Audit Report

Global Standard Food Safety Issue 8

1. Audit Summary			
Company name	Vion Boxtel BV	Site Code	1768974
Site name	Vion Boxtel BV		
Scope of audit	The slaughtering of pigs, the deboning, cutting to specification, slicing, packing in bulk, bag in box, consumer packaging of pork (fresh, vacuum packed, modified atmosphere, chilled). Production and packing in bulk of mechanically separated meat.		
Exclusions from scope	The intestinal washing process		
Justification for exclusion	Segregated process with clearly differentiated products		
Audit Start Date	2022-06-20	Audit Finish Date	2022-06-23
Re-audit due date	2023-06-28	Head Office	No

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 Programme	Announced
Previous audit grade	A		Previous audit date	2021-06-04	
Certificate issue date	2022-08-23		Certificate expiry date	2023-08-09	
Number of non-conformities			Fundamental	0	
			Critical	0	

2. Audit Results

	Major	0
	Minor	8

3. Company Details

Address	Boseind 10 5281 RM Boxtel		
Country	The Netherlands	Site Telephone Number	31 (0) 658196411
Commercial representative Name		Email	
Technical representative Name		Email	

4. Company Profile

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

Shift Pattern	2 shifts Monday/Friday and regular 1 shift at Saturday
Subcontracted processes	No
Other certificates held	ISO9001, IFS PIA, BLK, IKB, QS, SQMS,
Regions exported to	Europe Asia North America Oceania Africa

4. Company Profile

	Choose a region
Company registration number	EG 61 NL
Major changes since last BRCGS audit	Crate washing department was recently renewed Seasoned meat preparations wewre no longer produced: skipped from the scope

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 pigs per day in 2 shifts. Main customers are industrial meat processing companies in Europe, Asia, USA 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 about own employees and temporary 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 and job coaches in the company for communication purposes.
In 2020 the site was enlarged to integrate the processing of pork middles in the site in Boxtel. In Q1 2021 the processing of middles is started in Boxtel including a new system of packaging based at the use of – crates. The scope is changed in line with the current processes and products.
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.) The surface is 28500 sq. metres. The used quality system is based at HACCP-principles. The pork is packed at semi-bulk level, partly vacuum or MAP packed. Also some vacuum-packed consumer goods for the Greek market are produced. EG number is NL61 EG.
SDP meat preparations was stopped last month, so product category 3 is out of this scope.
Website: www.Vionfoodgroup.com.
The site is audited against the requirements of BRC food 8; additional modules are not a part of the audit. Due to Covid 19 the use of plastic screens at the cutting lines, are still in use, at some area's mouth masks are still worn but no other measures.
The HQ processes are not audited separately for BRC and integrated in the audit of the site

5. Product Characteristics

Product categories	01 - Raw red meat 03 - Raw prepared products (meat and vegetarian) Category Category Category Category Category

5. Product Characteristics					
Finished product safety rationale	Chilled red meat, short shelf life 5-8 days and chilled red meat vacuum / MAP packed, short shelf life 14-21 days				
High care	No	High risk	No	Ambient high care	No
Justification for area	Justification: No high risk or high care production assigned on site. All products undergo full cooking prior to consumption on 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	Welfare (GB = Good Farming Bacon) and BLK 1star (FS = Good Farming Star				
Product recalls in last 12 Months	Yes				
Products in production at the time of the audit	Mager met 80-20, shoulder 2D, shoulder 4D, Neck , Pharma ham, neck without bone, platte bil				

6. Audit Duration Details			
Total audit duration	32 man hours	Duration of production facility inspection	16 man hours
Reasons for deviation from typical or expected audit duration	Processes with repetitive work		
Next audit type selected	Unannounced		

Audit Duration per day			
Audit Day	Date	Start Time	Finish time
Day 1	2022-06-20	08.00	17.00
Day 2	2022-06-21	08.00	17.00

Day 3	2022-06-22	08.00	17.00
Day 4	2022-06-23	08.00	13.00

Audit Team	Auditor number	Name	Role
Lead Auditor			Lead Auditor
Second Auditor	NA		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
, site manager	x			
, site manager	x			x
QA manager	x	x		x
HR manager	x		x	x
Assistant maintenance manager	x	x		x
Manager cutting areas	x	x		x
Manager slaughtering and packaging areas	x	x		x
Manager planning		x		x
Manager mager met/DMM	x	x		x
Vos/facility	x			x
Maintenance:			x	
QA:			x	

Chilling:		x		
Slaughter dep. :		x		
Dep. Asia:		x		
Exp;		x		
Cutting dep.		x		
Packing:		x	x	
Kam/schoulder dep';		x		
Middle:		x		
Dry storage:		x	x	
Pack flex fresh		x		
And many more employees on site		x		

GFSI Post Farm Gate Audit History		
Date	Scheme/Standard	Announced/Unannounced
2021-06-04	BRC Food 8	announced

Document control			
CB Report number	RQA9832737- 4633046		
Template Name	F834 Food Safety Audit Report Template v11		
Standard Issue	8	*Template issue date*	2022-02-15
Directory allocation	Food	*Version*	1.0

Non-Conformity Summary Sheet

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

Critical			
No.	Clause	Detail	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	3.7.2	During production of “Mager met”, the fat% was measured by the . This was verified every hour. In case a sample of a dolav/crate was rejected (fat% out of specification), the dolav with product is rejected (which was recorded) and need to be re-worked. Records do not show the corrective action on these rejected batches. **Closed to be verified on site**	We are looking at how we can capture this	We have adapted the checklist F-BXT-NL-10067, so that we can record rework on this in a traceable manner **(see attachment 1)**	This was not sufficiently secured during the integration of the .	2022-07-20	
2	4.4.10	In the dry non-food storage on the second floor, some water puddles (condense) seen on the floor, probably caused by cumulation of condense, caused by a deviation in the condensation point of the cooling installations hanging on the	The floor was dried shortly afterwards **(see attachment 2)**	We have lowered the room temperature of the warehouse. However this is not always sufficient. We have planned a consultation with the supplier to look at the possibilities to prevent	Due to the high outside temperature during the weekend, the moisture in the warehouse condensed on the floor above	2022-07-20	

Minor							
		ceiling in the (expedition) room below this area on the first floor. **Closed to be verified on site**		this. As soon as this is known, this will also be implemented.	the evaporators. Extreme temperatures may have been insufficiently taken into account when planning the new building.		
3	4.6.1	In DMM production area was seen that two pieces of the white belt underneath the metal detection were missing (direct food contact). **Fully Closed**	The belt is repaired the same day. The chance that plastic has ended up with a human product is unlikely.**(see attachment 3)**	The employees who carry out the (pre)-ssop have been retrained. so that they pay attention to the completeness of machines and belts.	Not all employees were alert enough to notice	2022-07-20	
4	4.9.1.1	Storage cleaning chemicals: acid and alkaline chemicals stored on same drip tray which can cause gasses in case of spoilage (can cause dangerous situation). This was seen in dedicated chemical storage (outside) and in storage near the crate	We placed the Acid separated from the alkaline chemicals.	We placed storage information on the drip tray in the storage outside. An additional drip tray at the crate washing. **(see attachment 4)**	Not all employees were aware of this requirement.	2022-07-20	

Minor							
		washing machine of the new building. **Fully closed**		We instructed the employees.			
5	4.11.2	The frequency of cleaning of the evaporators and/ or airsocks seems not to be enough to ensure appropriate hygienic standard. Black spots on the ceiling near the airsocks were seen and the evaporator at the long/liver (hartslag) split department was not clean. Frequency of cleaning was set on 1x year. **Fully Closed**	Both the socks and the ceiling around them have been cleaned (already planned). The contaminated evaporator was still cleaned during the audit. **(see attachment 5)**	The washing of all air socks is planned. For those high in production hang 1/year and for those low in space hang 2/year, as indicated in the frequency chart.. The cleaning company expects the frequency as in the schedule to be sufficient. We can see this next year. Evaporators are cleaned by the cleaning company present as a special assignment, when an evaporator is dirty. Re-instruction departments, if there are deviations with ceilings/airsock or	Boxtel Phase 2 (new factory) started last year. This year is the first cleaning. Probably because of the building material we now see black stripes along the air socks on the ceiling. The evaporator cleaning is not laid down in a schedule, because the frequency of cleaning is very dependent on the position of	2022-07-20	

Minor							
				evaporators, report this to FD.	the evaporator, where it is exactly, and on the temperature and use of the room. If necessary, cleaning can be done more often, but this must be reported.		
6	4.11.5	Some belts were not dried up after cleaning, before starting which was not noticed during the pre-check for start-up after cleaning (Pre-ssop).: Water drops were seen hanging at underside of the belt frame at the deboning department (voorstukken): the belt was situated above another belt moving raw material. Also water drops seen hanging at the “hammenlijn”.	the drops were removed soon after the constatation. **(see attachment 6)**	During the pre-ssop round for production, these points are now checked daily, The belts are also dried where necessary and all drops are therefore removed. However we see, that these drops return throughout the day. Because we don’t have immediately found a solution for this, The maintenance	Depending on the weather it it possible that there will be condensation during the day. Not all executives were alert enough to notice	2022-07-20	

Minor							
		Closed to be verified on site		will see if they can solve this in a certain way, to prevent this problem. Until then, our conveyers are instructed to continuously walk along the lines during the day, and if necessary. to remove drops. Also our executives are reinstructed to be alert on this			
7	6.1.3	Product (chilled) packed in crates/ boxes after cutting/ deboning, may be stay stored at the department for max 1 hour (CP 32), after one hour these products must be transported to the buffer cell (0°C) (description CP instruction). No records could be shown, not clear was how this CP is managed and controlled.	The products were transported to the cold store.	The time is stated at the 1st E2 crate on the pallet. After max. 1 hour the entire pallet goes to the cold store. **(see attachment 7)** Monitoring by foreman.	Instruction of the foreman was missing.	2022-07-20	

Minor							
8	7.2.1	The general hygiene rules P-Food-10017 7-Jan 2021 were not always complied with: -incidents noticed on work jackets which were brought into the canteen (however folded), instead of leaving them in the changing rooms -In middle deboning area, mouth masks were worn, touched with hands during packing meat into the vacuum machine.	Instruction **(see attachment 8)**	We are preparing instructions to make it clear to our employees that they do not use their mouth masks in the production. Especially if you put on the mask properly. In addition, they also use a clean mask after every break. Such instructions are also drawn up for work coats, so that they remain in the changing rooms. By doing this as much as possible with image material, this will also be better understood. These instructions are shown on the screens in the canteens, so that we can reach everyone.	It seems that some new employees found it easier to take their work clothes into the cafeteria. This may be insufficiently treated in the current intake. We are still obliged to wear mouth masks from third countries in the cold production areas. In addition, we see that if the masks are not placed correctly, they can shift. But there are also	2022-07-20	

Minor							
				In addition, we are already supervising this and calling the employees to account.	employees who believe that they should turn them off when they speak.		

Comments on non-conformities
Click or tap here to enter text.

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	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

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 (Vion Operating System) 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. There are non-negotiable objectives set for 2022: e.g. training (improve intake, yearly refresh training, HACCp training for leaders and managers, digital SSOP and PRE-SSOP, data integrity, cat. Material integrity and 14 more (quality) goals. Other objectives are related to the food safety culture (training) and product flow management at shop floor / WIP / Digital checklists. Also training goals were set on training executives (management on the floor) on Integrity, FS culture, IFS PIA and how to involve employees in this.Progress of the objectives is reported at a 4-weekly base during the tier 2 meeting.

Clearly defined Food safety and quality policy 2021/P-BXT-NL-10126 seen in which the intention of the site to produce and deliver safe, good, reliable and sustainable products is described; signed by the site managers 2022-01-21

The progress of realisation of objectives are monitored via the Q-based Q-report. (seen report Q1-2022) and Q4 2021. Reviewed aspects in the Q-report are animal welfare, EKS, complaints, food safety, suppliers, training and food safety culture. Yearly management review process covering the period July – June. The management review report July 2020 – June 2021 is seen which was confirmed by management at 2022-01-28, seen minutes of 2022-01-28; 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 (conf. reportig system) for all employees as part of the Good Business Practise guide, based at the possibility to report via telephone anonymous concerns. Also a speek up procedure is implemented. There have been some notifications by NVWA in 2021 for Vion Boxtel on hygiene issues. These were now demonstrably solved. These notifications were also reported to LRQA conform requirements.

The BRCGS audit due date is 2022-06-28 and the audit is scheduled in time. The audit time is 4 days conform requirements.

The company has an original BRCGS food document, the logo use is in conformity with the guidelines.

The outstanding NC’s from the previous audit were monitored via the action list MT and all fully closed.

1.2 Organisational structure, responsibilities and management authority

The organ chart P-BXT-NL-10028 is up-to-date (version 2022-04-22 seen) and in line with the current organization, The responsibilities for the management of activities are defined which ensure food safety, integrity, legality and quality and are clearly allocated and understood by the managers responsible, which was verified during the audit. Clearly documented was who deputises in the absence of the responsible persons. Job descriptions are reviewed, which were in line with the responsibilities.

The job description of the cooperative shift supervisor and QA employee are verified; no remarks. Performance is reviewed by day-to-day management and yearly during the POP/PPP reviews.

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

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 (including radiological risks) and physical risks for all steps in the production process, packaging material and general elements. The generic HACCP analyses of Vion is documented as P-FOOD-10000. 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 defence (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/version 2022-05-06. The site has 8 CCP's and 40 control points (CP's).

The QA manager is the food safety team leader; he is sufficient educated and well experienced. The Food safety team exist of the MT of the site and knowledge of HACCP. Quality and food safety are fixed agenda topics of the weekly tier 1 meetings.

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, corrective actions are addressed directly and corrections are demonstrably recorded and verified. .

Flow diagrams are seen and is verified for the process of removal of testicleless and production of season diced pork (DCP); recently changes were also processed in the flow diagrams; no deviations found. Yearly review of flow diagrams as part of the re-assessment process. In 2021 the flow diagrams are extended with the new processes / fase 2 project and these are up to-date.

Different product groups are applicable (Procedure Products Boxtel P-BXT-NL-10.170 2022-04-07):

- Fresh pork meat (Dutch origin).

- 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 ( )

The company has defined 8 Critical Control Points (CCP's) (seen also overview P-BXT-10118 2022-04-07):

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

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

CCP records are verified for 16-17-18 March 2022 and during the audit on site, no deviations found.

There's a yearly verification of the HACCP system, the report of the last reassessment (Jan 2022) reviewed period is 07 2020– 06-2021) is seen. The review of the food defence risk assessment is part of the reassessment process.

HACCP team members are demonstrably trained and have good knowledge of the QMS. Team leader is Q Manager. For this yare one of the goals is to perform a special HACCP training for leaders and managers, to increase awareness on food safety and culture knowledge.

Changes in process and products are validated by the food safety team.

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

3. Food safety and quality management system

3.1 Food safety and quality manual

Vion Food is using a common digital system ( ) for the documentation related to the food safety and quality manual for all sites in the Netherlands and Germany. This is managed by the central QA department. Each site has its own area within the system for local procedures and work instructions. All members of the local MT, team leaders and employees QA have access to QOL.

3.2 Document Control

Changes are processed via a workflow system in . Procedure document control is PVion-10007; Process is verified for used method at the refurbish workplace in slaughtering process (use of bags for related organs in case of rejection of a carcass) F-BXT-NL-10062 and the described process is up to date with the current practice. Adjustments can only be performed by dedicated QA employees incl verification (4 eye principle)

3.3 Record completion and maintenance

The following records are verified as part of the vertical test: SSOP's, pre-SSOP's, CCP checks, knife checks, label checks, pre shipment. Sampled dates were 15-16 March 2022 and during the onsite audit; no deviations found. Storage term of records is 3 years.

3.4 Internal audits

The internal audit plan 2022 is seen. 4 internal audits are scheduled throughout the year and covering the requirements of the BRC standard in basic.

The frequency at which each activity is audited was established in relation to the risks associated with the activity as the reception of pigs (quality standards and healthy was audited min. 2 x year and all other activities also 2 x year. Internal audits are planned and performed by employees managed by HQ. The last internal audit report is kept 2022-03-14, actions are addressed and follow up was demonstrable. The qualification of internal auditor is verified: QMS auditor training finalized at .

Hygiene and fabrication inspections are kept at a daily base (pre-SSOP and SSOP checks). On top of that the QA department is verifying the SSOP results during the Agar sampling and EKS checks.

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/HQ responsibility within the Vion Group.

Vion Farming is taken care for the suppliers of livestock (pigs and cattle) from the farms.
Process is documented in P-NL-Food 10157 and verified for pork, canalisation GB delivered (trace test) at 2022-03-15 and during the assessment on site

- UBN IKB approved
- UBN IKB approved
- UBN IKB approved

GB canalisation is based at IKB certification

Purchasing processes of raw materials (ingredients) and packaging materials are managed by the HQ via approval procedures (incl. GFSI / chain certification status and questionnaires) 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 the middles from the Vion site in Apeldoorn (also BRC certificated).
There's a yearly assessment of suppliers; each Vion site is asked for input. No serious high-risk suppliers are identified. Overview 2022-02-11 is seen: input from Vion Boxtel about suppliers of packaging materials and services is seen.

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 also processing pork middles, delivered by the Vion plant in Apeldoorn. The temperature of incoming meat is controlled as CCP6.
Ingredients and packaging materials are received at the dry central warehouse of Vion, also located in Boxtel, but management by the HQ and undergo visual inspection.
Seen supplier of foil as primary packaging OPI, BRC Packaging certified.

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 2022-02-11. Is verified for suppliers of services ; no remarks. Assessment of suppliers of transport companies by transport audits based at the yearly planning transport audits Vion. Audit reports of transport companies are seen; no remarks.

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 and verified during the audit

- Schoulder 2D
- Voorstukken front pieces
- Frozen pork
- Blue LDPE bag
- Foil

Specifications were available in an up-to-date version. Review of specifications is at least 1 x / 3 years.

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. Used methods for improvement is based at go-look-see approach. Most of the start-up issues of Fase 2 Boxtel are solved, although there are still action points related to the project as input to finish the validation. Corrective actions defined after etection of a rat at washing area: new visit check was planned and performed). Corrective actions on sampled Internal audits were also checked for, good follow up and corrective /preventive actions were demonstrably taken.
Minor NC 1 was defined on section 3.7.2 as no information could be shown on re-worked product after checking by the . Records do not show the corrective action on these rejected batches.

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). Process is seen in practise during the site audit for fallen meat in the cutting area; no deviations seen. 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) are allowed to release products

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, managed by

- Porks bear an earmark (+ accompanied by track record and VKI)
- Information earmark is linked to the chip in the slaughter hook and recorded in
- 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 (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. Reports sampled of these traceability tests were seen 2021-07-21 (incl. recall test), 2021-10-06, 2022-04-08 2022-04 11/12 of 22.04.2021.

During the audit a vertical test is kept for the product art Pork Loin Back ribs 17-23 mm packed in blue LCDP foil in carton boxes (to be frozen), packed at 2022-03-17, 3 pallets order produced. The

product is transported to the frozen storage of and is exported in container . The test was performed well within 3 hours, showing a sustainable system of tracking and tracing of product and corresponding documentation.
Documents showed during the test: End product specification, specification spices and packaging material, 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 checks, PRE SSOP, Verification list CCPs, Monitoring list CCPs, Pre-shipment control list, knife control checks. Trace for/backwards. 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 of Pork meat, hanging fresh, 2022-06-15 on bad smell (cause was found that product was stored too long because of the Eastern weekend, by mall function on mild chilling), the complaint handling is demonstrable. 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. The trend is slightly upwards for complaints in 2022 on weight complaints, no serious quality complaints were recorded.

3.11 Management of incidents, product withdrawal and product recall

There is a Vion overall 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 recall was 2021-07-21; report is verified; no remarks. No recalls since last BRC audit.

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

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 and a the storage location for packaging materials and technical components for all dutch Vion sites.
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).

4.2 Site security and food defence

24h/7 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 at all potential entry points to the plant. Reassessment Food defence executed 2020-10-20 including verification of the food defence plan. Actual site diagrams are seen. Recently a new gate at transport site of supply of pigs was installed which open and closing system is working very fast. This is an improving step on food defence on even more reduction of possible entry of unannounced guests which is minimised.

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 2020-11-25 is seen and contains the flows in conformity with 4.3.1.

During the site audit was noticed that attention is needed for the hygienic condition of equipment in the red tag area; this is reported as a minor NC.

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 dry storage: **Minor NC 2 defined on 4.4.10** because of puddles water in this dry storage. False ceilings are in place in manufacturing area, which are full closed. There's a technical area above the new production area of the middles and packaging area for technical parts like the ventilation system.

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. Hand-washing water or for equipment or plant cleaning is supplied in sufficient quantity, is potable at point of use and poses no risk of contamination according to applicable legislation. The distribution system was seen in an up to date schematic diagram of the distribution system on site. 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 26.03.2021, all results were within the standard. Also seen report water quality Q1 : all results were within the standard.
Dry ice is used for cooling purposes, CO2 gas is used for packaging purposes. Used gas and ice is food approved.

4.6 Equipment

Equipment was suitably designed and used to minimise potential contamination. The used equipment is suitable for its purpose. Used stainless steal is RVS304. New equipment is purchased as required and specified. DOC was seen of belts. **Minor NC 3 was defined for 4.6.1** on missing pieces of the belt of DMM. MOC process is used for the validation of new equipment; report seen for the fase 2 process (F-BXT-10120, dated 2021-05-06).

4.7 Maintenance

The process equipment and main process steps are monitored by the maintenance department via a system in combination with camera surveillance at critical technical points of the installation. Systems are generating SMS messages to mechanics in case of failures and deviations. In 2021/2022 the maintenance planning system is changed into and all machines are incorporated in the system. Process is verified for the air treatment equipment (last maintenance in 2021-12-09) and PT1000 chilling 2021-12-17. There's a continuous dialog system with the external company about the performance of their equipment (contract 2020-10-28). 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 an FDA H1 status (food grade), verified for ;
MSDS sheet is seen and lubricant is food approved. 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 and extended last year due to the fact that the site has 800 new employees. 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 sole 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 segregated area at the outside area of the site. Proper storage areas and fridges 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 not always stored separately and away from production. (**Minor NC 4 4.9.1.1**) Authorised access by cleaning company and production department. MSDS available and specifications confirm suitability for use in food processing industries. This is verified for , and. MSDS documents and specs are seen, and the used dosages are in conformity with the prescribed dosages. Employees handling cleaning chemicals are demonstrably trained which was checked for facility employee .

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. Good notification and control were seen.

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. F-BXI-NL-10057 2021-08-30 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 by the QA department, which is documented as a map of the specific department. Verified for the glass audit in at 2022-06-13 (cutting), 2022-03-31 (dep. Slaughter), 2022-03-25 (dep.). Follow up of action points is demonstrable.

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

Only the use of metal detectable pens is allowed

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. X-ray equipment is in use for the SDP products to detect foreign bodies like plastic and plastic.

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 packed products, tongues, mager met, DMM and vacuum-packed products. Appropriate foreign body detection equipment (metal detectors) is in place, calibration of equipment is demonstrable. Metal detector checks are performed correctly, as well as registration of results and, in case of non-conformance, corrective measures. Used test pieces are 4.0 mm Fe, 5.0 mm non-Fe and 8.0 mm SS.

4.10.4 Magnets

Magnets are not in use

4.10.5 Optical sorting equipment

No use of 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. However deviation was seen on frequency of cleaning of the evaporators and/ or airsocks which resulted in **Minor NC 5 4.11.2**

Specific or dedicated equipment, such as wizard knifes and balances are cleaned by own employees. Also the chilled storage areas are cleaned by own employees, working at the facility management department.

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 of 15-17 March 2022 (vertical test) and during the audit on site Cleaning schedules of are available and cover equipment, plant, buildings and services (with daily / weekly / monthly cleaning frequencies). Seen for the new production facilities / fase 2. Low frequent cleaning schedule (ceilings, walls above 2,5m, evaporators) are scheduled via the overview of periodic cleaning tasks. Pre-SSOP registrations are carried out correctly, deviations from schedule are followed up properly. However **Minor NC 6 on 4.11.5** was defined as belts were not dry after start up deboning /using belts.

Agar results are showing a slight increasing trend, but still below the standard. This is caused by a low water pressure due to the increased water usage due to the enlargement of the process (fase 2). Extra vessels are bought, and the issue will be solved within a couple of weeks.

During the site audit a dirty protective case of the fat analysing equipment at the mager met production area is found; this is reported as 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 ; CIP process blood vessels is verified with agar sampling. Results 2021 – 2022 are seen and are all good.

4.11.8 Environmental monitoring

Environmental monitoring is based at Listeria swabs with a frequency of 4x/year. Results of 2020-2021 are verified. There were a few positive results linked to cleaning of drains. Corrective actions are taken and effective, based at the results of the resampling.

4.12 Waste

The site has several types of waste materials. The removal of waste is done by contracted and only 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 are 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 was set risk based and performed 8x/year and a yearly in-depth inspection. Competences of pest control inspector is verified (EVM recognised until 2027-5-8). Pest control is part of the regular HACCP training for employees, to understand the signs of pest's activity and increase awareness. In case of detection, manager needs to be informed.

Report of the inspections at 2022-04-26 (incl. lamps/ plates check) and visit 2022-06-14 report was seen also on extra check on rat detection (outside near washing area), no infestation situations reported.

Measures for bird protection by the use of bird pens.

Follow up of recommendations of the pest control agency: 1 outstanding point related to maintenance of the outdoor area, which was in process during the audit.

The in-depth inspection was kept at 2021-08-18; one action demonstrably in progress (building environment) and of all other actions follow up actions are finalised.

The trend analysis of the pest control activities is part of the reassessment process. Stable trend, low activity of rodents and insects.

4.15 Storage facilities

The company is producing fresh pork meat. Carcasses are stored 1-3 days before they are cut to specification. Storage temperatures are controlled automatically via the system. Used temperature standards are in conformity with the legislative demands about temperature. Is verified for the temperature in storage area 18 (WIP) at the 2022-03-17 and the carcas storage 6 (2022-03-15): seen temperature is below the Vion standard and legal standards,
Production and expedition processes are organised based at the FIFO principle. Part of the production output is distributed to contracted frozen storage locations. Seen audit report of frozen storage 2022-03-14, ok

4.16 Dispatch and transport

Temperature during dispatch of the product is a CCP. Records of the CCP check and the pre-shipment process were verified during the audit and as a part of the vertical test. (17 March 2022) 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

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
4.9.1.2.	No strongly scented or taint-forming materials in use
4.9.4.	No products packed into glass or other brittle containers
4.10.2.	No filters or sieves in the process of this company
4.10.4	No magnets in use
4.10.5	No optical sorting equipment
4.10.6.	No container cleanliness-glass jars, cans or other rigid containers in use

4.13	No surplus food and products for animal feed in this company

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. The MOC procedure is used for the validation of the new middles processing department / fase 2; report 2021-06-05 is seen. The validation is still ongoing.

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. The system is the ‘‘cloud’’ , all used label printers are linked to .

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-10049, reviewed at 2021-05-20. Aspects like replacements and substitution are part of the vulnerability assessment. The company is certificated for IFS PIA. A daily mass balance is one of the requirements of the scheme. This is verified for 15 and 16 March 2022 (vertical test). The mass balance was within limits and is caused by a typical aspect in slaughterhouses: pigs staying overnight in the stable.
Organisation is certified for: QS, IKB, Better life 1*, SQMS, and IFS PIA.

5.5 Product packaging

The packaging and supplier approval are 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 Blue LDPE bag, used for the packaging of SDP

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, pathogens, blood samples, shelf life water, etc.) are subcontracted to an accredited laboratory operating in accordance with ISO 17025:
A microbiological monitoring program 'procedure planning monstername 2021 / P-BXT-NL-10011 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.

Sampling process is verified for Ham 4D /art . At request of the customer each produced batch is sampled at protein/fat/Salmonella/Listeria/ecoli; several results are checked; no deviating results seen.

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). Results of the monitoring programme are part of the quarterly based review of the food safety and quality system. Results are verified: stable trend for PCA, Salmonella has some positive results, no need for further action, because of the full cooking step in the chain (VO 2072:2005); no listeria in products found.

5.7 Product release

Products are released after the pre-shipment controls (e.g. packing/ temperature/batches) , 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 vertical audit (16/17 March 2022) (F-BXT-NL-10048)

5.8 Pet Food

No production of pet food.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.3; except 5.3.3.	No allergens
5.8	No production of pet food

6. Process control

6.1 Control of operations

Process conditions and methods are well monitored and re-validated when necessary. In case of breakdown of critical equipment, a system and procedures 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 aspects 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 at 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 including a test with Artificial Intelligence aspects in it.
The cooling system is linked to the system. In case of failures in the system an alarm system is in use. The temperature in the WIP/0 ºC storage and carcass cooling 6 is verified for 15 March 2022 (vertical test). Temperature was < 2 C.
Minor NC 7 was defined on 6.1.3 because CP 32 was not fully clear documented (storage of fresh meat) at production area
Daily meetings between management of the slaughtering department and maintenance department about break downs. This approach has reduced the level of breakdowns in the slaughtering department. This process will also be being implemented for the whole site.

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 art. numbers . The line was emptied including the site products. 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 (neck packaging) is seen; is calibrated at 13.03.2021.

6.4 Calibration and control of measuring and monitoring devices

Critical measuring equipment are listed in P_BXT-NL- Kal 10123: thermometers (CCP related), weighing scales, fat analyser 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 thermometers, (gas measuring) and scale expedition and slaughter department.

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

7. Personnel

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

There's an introduction training (incl HACCP, food defence, allergens and general hygiene rules) 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.
For the following employees training records are verified incl. the test results of the training followed after finishing the training sessions:

- 2022-04-21
- 2022-06-13
- 2021-03-26
- 2021-10-14
- 2021-03-26

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; version 2021-01-07 The document is covering the requirements of the BRC 8 standard. The wearing of any jewellery isn't allowed, medicines are stored in personal cabins only. Cuts are covered with detectable plaster incl. gloves. Effectiveness of the hygiene procedures for personnel is part of the SSOP systematic.
A sample of each batch metal detectable plasters is demonstrable tested.
Minor NC 8 on 7.2.1 as folded working clothes were brought into the canteen.

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 (incl. visitors) 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 and for some workstations more often. 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 , which is an approved supplier of services within Vion.

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. As a result of the Covid 19 protocol face masks are still worn in some areas (specially deboning and packing areas, as people are working close to each other).

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

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

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
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 BRCGS section 2.10.		
13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRCGS 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): A. Scale and severity of		

	threat if a contaminant is added to product B. Degree of physical access to the product C. 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 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.		
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		
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		

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.		
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.		
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.		
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.		
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.		
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.		
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.		
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.		
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.		
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.		
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.		
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.		
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.		
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.		
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).		
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		

14.1 Additional Specifier requirements

14.1 Traceability

Click or tap here to enter text.
14.2 Environmental Monitoring
Click or tap here to enter text.
14.3 Product inspection and laboratory testing
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14.4 Protective clothing: Employees or visitors to production areas
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