Audit Report

Global Standard for Food Safety Issue 7: July 2015

1. Audit Summary			
Company name	Vion Food Group	BRC Site Code	17768974
Site name	Vion Boxtel BV		
Scope of audit	The slaughtering of pigs and the deboning and cutting to specification and packing in bulk and consumer packaging of chilled pork, including Good Farming®-meat.		
Exclusions from scope	The intestinal washing process		
Justification for exclusion	Segregated process with clearly differentiated products		
Audit Finish Date	2018-06-20		
Re-audit due date	2019-06-28		

Voluntary modules included		
Modules	Result	Details
Choose a module	Choose an item	
Choose a module	Choose an item	
Choose a module	Choose an item	

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	A	Previous audit date	2017-06-14		

Number of non-conformities		
	Fundamental	0
	Critical	0
	Major	0

	Minor	10

3 Company Details

Address	Boseind 10 5528RM Boxtel		
Country	The Netherlands	Site Telephone Number	+31
Commercial representative Name	Mr.	Email	@Vionfood.com
Technical representative Name	Mr.	Email	@Vionfood.com

4 Company Profile

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

Subcontracted processes	No
Other certificates held	ISO9001, IKB, Tesco approved, SQMS, QS, Better life 1 star, Chain of Custody
Regions exported to	Europe Asia Oceania Choose a region Choose a region Choose a region
Company registration number	EG 61 NL
Major changes since last BRC audit	Change in raw materials: Belgium pigs, changes in management and value flow, cooling of organs with water bath (change in CCPs waiting for approval of Dutch Authority)

4 Company Profile

Company Description

Vion Boxtel BV is the biggest processing plant of pigs to meat and meat products in the Netherlands. The company is part of the Vion Food group. The company is slaughtering about pigs per day. Main customers are the retail plants of the Vion Food group (Vion Groenlo, Distrifresh) and the bacon plant for the British market and Asia (Vion Scherpenzeel), as well as companies producing for large retailers, such as . The company also delivers directly to retail international and industrial customers. Legs are particularly produced for Spain and Italy. All pigs are bred by Dutch and Belgium farmers and reared conform the Good Farming principles (IKB); a part of them are also reared regarding special Welfare demands. The company has a approved system to comply with welfare demands. The company has ca. own employees with a possible extension tc workers. A considerable amount of the employees is working at a temporary base in 2 shifts. Most of them are from East European countries such as Poland. 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 officially approved 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-study. The pork is packed at semi-bulk level and there are some vacuum-packed consumer goods. EG number is NL61 EG. Website: www.Vionfoodgroup.com

5 Product Characteristics

Product categories	01 - Raw red meat Category Category 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				

5.Product Characteristics

Allergens handled on site	**None** Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	**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	**Raw red meat of pork from slaughtering till primary cutting: half carcasses, legs, shoulders, middles, bellies, necks, loins, minced meat, organs, vacuum packing of fresh meat**

6 Audit Duration Details

On-site duration	24 man hours	Duration of production facility inspection	12 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)	2018-06-18	9:00	17:15
2	2018-06-19	9:00	17:30
3	2018-06-20	9:00	17:15

	Auditor (s) number(s)	Names and roles of others
Auditor Number		– Lead auditor
Second Auditor Number	N/A	- Trainee

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 1.1.9) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Plant Manager	X			X
QA manager & Facilities	X	X		
, Manager Slaughterhouse		X	X	
, assistant Technical department	X		X	

Present at audit				
employee Slaughterhouse/ CCP controller		X	X	
Foreman slaughterhouse		X		
Department manager veredeling department		X	X	
Department manager veredeling department		X	X	
, Retouren and incoming meat		X	X	
facilitair manager			X	
Production manager internal logistics and packing Asia	X			X
operators expedition		X	X	
Employee QA department			X	
, Employee QA department			X	X
Employee QA		X	X	
Manager HR	X			X
Production manager Slaughter- and cutting department	X			X
, Manager Cutting department	X	X	X	X
Financial Controller	X			X
Manager Planning	X			
Production manager veredeling and packing department	X			X

Non-Conformity Summary Sheet

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

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

Major

No.	Clause	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.	Clause	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	2.7.1.	The Groups procedure Hazard analyses P-FOOD-10000 and based on this procedure, hazard plan for the site P-BXT-NL-10116, dated 8-6-2018, do not document the potential hazards during:	We altered those changes in our documentation which had potential hazards and which were not already recorded.	**Preventive action:** We discussed with the department managers that they should inform the quality department in case of any change of the production process,	Evidence sent by mail: adjusted Hazard plan of the site P-BXT-NL-10116 rev 29, dated 11-7-2018. Including the items mentioned	2018-7-20	Fully closed by

		- ham storage (hams are produced in Boxtel but kept in the trailer during the time that there is no time/ place for deboning) - the process of "mager met" and packing of collars (ice is used for cooling) - the cooling process in the watertank in the organ chiller department - the risk of specific pathogens (non-proteolytic Clostridium botulinum) during the vacuming process and shelf life of max 21 days No direct risk assessed because control measures were seen: temperature measurement, use of ice, testing of water, micro analyses and Com Base growth model for Clost. bot (non-prot) for 14 days vacuumed meat		then we can decide if we have to alter the documents. Preventive action: **Cause analysis:** Some processes where altered some time ago, and because the altered process is similar to already described processes, it is not always needed to add them in all the documents. The validation of the water tank was not completed yet and therefore this was not yet added to the documents We as Vion reasoned out that there was no risk Clostridium botulinum) during the vacuuming process and shelf life of max 21 days,			

				therefore the hazard analysis is not altered			
2	2.14.1	Validation report "Organen cooling update" dated 15-6-2018, does not contain a conclusion or formal approval by the HACCP team, demonstrating that all risks were under control before the organisation started the process on site (this eventually with a corrective action list with low risk actions to be executed). During audit, the process was assessed including analyses executed (water, listeria), temperature control, glass audits. No direct risks identified. However, follow up of validation and corrective actions need to be taken and finished.	The validation is completed and approved by the HACCP team	**Preventive actions:** Potential risks are checked now by Risicobeoordeling nieuwe machine, ruimte en proces F-BXT-NL-10120 before changes are made. A complete validation can only be created after a change is implemented. As stated in Procedure Validation of the HACCP system P-VION-10003 **Cause analysis:** We did not record the risks because we found no new risks.	Evidence sent by mail: Validation report dated 6-7-2018 including analyses and conclusions. Approval of the validation by multidisciplinary team during the HACCP meeting of 10-7-2018	2018-7-20	Closed by Follow up will be given next audit to correct validation process with approval before use (process or equipment).

3	3.4.1	Internal audits including the whole standard are executed only 2 times a year. One unannounced (executed 25-10-2017) and one announced (was planned in May but now scheduled the end of June 2018). Because not all requirements are audited each half year, the consequence was that with delay of the audit scheduled the TD and audits at the office are not executed yearly/ during the year. (processes/ activities were clearly added to a year schedule as corrective action after the audit of 18-5-2017)	4 internal audits are performed on a yearly base. 2 regular internal audit 1 animal welfare audit and 1 Pre In these audits all departments are covered.	**Preventive action:** We will discuss the regular internal audit with the QA group. How we can assure that the audits are performed as planned. Also we will consult the other audit reports when needed. **Cause analysis:** At the moment there is no supervision of the planned audits. We forgot to consult the other audit reports.	Evidence sent by mail audit found which was executed on 28-8-2017 (not provable during audit) including part of the IFS requirements	2018-7-20	Closed by Follow up will be given to execution of the audit plan of the audit and scheduled audits to see if all activities are covered at least annually
4	4.3.4	According to EG 853/2004 the organisation shall have facilities for disinfecting tools with hot water of at least 82 degrees, or an alternative system that has an equivalent effect. The equivalent effect was not	We planned a test to prove that the disinfection with for knives & belts is equivalent to water of 82 degrees.	We tested the disinfection with for knives & belts to prove that is equivalent to water of 82 degrees.	Evidence sent by mail: Tests performed with on cfu and Enterobacteriaceae	2018-7-20	Fully closed by

		provable for the cleaning with . used for knife and glove after "meat fixing" at the cutting department.		**Cause analysis:** We were testing at the cutting department and did not yet tested the affectivity as stated by the producer	on 2-7-2018 with good results		
5	4.6.2	By incident control measurement equipment was not disinfected directly before use: - expedition: temperature measurement equipment was not disinfected as documented in P-BXT-NL-10084, dated 19-2-2018. - "veredeling": test pieces were disinfected but laid on table/paper before used for check of the metal detection system (In general good monitoring of temperature including correct disinfection and daily verification was seen during the audit).	The staff was reinstructed directly., to stay calm and relaxed and to use the alcohol tissues as instructed.	**Preventive action:** We altered the instruction of the CCP temperature check and the procedure of the metal detection. The use of alcohol tissues is added. Therefore we are sure that the staff is correctly instructed. During the verification of the CCP and the Ssop this will be monitored. **Cause analysis:** The concerning staff was in some way a	Evidence sent by mail adjusted procedure P-BXT-NL10171 dated 13-7-2018 with disinfection step and sigh on the wall to use monitoring equipment correctly. Verification step is part of the daily process	2018-7-20	Closed by Follow up will be given to practice: correct use of disinfected equipment during monitoring activities

				bit stressed by performing the checks during the audit.			
6	4.8.1	Cleaning facilities are used for shoes when entering the production department. During the audit was assessed that someone from the production went outside with a waste car and entered again into the production department via the back door of the site. There is no cleaning facility for boots or wheels at the back side.	The concerning staff is reinstructed that only after production, it is allowed to enter the production area from outside without hygiene measures, because than there is no possibility of cross contamination, because the product are stored in the cold stores and the cleaning en disinfection is performed by the cleaning company.	**Preventive action:** We informed the managers, that if the routing has to be changed, first contact the quality department, to check if this is according requirements and document have to be altered. Also a sigh is placed next to the door. **Cause analysis:** Due to the fact that the crusher can't handle carcass parts anymore the Category material had to transported by cars instead off pipeline.	Evidence sent by mail: photo of sigh on the door	2018-7-20	Closed by Follow up will be given to practice: correct use of routing from inside to outside and vice versa by staff

				They forgot to check if this meets the requirements.			
7	4.10.1.2	For production of "mager met" it is not provable that industry best practice is applied. Yearly calibration is executed but no validation, proving most sensitive practical setting which allows consistent rejection without false rejects, using test pieces of a size just above the limit of detection.	We tested to spread the "mager met" to improve the sensitivity for stainless steel. We could reduce it to 7mm. Therefore we adjusted the form and the metal detection check to this. The supplier will perform a new calibration on 16-07-2018.	**Preventive action:** We let us advise by the supplier of the metal detector, when we need a new metal detector or want to use it for another product. **Cause analysis:** We bought a new metal detector, without checking if our product flow could be spread.	Evidence sent by mail new form for metal detection with lower sensitivity of SS (7 instead of 8 mm): F-BXT-NL-10070, dated 6-7-2018	2018-7-20	Fully closed by
8	4.11.2	According to procedure different knifes (yellow and black) are used to ensure changing of knifes during the break. At the cutting line it was assessed that this was not executed correctly; a box with knives of wrong colour was still hanging at the line	The knives box was stored it the rack for cleaning. The staff was reinstructed, to change the knives box at every break.	**Preventive actions:** We informed the foreman and staff which perform the Ssop to check this during production. **Cause analysis:**	Evidence sent by mail: check by SSOP F-BXT-NL10038 on 3-7-2018 of CP2 cross contamination by knife	2018-7-20	Closed by Follow up will be given to practice the correct cleaning of knives (use of correct

		although operator was on break.		This was a new staff, who forgot to change his knives box.			coloured knife-boxes on the cutting line)
9	5.2.1	During the trace test, the invoice to the supplier of article 45403, 20014,4 kg delivered on 24-4-2018 was not in accordance with product produced. The product fresh pork shoulder 4xD in vacuum was correctly labelled and produced on 21-4-2018, with slaughter date 20-4-2018 and best before date of 12 May 2018. The invoice including "Declaration of Producer", health certificates and packing lists documented a production date of 24-4-2018, slaughter date of 20-4-2018/19-4-2018 and best before date of 15 May 2018.	We cannot correct this invoice anymore. But we will keep the correct data in case of a recall. However we will perform additional checks to prevent this from happening again	**Preventive actions:** An additional check of the products in stock, not yet set in an order will be checked after scanning to an order. **Cause analysis:** Due to the fact that our warehouse system had a revision, the original data was lost. We did not noticed this during scanning and loading therefor the document department received the wrong data.	Evidence sent by mail: paper with additional check to be performed on the products in stock, these products not yet set in an order will be checked after scanning to an order.	2018-7-20	Closed by Follow up will be given to practice evidence of additional checks executed and correct invoice

10	6.1.2	During the audit on 19-6-2018 it was assessed that the temperature of organs was measured above limit on 13.00 hours (kidneys) and 13.30 hours (diaphragm) and documented on F-BXT NL-10161. Corrective actions taken (use of ice/ storage in cooling department) were not provable.	The staff is reinstructed to record the exact corrective action . The Kidneys and the Diaphragms are measured again before loading, no deviations were found	**Preventive actions:** We discussed if the method of recoding and instruction was sufficient, with the manager and foreman. Therefore the checklist is altered, with a recheck and the supervisor must be notified when the temperatures are too high. **Cause analysis:** The staff was due to the fact of the language barrier not fully aware of the conditions from the actions. Also could therefore not explain the actions which were taken	Evidence sent by mail adjusted F-BXT NL-10161, dated 13-7-2018, including corrective actions to be taken.	2018-7-20	Closed by Follow up will be given to practice and correct documented actions taken.

Lloyd's Register LRQA

Comments on non-conformities

Voluntary Modules Non-Conformity Summary Sheet

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

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

FSMA Module Non-Conformity Summary Sheet

Critical

No.	Clause	Details of non-conformity	Anticipated re-audit date

Major

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

Lloyd's Register LRQA

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

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The company has a management team which meets regularly. Formal communication meetings are held at several levels within the organisation; weekly MT (Plant manager, 3 production managers, HR manager, Controller, QA manager and TD manager, Planner), daily level 1 (department managers, planning, F&A, QA, HR, FD and TD)), 3-dayly Team huddle (department manager, team leader and operators). Records seen: Minutes of meeting MT, planning boards and action lists.

Food safety and Quality is part of the policy "Passion for better food" P-BXT-NL-10126 and signed by the plant manager on 3-1-2018.

Relevant Quality Objectives for 2018 have been defined for Safety, People, Delivery and Costs. More specific: eg. reduction of complaints, waste control, training of staff, optimising of quality and efficiency besides several projects.

The management review is kept at a yearly base, a clear management review June 2016– June 2017 is demonstrable and discussed during the MT meeting of 1-9-2017. The review contains the verification of the HACCP system, complaints, the review of the objectives, training activities, changes and the preventive and corrective actions.

The management review contains also evidence for continuous improvement (e.g. PDCA cycle, projects (organ chilling) and microbiological analyses by).

The 8 non-conformities identified at the previous BRC7 audit against the Global Standard for Food Safety are effectively corrected: the minors were fully closed.

1.2 Organisational structure, responsibilities and management authority

The organisation is defined (Organogram 31-5-2018). is Site Manager from Vion Boxtel BV.
The departmental managers directly report to the Site Manager. The Key staff (Controller, HR Manager, Planner, Coordinator QA, Manager TD, Manager Service Bureau and the 3 production managers) directly report to the Site Manager.
There have been some changes in responsibilities, circulation of staff who was already working for the site for a long time.
All staff personnel have job descriptions. They give the summary, essential duties and responsibilities, prerequisites, physical demands and work environment.
Procedure P-BXT-NL-10247 describes the arrangements for absence of staff.
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.

Details of non-applicable clauses with justification	
Clause reference	**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 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.
The QA manager is the food safety team leader; he`s sufficient educated and experienced. Food safety team meetings are on request, but the team leaders of the safety team are also part of the MT (multidisciplinary composition) which meets weekly. (P-BXT-NL-10028, dated 31-5-2018)
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.
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 meat products and a few vacuumed consumer products (Italy).
The company has defined 8 Critical Control Points (CCP's) relating to product safety and the scope of the BRC audit following P-FOOD-10000, dated 29-7-2014:

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 (50%) at dispatch, <= 31,2 ºC;
5. Temperature control of partially chilled pork meat (70%) at dispatch <= 21,9 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.

Procedure P-BXT-NL-10177 dated 8-6-2018 documents the CCPs. CCP 4 and 5 have been changed lately waiting for approval by the Dutch Authority, there has been no production of partially chilled pork meat since. New limits will be:

Temperature control of partially chilled pork meat, during 6 hours of transport, surface <= 7,0 ºC;

Temperature control of partially chilled pork meat during 30 hours of transport, surface <= 7,0 ºC, temperature <= 15,0 ºC .

The Hazard analyses of Vion Boxtel BV is documented as P-BXT-NL-10116, dated 8-6-2018.
Flow diagram is prepared and available on VION on-line: P-BXT-NL-10026 from 10-11-2017. This procedure includes 6 flow diagrams: Entering pigs, Clean slaughtering, Chilling/ cooling, Cutting, Packing, Expedition.

Validation takes place of changes in products or processes, which may affect food safety aspects. Verified for organ chilling, dated 15-6-2018.
Daily verification is part of the production process and assessed. The verification report of period 17-10-2017, as part of the management review is seen. Corrective actions are discussed in the MT-meeting. Also quarterly report was assessed of 6-4-2018 including follow up of KPI's.

Minor NC: hazard analyses was seen not complete.
Minor NC: Validation report does not contain a conclusion or formal approval, demonstrating that all risks were under control before the organisation started the process.

Details of non-applicable clauses with justification

Clause reference	Justification

3. Food safety and quality management system

3.1 Food safety and quality manual

The company has a Quality Manual, complying with ISO 9001 and BRC 7 requirements, which states the company's commitment to quality and food safety. The quality manual is the total of all quality documents, including procedures, work instructions, HACCP analysis and registration forms.

3.2 Documentation control

An electronic quality manual named ' is in place. Changes in old versions of documents are maintained and checked during the audit.

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 (and 5 years elsewhere).

3.4 Internal audit

There are detailed schedules of internal audits against documented procedures, carried out by trained independent staff. Last time the audit was executed by QA manager of Groenlo, who is a trained independent auditor QMS and had TOJ for BRC).).

Twice a year the production sites and involved departments are audited. There is a schedule for the internal audits according to procedure 'interne audits' (P-VION-10011). The audit frequencies are based on the risk of the activity to the business, the operation and the customers. A hard copy of internal audit reports is maintained.

Non-conformities are clearly listed with their corrective actions. Nonconformities seen for audit of 25-10-2017 (Vion unannounced audit) including verification of the nonconformities of the audit of 18-5-2017. Results of the internal audit are reported to the personnel responsible. Minor and Major nonconformities which arise are documented following the internal procedure. The corporate quality department has to accept the action plan suggested. Detailed records of former internal audits (4-11-2016) are available.

Minor NC: With the delay of the audit of May 2018, it was not provable that all requirements were audited yearly.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials 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 product delivered (trace test and during the audit by

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

3.5.2 Raw material and packaging acceptance and monitoring 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 government).
Vion Boxtel BV is also processing meat, delivered by other Vion plant in Apeldoorn (Dutch hams). The temperature of incoming meat is CCP6.
Packaging materials is 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).
There's an audit plan for external suppliers, based on risk management.
Yearly monitoring of suppliers is executed and seen from 11-2017. The monitoring is executed as part of the overall monitoring of the Vion Food Group. Supplier of pest control, cleaning and protective clothing (gloves) was part of it.

3.5.4 Management of outsourced processing and packing

No outsourced processing (subcontracted: freezing of packed product in collaboration with customer.) The cold store is an approved supplier

3.6 Specifications

Specifications for raw materials, packaging materials, cleaning agents and finished products are available. Samples of specifications taken at this visit demonstrate control. This is verified for:

Customer requirements: "Vion klantkaart" article Jowl steak and article schoulder 4xD in vacuum.
Foil: foil including migration tests and Declaration of conformity
Pigs: Welfare, IKB, BL (several checks during delivery on authenticity, antibiotics, etc)
Others: Cleaning agents: and ., transport belt, nitrile gloves.

3.7 Corrective and preventive actions

In general, good follow up was seen from corrective and preventive actions taken by the company; e.g., complaints, audits, PRE SSOP and SSOP inspections, out of spec analyses, blocked products.
Improvement and prevent of recurrence of failures was provable.

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. Good follow up according to procedure was seen during the audit for received retour (Product thick skirt was blocked because temperature was above limit).

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)
- Retail (separate cell and label)

During the audit a traceability test was performed on article shoulder 4xD in vacuum produced on 21-4-2018 including mass balance, specifications, process records, (pre-shipment) checks and distribution details. 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.
Yearly trace tests are documented verified upwards and backwards. Besides that, daily integrity calculations are performed on production of different classified pigs: Belgium, Star, Welfare and others.

3.10 Complaint handling

Complaints are received by Sales at central office (Boxtel). Any complaints which are considered to be attributable to the site are communicated and investigated. The procedure for complaint handling (P-BXT-NL-10096) defines types of complaints and addresses requirements in terms of incident reporting as these are escalated to relevant personnel for review and action (corrective / preventive) as appropriate. All complaints are trended and reviewed by the site management team based upon database and weekly reported (K&M-monitor).
There is a KPI on complaints, for 2017/2018 set on: 90/week and food safety 0,02/ 1000 kg.
Complaints are well managed with weekly performance documented and provable actions taken.
In 2017 there were 4718 complaints (not taken into account weight and sales complaints and in 2016 there were 4778 complaints). This was less than in the years before. In 2017 there were 428 food safety complaints and in 2016: 455. Most of the food safety complaints were plastic complaints (foil, parts of

crate, dolav), corrective actions taken were provable including root cause. (Besides that, there were some glass complaints and Metal complaints (16; mostly related to injection needles used by the farmers).

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 time 8-2-2018. No recalls since last BRC audit.

3.12 Customer focus and communication

Bulk products are delivered with product specifications based on customer requirements. Specific cutting requirements are documented in meat specifications assessed at the lines.

During the audit follow up was given to specific requirements from customers; eg specific cutting requirements, best before dates, metal detection requirements on tongue, weight, colours of packaging and specific micro analyses.
Only a few products are direct delivered as consumer products eg. king size tenderloin for Sweden.

Details of non-applicable clauses with justification

Clause reference	Justification

4. Site standards

4.1 External standards

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 Security

24h 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 29-7-2016 and documented. This plan was reviewed during the yearly verification process.

4.3 Layout, product flow and segregation

The 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. Plan of 11-5-2017 assessed.

Minor NC: Not provable was that knives were disinfected equivalent to the system documented in 1935/2004

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. 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.

4.5 Utilities – water, ice, air and other gases

Utilities constructed, maintained and monitored to a good level. The water used for cleaning and process is mains water. Testing of water (chemical/microbiological) is incorporated in the testing programme(s) P-BXT-NL-10009 and P-NL-Food-10.196C. The samples are analysed by , which is an ISO 17025 accredited laboratory (L132). Water quality is defined as a general control measure. A new plan of the water distribution system from 2016 is in place. Tests are executed 4 times a year, last tests assessed from 26-3-2018, with good results.

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 chilling of organs assessed. Food grade / contact compliance documents were seen from transport belt.

Minor NC: By incident control measurement equipment was not disinfected directly before use.

4.7 Maintenance

Equipment is maintained using the maintenance system ( ). This will be replaced by in the future. Maintenance consists of ca. 30 employees; mechanics and a manager and assistant manager. Maintenance is also outsourced to established 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.

Lubrication is planned and all used lubricants are food grade with a FDA H1 status (food grade).

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 separated from the production but in production also a technical department is available named "het bunkertje".

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 is 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.

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. Temperature is checked following HACCP plan.

No high risk / high care operation.

Minor NC: There is no cleaning facility for boots or wheels used at the back side.

4.9 Chemical and physical product contamination control

Raw material handling, preparation, processing, packing and storage areas

Chemical cleaning agents are well controlled. Good manufacturing practices are in place in production. Storage and application of chemicals are in line with the requirements

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.
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 checklist. New plans were made for 2018 to use. Glass audits assessed from 6-3-2018 including the hygiene corridor and organ chilling department.
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 meat products (only non-food area; storage of packing materials).
4.10 Foreign body detection and removal equipment
4.10.1 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, area for tongues and "mager met". Minor NC: For production of "mager met" it is not provable that industry best practice is applied.
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, executed 14-5-2018. 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.

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. Procedure for cleaning and planning were assessed.

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) were also assessed. 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.

Cleaning is validated 27-5-2016. Dosage units are calibrated yearly by external party and supplier of cleaning agents and the check in 2018 was seen during the audit. Cleaning agents are labelled and stored in a locked area. Segregation is used for cleaning agents and for internal use by Vion Boxtel.

Analyses (agar, pH) are made of the controls for cleaning effectiveness. The results are discussed with and used for a bonus/malus system.

Listeria tests on environment are executed 4 times a year 10 places. One positive analyses last year in the cutting department (12-10-20170. Corrective actions (cleaning consultation) provable including new analyses taken which was negative (17-10-2017).

logbook was assessed, as well as several pre-SSOP's and the agar and swabbing results. Corrective action in case of unsatisfactory cleaning is demonstrable and registered on the pre-SSOP list (distinction is made between direct corrective measure, or repeating cleaning after production). Verification on cleaning takes place (F-BXT-NL-10005).

Minor NC: Different knifes (yellow and black) are not correctly used to ensure changing and cleaning of knifes during the break.

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.

4.12 Waste / waste disposal

There are contracts with two licensed waste disposable companies:

- Paper-carton and other non-food waste materials (
- Category 2 and 3 waste

The waste collection is clearly identified during storage and stored segregated

4.13 Management of surplus food and products for animal feed

It's the policy of the organisation not to use surplus food for third parties. There are 2 products going to consumers, those products are labelled at the end of the process. Products identified for waste are unpacked and segregated

4.14 Pest Control

External subcontractor services the pest control since 29-3-2016. Points of attention are:

- Rodents
- Cockroaches and crawling insects
- Flying insects

The frequency of control is 8 x / year; maintenance of EFK is 1 x / year and determination 4 x / year. All documentation is present in the contract map of and electronically. Analyses can and are made from this programme. Maps are available (online) detailing the location of baits / traps, electronic fly lamps, etc. All MSDS and specifications of used pesticides are present. No toxic pesticides are used in the production area. Infestations are reported via the online programme.
Records were seen from 7-3-2018 and 14-6-2018 and PRI (in-dept pest control survey) executed on 17-10-2017.
Trends are available and follow up of corrective actions. Extra actions were taken during pest activity from rats outside verified for 23-5-2018. (Space under the site was renewed last year as preventive action on pest).

4.15 Storage facilities

The company is producing fresh meat. The main part of the production is delivery daily chilled. Carcasses are stored 1 day before they are cutted and boned. Storage temperatures are controlled automatically via the system. Used temperature standards are in conformity with the legislative demands about temperature, this is verified for the cooling departments and production rooms (beneath 12 degrees).
Production is organised based at the FIFO principle. Production is sold to customer or Vion West who has a subcontracted storage and freezing at Both cold stores are BRC-certificated for storage and distribution and approved suppliers.

4.16 Dispatch and transport

Temperature during dispatch of the product is a CCP. Records were verified during the audit and during the audit also the verification process of the organisation is checked (verification of temperature is daily performed by the organisation) via CCP checklist F-BXT-NL-10045. All checked CCP's are checked at random to verify correct measurement and registration, twice a day by production leader or other approved verifier on F-BXT-NL-10048.
Transport is organised and scheduled by the Service desk. They are only making use of 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. Sampled transporter ( ) was GFSI certificated and questionnaire was in place.

Details of non-applicable clauses with justification

Clause reference	Justification
4.3.5.	No high risk, products undergo full cooking prior to consumption

4.3.6.	No high care, products undergo full cooking prior to consumption
4.3.7	No ambient high care, products undergo full cooking prior to consumption
4.4.4	No high care or high risk area
4.4.13	No high risk, products undergo full cooking prior to consumption
4.5.3.	No use of non-potable water
4.7.5.	No high risk or high care area
4.8.4.	No high risk, products undergo full cooking prior to consumption
4.8.5	No high risk / high care / ambient high care in place.
4.10.4	No magnets in place
4.10.5	No optical sorting equipment in place
4.10.6	No glass/brittle plastic containers used.

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.

Shelf life / best before date trials are coordinated by the central QA department of Vion Food, except for shelf life trials on customer demand. Data derived from these tests is, when applicable, adopted by Vion Food. 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).

5.2 Product labelling

Bulk products are delivered with product specifications based on customer requirements. For customers with specific requirements an agreement is signed, it includes positive release and more than the standard analyses each batch (like Salmonella free for king size vacuuming product for Sweden).

Minor NC: The invoice to the supplier of article , delivered on 24-4-2018 was not in accordance with product produced and its label. Wrong slaughter date of 20-4-2018/19-4-2018 and best before date of 15 May 2018.

5.3 Management of allergens

No allergens on site under current scope, only production and handling of fresh meat.

5.4 Product authenticity, claims and chain of custody

There is a procedure P-BXLNL-10216 Risk management third lands IKS and process/ product integrity dated 13-6-2018.
Vion Boxtel uses the GoodFarming* mark for designated meats, which are controlled and monitored throughout the chain (from breeding, livestock/pigs to slaughter). Products of this label carry a "GB" claim at dispatch. Most of the processed livestock has a good farming * origin, this is more than the actual sales of good farming * products. During the receipt of pigs authenticity is checked by using the portals were IKB/Welfare farmers are registered.
Daily a mass balance of the good meat is made containing the different marks: Belgium, good farming*, Welfare and others, and was assessed of 15-6-2018 (0,3 % deviation that day).

Organisation is certified for: QS (SGS, 20-11-2018), IKB (2-11-2018), Better life 1* (1-11-2018), SQMS (14-3-2019), (green audit executed 1-12-2017 by), Chain of Custody (13-12-2018).

5.6 Product packaging

The packaging and supplier approval is controlled at Vion Food central office. The central system is a part of the multi-site ISO 9001 approval. Primary packaging materials are appropriate for the intended use. 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.

5.8 Product inspection and laboratory testing

5.8.1 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;
Besides above analysis specific tests on customer demand are executed and yearly tests on ochratoxin and heavy metals.

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.
Microbiological results from "shoulder 4xD in vacuum" from 2018 YTD were assessed besides an overview of analyses performed on carcasses, trimmings, deboned meat, technical cuts, by-products and organs.
When results were above CCMT standard (beneath legal standard), corrective actions are taken. Besides better performance last year provable improvements were seen for the decontamination oven to reduce Salmonella and entro's on carcasses.

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).

Details of non-applicable clauses with justification

Clause reference	Justification
5.3	No allergens on site

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. This was verified during the audit when there was a problem with the oven.
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.
The cooling system is automated and registered real time.

Maintenance of the cooling equipment has the highest priority. Real-time temperature-recording equipment is linked to an automatic alarm system. Alarms are set and maintenance department is notified of any alarm. The system is tested regularly.

Minor NC: Corrective actions were not provable after temperature measurement of organs above limit on 19-6-2018.

6.2 Labelling and pack control

Packaging takes place in line with production planning and customer requirements. QC tests (product labelling, traceability code, shelf life, disclaimer, seal control) carried out in accordance with specifications. At the packing department, checks on labelling are carried out between batches. These products are checked on labelling also after pelletizing to ensure that correct labels are used.

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 the weighting scales of 3-1-2018 by assessed (eg. serial number).

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 PT 100 ( ) executed 1-10-2017. Control of temperature device equipment nr. 401 and 201 executed internal on 12-6-2018 with referential temperature device 15169122 calibrated by . 2-3-2018.
Metal detection device was calibrated 22-3-2018.

Details of non-applicable clauses with justification

Clause reference	Justification

7. Personnel

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

The HR department is responsible for archiving and monitoring training records. CCP trainings for CCP 1 to 8 was seen for several operators and workers (Training on CCP every 3-year verified for (26-11-2015) and (17-3-2017). Daily verification execution of CCP was seen. The hygiene training/induction

training with test was assessed during the audit and present for 4 sampled employees. Since 5-3-2018 this is arranged by e-learning/ film and 50 questions to be answered.

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 7 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.

7.3 Medical screening

The medical screening is part of the intake of new employees and part of the instructions to visitors. Assessed for 4 workers, among which temporary workers. (Review every 5 year). 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.

Details of non-applicable clauses with justification

Clause reference	Justification
7.4.4.	No high risk or high care area

Module 8 - Traded Goods	
Scope	
8.1 Approval and performance monitoring of manufacturers/packers of traded food products	
8.2 Specifications	

8.3 Product inspection and laboratory testing
8.4 Product legality
8.5 Traceability

Module 9: Management of Food Materials for Animal Feed	
Scope	
9.1 Management Commitment	
9.2 HACCP	

9.3 Outsourced Production
9.4 Specifications
9.5 Traceability
9.6 Chemical and Physical Product Contamination Control
9.7 Labelling
9.8 Training

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 15 FSMA Preventive Controls Preparedness Module

Item no.	Clause	Module item	Conforms (Y/N)	Comments

1	117.20	Handwashing areas, dressing and locker rooms, and bathrooms must have adequate lighting.		
2	117.37	The water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
3	117.40	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	117.80	Ice used in contact with food must be manufactured in accordance with the good manufacturing practice (GMP) requirements of 21 CFR § 117.		
5	117.110	Where defect action levels (DALs) 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	117.130 (a)	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 that affect food safety.		
7	117.130 (b)	All identified, known, or reasonably foreseeable hazards must be evaluated to determine 'hazards that require a preventive control' (i.e., significant hazards).		
8	117.135	Establish one or more preventive control(s) for each identified 'hazard that require 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	117.139	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 of recalled product (i.e., destroy, divert, repurpose).		
10	117.145	Establish monitoring activities and a written procedure for each preventive control in a manner consistent with the requirements of BRC section 2.10.		
11	117.150	Establish corrective action procedures when preventive controls are not implemented in a manner 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	117.160	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring revalidation 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	117.165 (a)	The PCQI (or authorized designee) reviews the 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 their authorized designee) reviews the verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record has been created.		
14	117.165 (b)	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 an analysis • corrective action procedure where a pathogen is detected.		
15	117.165 (c)	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 the analysis • corrective action procedure where a pathogen is detected.		
16	117.165	Devices used to **verify** preventive controls must be calibrated.		
17	117.180	Identify a PCQI responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training or qualifications via job experience.		
18	117.305	All records required by 21 CFR § 117 must include: • the date and time of the activity being documented • signature/initials of individual performing the activity or conducting the record review • information to identify the facility (e.g., name and location) • the identity of the product and lot code where applicable.		
19	117.310	The owner, operator or agent in charge of the facility must sign and date the written food safety plan initially and again upon any changes following reanalysis.		
20	117.315	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	117.405	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	117.420	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	117.430	One or more supplier verification activities (as defined in 21 CFR § 117.410(b)) must be conducted for each supplier **before** using raw materials and ingredients **and** periodically thereafter at an adequate frequency.		