of the vulnerability assessment. The company is certificated for chain of custody. A daily mass balance is one of the requirements of the scheme. Mass balance of 19.03.2019 is verified and no deviations were seen.
Organisation is certified for: QS, IKB, Better life 1*, SQMS, ınd Chain of Custody.

5.5 Product packaging

The packaging and supplier approval is managed by the central purchase department at Vion Food HQ. There's a list of approved suppliers of primary packaging materials. Primary packaging materials are appropriate for the intended use. This is verified for the vacuum packaging film and all relevant documents (specification, food grade statement, migration tests) were available. Product packaging material is checked against visual standards of acceptability upon arrival at the site. There is a separated storage area for primary packaging materials.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Livestock/pigs are controlled by a veterinarian during the arrival at the slaughter department and during the process in the clean slaughter line (control for diseases intestinal check).

All analyses (hygienograms, microbiology, water. etc.) are subcontracted to an accredited laboratory operating in accordance with ISO 17025:
A microbiological monitoring program 'procedure planning monstername 2017-2018' and shelf life testing program 'Houdbaarheidsonderzoeken' (P-FOOD-10010 and P-NLFOOD-10165) are in place and were assessed.
The frequency of monitoring depends on the risk:
Carcasses own production: daily microbiological analysis of TPC, entero's, (pool) Salmonella (process hygiene);
Trimmings: daily microbiological analysis of TPC, entero's, (pool) Salmonella and listeria;
Deboned meat: 1 x / week microbiological analysis of TPC, entero's, Salmonella and Listeria;
Technical cuts, by-products and organs: 1 x / 2 weeks microbiological analysis of TPC, entero's, Salmonella and Listeria;

5.6.2 Laboratory testing

Results of TPC and pathogens (every thousand carcass) are analysed and reported monthly (KPI reporting). Trend graphs are applied. Results are analysed at trends at a monthly base (Q report). Tests are assessed for raw materials and finished goods. Process is verified for the Jowl Steak: results 28.05.2019, 12.06.2019 and 12.03.2019 PCA and ecoli analyses were seen: no remarks.
Results of the monitoring programme are part of the quarterly based review of the food safety and quality system. Results are verified: decreasing trend for PCA, this might be the positive effect of the mild chill process.

5.7 Product release

Products are released after the pre-shipment controls, which are carried out by the expedition department. The verification of CCP controls is part of the pre-shipment process. Verification procedure and checklists were assessed during the audit at dispatch and during the traceability test (F-BXT-NL-10048).

5.8 Pet Food

The company isn't producing any petfood.

6. Process control

6.1 Control of operations

Process conditions and methods are well monitored and re-validated when deemed necessary. In case of breakdown of critical equipment a system and procedure are in place for the proper handling of product. Verification of process and equipment takes place once a year. The results are used and discussed as input in the yearly management review. QA monitors aspect of the controls that might affect food safety, legal and quality characteristics. The control of operations is partly at visual inspection during the process by operators and supervisors. Checks are made on the SSOP forms for process controls, such as temperatures.
Via a camera system and the system there's a real time overview at the control of operations. Special attention for animal welfare aspects with camera supervision.
The cooling system is linked to the system. In case of failures in the system an alarm system is in use.

Daily meetings between management of the slaughtering department and maintenance department about break downs. A plan is running to improve the uptime of the process and the first results are visible (objective X-matrix 2019).

6.2 Labelling and pack control

Label checks are taken place at the start and end of production batch. During the site audit in the cutting department the product change is monitored from necks to necks Labels were changed via the system . Label check of 1st label was seen. No need for change of packaging

6.3 Quantity, weight, volume and number control

All products are sold by weight. Weighing scales are in place and subjected to calibration and maintenance programme. Calibration reports of balance LTC003 (used for the production of Jowl steak) is seen; is calibrated at 29.03.2019.

6.4 Calibration and control of measuring and monitoring devices

Critical measuring equipment are thermometers (CCP related), weighing scales and metal detection equipment. These are calibrated. Records were available.
The equipment used to measure on CCP's is identified. List of measuring devices in place. Calibration due date on equipment. Seen calibration of thermometer 102, 103 and 105; calibration records 13.02.3019 is seen. Metal detection device was calibrated 15-3-2019. Balance A152623 / 20 kg is calinrated at 10.02.2019.

7. Personnel

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

There's an introduction training for new employees including temporary workers. Employees engaged in the control of CCP's are trained regularly. Employees working in the dirty slaughtering department and stable get a dedicated training about animal welfare aspects, which is delivered by the

The following training records are verified:
- pre inspection training 18.07.2018
- CCP1 faecal comtamination 22.09.2011
- CCP 2,3,6,7,8 temperature of product 12.03.2018
- KUL/animal welfare training at 18.04.2019
- KUL/animal welfare training at 13.01.2019

Competence review is part of the yearly POP process and reassessment / management review.

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

The standards for personal hygiene are documented in the QMS as P-FOOD-10017. The document is covering the requirements of the BRC 8 standard. The wearing of any jewellery isn't allowed.
Effectiveness of the hygiene procedures for personnel is part of the SSOP systematic.
A sample of each batch metal detectable plasters is demonstrable tested. This is verified during the audit and the last received batch of plasters at 15.06.2019 was demonstrably tested.

7.3 Medical screening
The medical screening is part of the intake of new employees and part of the instructions to visitors. 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
Protective company clothing is facilitated to all staff, temporary workers and visitors and changed daily. Workers are divided per rank and agency by different colour hair nets. The standards for personal hygiene, dress code, medicines, jewellery and medical screening have been defined (P-FOOD-10017). These hygiene rules are effectively enforced and daily inspected as a part of the SSOP control. Protective clothes are provided in sufficient numbers. The laundering of protective clothing is outsourced to a contracted and specialised laundry (certification includes biocontamination control system and washing programs are verified). The wearing of sleeves, aprons and work coats isn't allowed during eating and smoking. Disposable hair nets are in use; beard snoods are in use. Cleaning facilities are provided. Work shoes or boots needs to be worn, facilities to clean the soles are available in the hygiene corridors at the entrance of the production facilities.

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
No high risk, high care of ambient high care zoning
8.2 Building fabric in high-risk and high-care zones
No high risk, high care of ambient high care zoning
8.3 Maintenance in high-risk and high-care zones
No high risk, high care of ambient high care zoning
8.4 Staff facilities for high-risk and high-care zones
No high risk, high care of ambient high care zoning
8.5 Housekeeping and hygiene in the high-risk high-care zones
No high risk, high care of ambient high care zoning

8.6 Waste/Waste disposal in high risk, high care zones
No high risk, high care of ambient high care zoning
8.7 Protective clothing in the high-risk high-care zones
No high risk, high care of ambient high care zoning

Details of non-applicable clauses with justification	
Clause/section reference	**Justification**
8.1-8.7	No high risk, high care of ambient high care zoning

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

Module 11: Meat supply chain assurance	
Scope	

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

Module 12: AOECS Gluten-free Foods

Scope	

12.1 Senior management

12.2 Management of suppliers of raw materials and packaging

12.3 Outsourced production

12.4 Specifications

12.5 Management of gluten cross-contamination

12.6 Management of incidents, product withdrawal and product recall

12.7 Labelling

12.8 Product inspection and laboratory testing

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018				
Item no.	Clause	Module item	Conforms (Y/N) or Not Applicable (NA)	Comments

1	13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
2	13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
3	13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
4	13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
5	13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
6	13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to		

		packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		
7	13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).		
8	13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
9	13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		
10	13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.		
11	13.1.11	Establish corrective action procedures when preventive		

		controls are not implemented consistent with the requirements of BRC sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).		
12	13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.		
13	13.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
14	13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method • Laboratory conducting analysis		

		• Corrective action procedure where pathogen is detected		
15	13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
16	13.1.16	Devices used to verify preventive controls must be calibrated.		
17	13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
18	13.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
19	13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan		

		initially and then upon any changes following reanalysis.		
20	13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		
21	13.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
22	13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		
23	13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.		
24	13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will		

		protect against contamination, including the following: - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
25	13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.		
26	13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant		

		vulnerabilities and actionable process steps • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
27	13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum): • Scale and severity of threat if a contaminant is added to product • Degree of physical access to the product • Ability of an attacker to successfully contaminate product—including consideration of an inside attacker A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.		
28	13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.		
29	13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency		

		for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.		
30	13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions		
31	13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation strategies. Verification procedures shall include: • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities		

32	13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence		
33	13.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
34	13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.		
35	13.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.		
36	13.4.1	Vehicles and transportation equipment must be maintained and		

		stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used. A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.		
37	13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.		
38	13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the		

		loader and carrier, which are appropriate for the type of food.		
39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.		
40	13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.		
41	13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper		
42	13.4.7	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems		

		• Responsibilities of the carrier		
43	13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.		
44	13.4.9	The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.		
45	13.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following: • Principles of food hygiene and food safety Produce safety standards applicable to an individual's job		
46	13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment		
47	13.5.3	One or more supervisors or individuals responsible for the operation must have successfully		

		completed food safety training equivalent to standardized curriculum recognized by the FDA.		
48	13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.		
49	13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.		
50	13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.		
51	13.5.7	Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.		
52	13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.		
53	13.5.9	Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of		

		adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria. Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.		
54	13.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007)," December, 2009 or equivalent method.		
55	13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to		

		minimize infiltration of pathogens into produce.		
56	13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.		
57	13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.		
58	13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.		
59	13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.		
60	13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
61	13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts. Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria:		

		• Target test (i.e., Listeria spp. or L. mono) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) The plan shall describe aseptic methods for sample collection and testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent).		
62	13.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts. The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono. If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process: • Resample positive surfaces and the surrounding area to determine the extent of contamination • Clean and sanitize the affected and surrounding areas • Resample and re-test to confirm the elimination of Listeria spp. or L. mono • Conduct finished product testing as appropriate • Take additional action to prevent recurrence and to		

		prevent adulterated food from entering commerce		