Audit Report

Global Standard for Food Safety Issue 7: July 2015

1.Audit Summary

Company name	VION Tilburg BV	BRC Site Code	1886989
Site name	VION Tilburg BV		
Scope of audit	The slaughtering of cattle and the deboning, cutting to specification and packing (foil or vacuum) of beef. The production and packing (foil or drum) of slaughter by-products, semi-processed scalded stomachs		
Exclusions from scope	none		
Justification for exclusion	na		
Audit Finish Date	2018-04-25		
Re-audit due date	2019-05-19		

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	2017-05-19		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	9

3.Company Details

Address	Enschotsestraat 28 5013 BD Tilburg		
Country	The Netherlands	Site Telephone Number	+31 0 13 462 08 00
Commercial representative Name		Email	@ vionfood.com
Technical representative Name		Email	@vionfood.com

4 Company Profile

Plant size (metres square)	10-25K sq.m	No. of employees	51-500	No. of HACCP plans	1-3

Subcontracted processes	No
Other certificates held	ISO9001, Organic, CoC, BL**
Regions exported to	Europe Asia North America Choose a region Choose a region Choose a region
Company registration number	NL 87 EG
Major changes since last BRC audit	Ceasing of processing of first stage of natural casing (cleaning/ salting of bovine intestines). Installation of x-ray equipment for fat measurement; employment of 20-25 employees from agency.

Company Description

VION Tilburg B.V. is a cattle slaughterhouse and industrial butcher. It is one of the 11 sites of VION Beef (3 sites in The Netherlands and 8 in Germany) who has also 13 sales offices world wide. Recently the second slaughtering house in The Netherlands in Leeuwarden is opened which had impact on the Tilburg site because knowledge and personnel was transferred. The location Tilburg is NVWA approved (NL 87 EG). VION Tilburg B.V. produces beef products and slaughter by-products (like organs, processing of stomachs (scalding) and the processing of first stage of natural casing (cleaning/ heating of bovine intestines)). The animals are bought by VION Rundvee B.V. at the general market. The capacity of slaughtering is about cows and bulls per day. Currently the market is out of balance. Last year a double amount of cattle was slaughtered as a result of the forced national reduction of cattle. Past months and during this visit a regular amount was re-established and processed. In addition to slaughtering fresh beef in quarters is purchased and deboned. And also trading in beef (outside scope)

is done. The cutting department is supplied by pre-selected carcasses and very first cutting. The department includes about 3 main routes (forequarter, hindquarter and butcher handling). There are many equivalent activities (deboning, cutting to specification). Packing is at semi-bulk level (no consumer packed items). Trimmings are packed loose in crates/ dolavs or vacuum packed. The by-products are packed loose in crates/ dolavs or vacuum packed. The main customers are operating companies in the VION Food Group, retailers related processing within the Netherlands and Europe, and business to business in Asia and Canada. The site is situated at an industrial area near the centre of the town Tilburg. The oldest part of the building is from 1920. In 2006 a new building for the cutting and packing departments has been constructed.

Currently plans are defined on extending staff facilities, extending storage of crates and primary packaging material, and alteration of offices..Some beef is sent to an external provider for freezing, packing and final storage (GFSI certificated.). Some products from sister VION company in Enschede are cross-docked in Tilburg..VION Tilburg B.V. is certificated against ISO 9001 (multi-site certification) and holds SKAL approval (001997), CoC declaration and certificate for trading of BL2* meat. At the moment the company employs approximately people (including subcontracted personnel). The production takes place in one shift. The surface is 15000 K sq. meters and the used quality system is based on two HACCP-studies.
www.vionfoodgroup.com

5.Product Characteristics

Product categories	01 - Raw red meat Category Category Category Category Category				
Finished product safety rationale	Cooled red meat and by-products. Beef intended for further raw processing is under a positive release regime.				
High care	No	High risk	No	Ambient high care	No
Justification for area	Appendix 2 has been applied. In general beef and by-products are heated in one of the next stages of processing at the customer. Beef intended for further raw processing and consumption is under a positive release regime.				
Allergens handled on site	Milk 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	Organic, Siementhaler
Product recalls in last 12 Months	No
Products in production at the time of the audit	Beef carcass (own slaughter), deboned technical parts of hindquarter and forequarter. Cuttings to specification (longhaas, broekstuk, rump, rundersnippers, vet, bovenbil gevliesd, sucade etc). By-products: liver, heart, tongue, Semi-processed by products: scalded stomachs and salted intestines.

6 Audit Duration Details

On-site duration	20 man hours	Duration of production facility inspection	10 man hours
Reasons for deviation from typical or expected audit duration	In line with newest audit duration calculator.		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2018-04-23	7:00	15:30
	2018-04-24	7:00	15:30
	2018-04-25	7:00	11:00

	Auditor (s) number(s)	Names and roles of others
Auditor Number		
Second Auditor Number	N/A	

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)	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Name / Job Title				

- Plant Manager	X	X	X	X
- QA Manager	X	X	X	X
- Foreman slaughtering department	X	X		
- Foreman slaughtering department	X	X		
- Maintenance manager	X		X	
- Head deboning and cutting department	X	X		
- HR Manager	X		X	
- Sales manager	X		X	
- Head slaughtering department	x			
- werkvoorbereider TD		x	x	
- Manager Vion Rundvee BV			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**

Comments on non-conformities

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	1.1.3	The management review is not complete as KPI on CAT 1 is not reviewed quarterly, safety figures are missing and listing of audits is not complete. **FULLY CLOSED**	Completed.with missing information KPI's. Starting Q2 reporting 2018.	PPA: Completing management review with missing KPI information. RCA: No full communication different departments.	Seen attachment number 1 Quarterly Review adjusted for Q1-18	2018-05-17	
2	3.5.2.1	There is no up to date list of approved suppliers of cattle. Cattle is bought by VION Rundvee BV exclusively for	Vion Rundvee is added as a supplier into the quarterly management report. Into the Q2 report a general yearly	PPA: Completing management review with supplier Vion Rundvee and judgment. Starting Q2	Seen attachment: number 2 with criteria and standards .	2018-05-17	

		VION Tilburg from traders and farmers. Procedure P-RDV-NL-10021 is available but outdated and not correct and as VION Rundvee does not operates under the scope of the certificate it is seen as a trader and it shall provide information on approval. (Identity per animal is known by VKI-UBN-number). **FULLY CLOSED**	judgment will be given.	reporting 2018. RCA: Vion Rundvee was "treated/seen" as part of Vion Tilburg. Formally it is another company.			
3	3.9.2	Mass balance is not correct as the returned goods are booked on the correct batch number but not as negative but	Financial controller was ordered to correct this situation during next trace request(s).	PPA: Instruction controller. RCA: Situation was never noticed.	Seen attachment number 3 with instruction	2018-05-17	

		as positive. Double counting of KG therefor in the batch in the trace test. **CLOSED TO BE VERIFIED**					
4	4.6.1	Insulation material on sterilisation water pipes is installed incorrectly in the slaughtering department. Cleaning is not possible, and material not applied correctly. System to verify correct application and correct material not demonstrable. **CLOSED TO BE VERIFIED**	Maintenance was ordering renovation situation insulation sterilization hot water pipes. Technical service has to check that used materials are correct for use.	PPA: Renovation and actualization non conformity's insulation sterilization pipes. RCA: technical service has other priorities.	Seen attachment number 4 with quotation for insulation pipes and installation.	2018-05-17	
5	4.9.1.1	There is not an approved list of all chemicals for	List(s) were made by technical	PPA: Instruction technical service.	Seen attachment number 5 with	2018-05-17	

		purchase and it is not demonstrable what is the specification and status of the oil in the compressed air equipment. **FULLY CLOSED**	service. Food grade oil was implemented in compressed air equipment. Lijsten zijn opgesteld door technische dienst.	RCA: Situation was never noticed			
6	4.11.2	The cleaning schedule has low frequent activities, but it is not demonstrable when these are done. System to record low frequent activities is absent and verification not demonstrable. **CLOSED TO BE VERIFIED**	Vion Tilburg and external cleaning company started actions for realization. Planned date realization is 1-9-2018.	PPA: Cleaning plan and frequencies part of meetings. RCA: Situation was noticed, realization not done (other priority's). Plan and execution is done, registration must be made better.	Seen attachment number 6 minutes of meeting with dd 9-5-2018	2018-05-17	
7	5.1.2	The installation of the new x-ray equipment is not	Correction done by HACCP team,	PPA: More attention HACCP team	Seen attachment number 7:	2018-05-17	

		conforming validation procedure P-VION-10003. HACCP team has not formally approved (the device and the method) and no formal validation is done. Not clear which criteria the x-ray operates on and how correct measurement is to be verified. Not clear how the machine has to be cleaned as cleaning chemicals are applied are applied not following instructions of the supplier causing accuracy and safety problems. **FULLY CLOSED**	verification is made.	by changes production process. RCA: Information was collected but not "managed as HACCP project" by the team.	verification report by HACCP team dd 16-05-2018		

8	6.1.1	During production the cutting board should be turned sometimes as indicated in company procedure P-TIL-NL-10207. The turning does not take place anymore which is not best practice. **FULLY CLOSED**	Procedure rewritten in and training given.	PPA: More attention during changes production. RCA: Continue production was introduced. Procedure not rewritten.	Seen attachment number 8 with training on the procedure dd 16-05-2018	2018-05-17	
9	6.4.2	Calibration of chemicals dosing in the hygiene/cleaning devices is outsourced to external company. It is clear not all devices are included and not of all included devices figures are plotted in the file of the calibration of 11-	Technical service updated the list with all devices (cleaning and desinfection) for calibration. Calibration was ordered and planned.	PPA: Update when new devices are (re)placed. RCA: No full attention for all devices.	Seen attachment number 9 with taken up all dosing equipment into and seen appointment confirmation per mail on calibrating.	2018-05-17	

		04-2018. **CLOSED TO BE VERIFIED**					

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**

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 Plant manager demonstrated commitment by explaining the policy and objectives. He is also a member of the HACCP team and leading the daily operational meetings. Yearly objectives have been defined and communicated with the employees. A so-called X-matrix based on lean management supports the control. This document is issued by HQ and to be completed by the site.
The yearly verification includes quarterly verifications (Q3 2017, Q4 2017, Q1 2018) and the total. This includes the follow-up of the objectives.
The objectives for 2017 have been reached. The objectives for 2018 focus on the building of new offices, rerouting of packaging materials and alteration of processing of intestines) as a semi-finished product as a base for natural casing production.
The Q1 2018 verification report was discussed in detail. The year report July 2015 – June 2016 complies.
Because of the absence of the Site Manager the opening and closing meeting of the audit was attended by the Production Manager.

Minor 1: The management review is not complete as KPI on CAT 1 is not reviewed quarterly, safety figures are missing and listing of audits is not complete.

1.2 Organisational structure, responsibilities and management authority

An organisation chart reflects the organisational structure. In case of the VION employees at middle and higher level job description are defined (responsibility and authorities). Deputisation is included in a scheme. On operational level the procedures defines details about decisions and follow-up.
A competence matrix reveals skills per employee, although the matrix is not yet adjusted to the 25 newly hired workers from the agency.

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, packing material and general elements. The HACCP team consists of: Plant Manager, QA Manager, Departmental Managers (HR, Cutting, Slaughtering, and Expedition) and Manager Maintenance. The HACCP team meets every week.

Flow diagrams are prepared and available in All process steps were shown. The accuracy of the flow diagrams is verified in the summer period.

CCP' s which are determined, including critical limits:

- CCP 1: Faecal contamination of carcasses; Zero tolerance for visible faecal contamination just before the carcass cooling step.
- CCP 2: Temperature control of cooled (vacuum) packed beef and by-products at dispatch (Expedition) core temperature of beef <7°C, internmediate surface contact temperature of vacuum packed cooled beef <6°C, core temperature of animal by-products <3°C, surface contact temperature of vacuum packed animal by-products <2°C
- CCP 3: Temperature control of external slaughtered cattke (carcasses) of approved suppliers. core temperature of beef <7°C, and (returned) cooled / vacuum packed beef and by-products. internmediate surface contact temperature of vacuum packed cooled beef <6°C, core temperature of animal by-products <3°C, surface contact temperature of vacuum packed animal by-products <2°C
- CCP 4. Removal of spinal cord at the slaughter department. Zero tolerance for visible spinal cord or husks of spinal cord just before the carcass cooling step.
- CCP 5: Transport of partialy chilled beef quarters conforming (EU) 2017/1981 with transport time of maximum of 6 hours. This CCP is not yet operational because there are no recognized companies accknowlegged by NVWA yet.)

Records are kept with the help of HACCP logs. A daily verification of the forms is conducted.

An overall process control plan is defined. This includes CCP's, CP and general control measures.

The yearly verification is part of the quarterly reports for the period July 2016- June 2017. Q1 2018 report was discussed for actual results.

Details of non-applicable clauses with justification

Clause reference	Justification

3. Food safety and quality management system

3.1 Food safety and quality manual

All documentation is managed by central and site level procedures ( ). Specific controls over the manufacturing process are defined in the HACCP documents that define CCPs and CPs. This system was found to be working effectively and meets the requirements of the Global Standard for Food Safety and ISO 9001. An electronic quality manual is in place and available to departmental managers. Documents for registrations are available (paper) at the departments.

3.2 Documentation control

Documents within are managed by the QA manager. Based upon sampling the correct versions were in place.

3.3 Record completion and maintenance

Records are made during the production process. This partly electronic (I&R tracing) and manual (HACCP logs and planning documents. All logs are verified before archiving.

3.4 Internal audit

There are schedules of internal audit made available by HQ against documented procedures, carried out by trained independent staff (VION sister company employees). There is a schedule for the internal audits according to procedure 'interne audits' (P-VION-10011).

Seen report of internal audit dd 4-4-2018 by (with focus on fundamentals BRC). The results of the audits sampled comply with the requirements. Deviations are reported, root cause and corrective actions defined, follow-up and verification is done as seen in the quarterly x-matrix.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials and packaging

Purchasing and supplier approval is a corporate quality department responsibility (at VION central office – VION Food). All suppliers (non cattle) are well monitored and followed up. Supplier approval is based on risk assessment and analysis.

Suppliers are monitored on an on-going basis. The assessment is based on enquiries at each VION site involved. The site Tilburg demonstrated the reporting of their experiences.
This results into an approved report of VION suppliers.

Tilburg has its own Procedure purchasing of extra meat (Bijkoop) P-TIL-NL-10105. Suppliers are formally approved and ensure they continue to meet their obligations to supply safe, legal and quality products.

Minor 2: There is no up to date list of approved suppliers of cattle. Cattle is bought by VION Rundvee BV

exclusively for VION Tilburg from traders and farmers. Procedure P-RDV-NL-10021 is available but outdated and not correct and as VION Rundvee does not operates under the scope of the certificate it is seen as a trader and it shall provide information on approval. (Identity per animal is known by VKI-UBN-number).

3.5.2 Raw material and packaging acceptance and monitoring procedures

Cattle are inspected at arrival in close cooperation with the veterinarian (NVWA). Completed VKI documents for each individual animal are defined as crucial. At CCP level beef (extra carcasses) are monitored. Application was demonstrated during this visit as a batch acceptation was seen during the audit. Incoming packaging materials are checked at the packing storage department.

3.5.3 Management of suppliers of services

Suppliers are monitored on an on-going basis. The assessment is based on enquiries at each VION site involved. The site Tilburg demonstrated the reporting of their experiences. This results into an approved report of VION suppliers. For transport companies a separate system is applied. The site Tilburg performs mini-audits on the transport companies at the site. An overall VION report reflecting all transport companies for the year 2017 is available. This is also in place for the cold storage suppliers.

3.5.4 Management of outsourced processing and packing

No parts of the own process (scope) is outsourced. The freezing and packing of beef by an external service provider is monitored based on audits and GFSI approval.

3.6 Specifications

Specifications for raw materials, packaging materials, cleaning agents and finished products are available. Based upon sampling the availability of specifications was demonstrated.
Dutch beef cutting specifications. General specification for beef products (including microbiological criteria and statement on pathogens). Specific customer requirements have been agreed for some industrial customers.

3.7 Corrective and preventive actions

A list of non-conforming situations is kept. Input is from audits, complaints and reported deviations. Deviations are reported, root cause and corrective actions defined, follow-up and verifications are reported. The minor NC's from previous visit were discussed and the situations did not re-occur.

3.8 Control of non-conforming product

Corrective actions will be taken in case of a non-conforming product. At the slaughter line the individual animal with defects is labelled. At the rework section corrections are made and formal release of the carcass is executed (with NVWA supervision).
At the beef and by-product processing departments products are blocked with red signs and specific areas for storage. Product can be devaluated from food to Cat 3, 2, 1; correct application was seen.

3.9 Traceability

Traceability system covers raw materials through work in progress to finished product including packaging materials and distribution according to procedure identification and traceability (P-TIL-NL-10067). This system is fully based on electronic data and written documents, day batch codes and bar codes:
- Cattle wear an earmark (+ accompanied by passport, track record and VKI according Dutch I&R)
- Beef carcasses / quarters get a serial number (together with date of slaughter + origin + classification)

- Quarters (own production + additional purchase) get a batch code (date of production + origin)
- Finished product is traced depending on the date of production (SSCC-number per peace / crate / box is scanned at dispatch)
- Primary packaging materials are tracked based upon the date of starting a new batch.

Internal trace testing is done several times per year as for several schems as Organic and COC these tests have to be done. And extra testing is related to customer initiated tests. Reported Recall and Tracing test was to be done in Feb 2018 butt postponed to May (forward, backwards, mass balance, timing and team assembling). During the audit a trace test is initiated by the auditor. Tracing of cow 128,4 kg UBN slaughtered 01-02-2018.
The beef products of this batch were traced forward towards the customers supplied and products still in stock. CCP records of the production day and dispatch of several days were collected. The CCP records of the day of slaughtering were made available. The test was conducted within 4 hrs.

Minor 3: Mass balance is not correct as the returned goods are booked on the correct batch number but not as negative but as positive. Double counting of KG therefor in the batch in the trace test.

3.10 Complaint handling

Complaints are received by the sales department (in Tilburg) directly from customers and via sales offices. Any complaint which is considered to be attributable to the site is reported, communicated and investigated. The number of complaints is about 8,5%, which is a decrease to last year. This is calculated per order line. Several PI's are set on complaints: on food safety; order/quotation/invoice, production, transport, labelling/packaging. Within this group the majority are commercial complaints (colour differences, not confirmed/ incomplete orders). 218 complaints in Q1 2018 are related to foreign bodies (hard plastic, soft plastic and metal). Overall, related to the amount of products a relatively low level food foreign object complaints is met.

3.11 Management of incidents, product withdrawal and product recall

There is a VION crisis and recall management procedure (P-FOOD-10015) which covers the process which is applicable for all VION sites. This includes requirements for stock, logistics, recovery, storage and disposal as appropriate. Part of the recall procedure is tested by the site in Tilburg 1 x / year (not yet in 2018) and the procedure is reviewed yearly by HQ. No recalls since last BRC audit.

3.12 Customer focus and communication

Communication with the customers is done by the sales representative. Results of the performances are received from the clients and the reports reveal compliance with the customer requirements.

Details of non-applicable clauses with justification

Clause reference	Justification

4. Site standards

4.1 External standards

The site has been designed and constructed for its activities at an industrial area. There are no local activities that are expected to have an adverse effect. This location has been suitable maintained and well equipped. External areas to production/ office buildings are maintained. A paved surface is applied around the building. No potentially risks assessed to product safety. A dirty and a clean paved way is installed as directed by law on slaughtering. Cars, trucks and vans have to disinfect when leaving the dirty area.

4.2 Security

Site boundaries are gated and well defined and 24 hour security is in place with badge control for employees on the single potential entry point to the plant. The site is fully fenced in and has camera surveillance. Separate storage takes place for cleaning chemicals and waste. The site is registered by The Food and Consumer Product Safety Authority (official approval NL 87 EG).

4.3 Layout, product flow and segregation

A site plan is in place with personnel flows and material/ product flows. Equipments are placed such as to minimise the risk of product contamination.
Low risk open product areas are defined. The BRC7 appendix 2 has been applied. The site map is up-to-date including the intestines area.

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

The oldest part of the building is from 1920. In 2006 a new building for the cutting and packing departments has been constructed and in 2012 expansion of the storage department took place. The fabric and internal condition of the site is suitable and satisfactory for the process. Walls, ceilings and floors were generally suitable. Floors constructed of granite are generally in good condition and maintained (repaired). False ceilings are used in manufacturing areas. They are totally closed. Glass windows are protected by foil. Suitable ventilation/ cooling provided into the factory.

4.5 Utilities – water, ice, air and other gases

Utilities constructed, maintained and monitored. The water used for cleaning and process is mains water. Water quality is defined as a general control measure and a water distribution plan is available. Quality of water is monitored in an adequate way (2 times a year).
The compressed air system is controlled by regular filter inspections and preventive renewal (each half year). No gasses are applied.

4.6 Equipment

The used equipment is suitable for its purpose. Use of well-known brands of equipment for food applications. Recently a new x-ray detector is installed on fat content measurement.

Minor 4: Insulation material on sterilisation water pipes is installed incorrectly in the slaughtering department. Cleaning is not possible, and material not applied correctly. System to verify correct application and correct material not demonstrable.

4.7 Maintenance

Equipment is maintained and on the planned (preventive and corrective) maintenance system ( ). Cooling equipment, calibration records are included. Maintenance department employs 8 service men. Maintenance is also outsourced to established companies within the food and meat business. Records to confirm that the preventive maintenance or preventive controls have been carried out as planned are in place. The focus is on realising preventive maintenance. The temperature of the cooled areas is monitored and alarms installed. The temperature of the disinfection point for knifes (>82 degrees) is monitored and alarms installed. A formal release takes place after repair during production activities.

4.8 Staff facilities

Changing facilities are provided for company personnel, agency workers, visitors and contractors to ensure correct work wear is worn prior to entry to any production area. Staff facilities are designed and operated to minimise the risk of contamination. Staff facilities are suitable for the operation and in the building of the new offices coming year alteration and improvement of staff facilities is foreseen. Outdoor clothing and shoes are stored separately from work wear. Hand-washing facilities are provided in toilets and at entry points to production areas with hand-free soap tap operation and single use paper towels or air technology. Before entering the production areas a sole washer is installed and an extra hand disinfecting system.
No high risk or high care production. Two rest rooms and catering facilities are provided for staff. Eating is allowed in the canteen; smoking is only allowed in a separated area of the canteen.

4.9 Chemical and physical product contamination control
Raw material handling, preparation, processing, packing and storage areas

Control over cleaning chemicals on site was demonstrated. Separate storage facility for cleaning chemicals with authorised access by cleaning company and production department. MSDS available and specifications confirm suitability for use in food processing industries from supplier and

4.9.1 Chemical control

Minor 5: There is not an approved list of all chemicals for purchase and it is not demonstrable what is the specification and status of the oil in the compressed air equipment.

4.9.2 Metal control

A knife handling policy is in place.

4.9.3 Glass, brittle plastic, ceramics and similar materials

All glass surfaces are foil protected. At each start of the day a visual check is done for nonconforming situations for each department, pre-SSOP record per department.

4.9.4 Products packed into glass or other brittle containers

Na

4.9.5 Wood

Only fully packed products are stacked on wooden pallets. Wood is not allowed in open product departments.

4.10 Foreign-body detection and removal equipment

4.10.1 Foreign-body detection and removal equipment

Metal detection takes place after packing of beef. Not all products can be metal detected due to size of packed volume. Procedures are in place in case the metal detector does not detect the test bullet (CP level). Metal hazard is controlled by metal checks in relation to the hazard analysis. Records and corrective actions could be demonstrated.

4.10.2 Filters and sieves

Not applied

4.10.3 Metal detectors and X-ray equipment

Metal detection takes place after packing of beef. Not all products can be metal detected due to size of packed volume. Procedures are in place in case the metal detector does not detect the test bullet (CP level). Metal hazard is controlled by metal checks in relation to the hazard analysis. Registration and corrective actions could be demonstrated.
Since a few months X-ray detection is in place to analyse on fat content. Validation not yet ready although in place (see minor in 5.1).

4.10.4 Magnets

na

4.10.5 Optical sorting equipment

na

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

na

4.11 Housekeeping and hygiene

Cleaning of equipment is carried out according to documented and detailed cleaning schedules. These detail the chemicals to use, precautions to take and method of cleaning. Cleaning is done by subcontractor in the evening / at night when production has stopped.
Some machines and areas are cleaned by own rained personnel (vacuum packing machines and intermediate storage areas for beef carcasses).
The effectiveness of the cleaning and disinfection process is followed by hygiene audits (pre-SSOP) and hygiene programs. TVC swabs checks are planned and reported. Swabs for pathogenic bacteria like Listeria monocytogenes can be initiated based upon specific situations, and since an issue on Listeria is reported, actions are in place to follow up. Records of checks are maintained and were sampled during the audit. Cleaning schedules of are available ('Reinigings- en desinfectieschema' P-TIL-NL-10081) and cover equipment, plant, buildings and services (with daily / weekly / monthly cleaning frequencies). Low frequent cleaning schedule (ceilings, walls above 2,5m, evaporators) assessed also.
The follow up of cleaning is done by daily visual inspections (pre-SSOP), hygiene program by means of agar and microbiological analysis (P-NL-FOOD-10031) of end products to ensure the cleaning was

effective.
Review of records assessed. Cleaning was being carried out as planned. Verification takes place.

Minor 6: The cleaning schedule has low frequent activities, but it is not demonstrable when these are done. System to record low frequent activities is absent and verification not demonstrable.

4.11.7 Cleaning in place (CIP)

Blood collecting equipment is cleaned in place (CIP). CIP processing is under control by the customer in house ( ) and done by VION personnel. Residue control after cleaning is conducted by VION Tilburg.

4.12 Waste / waste disposal

Waste containers are available throughout production areas and are emptied regularly to prevent an accumulation of waste. No trademarked materials applicable. Partly the waste is collected for animal feed. Legal requirements are met (e.g. separate storage and clear identification). Waste disposal is handled by licensed contractors:

(paper, plastic, e.g.), (category 1), (fat), (bones), (category 3, feed).

4.13 Management of surplus food and products for animal feed

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4.14 Pest Control

Pest control is contracted to (since April 2016), HQ contract. Service contracts are available to specify the requirements and contractual obligations of the pest control contractor. The company has a contract about the pest control of rodents, cockroaches, crawling insects and flying insects. The frequency of control is 8x/y for rodents, insects. Maintenance of EFK is 4x/y and an in-depth pest control survey is done once a year. Next to this visit a quality inspection is done. The EFK's have a removable glue plate which facilitates counting. All documentation and visit reports are available on the website/online platform. Occurrence of infestation has been reported (incidents, not in production areas). Trend wise no situations of concern.

4.15 Storage facilities

General handling procedure and temperature control is applicable during storage (CP). Cleaning and maintenance records can be shown. Documented procedures are in place to ensure product temperature requirements are met. All products are labelled. Stock rotation is FIFO.

4.16 Dispatch and transport

Transport is subcontracted. Temperature is monitored and logged. On a daily basis products are sent to customers or aff site freezing storage facilities. VION Tilburg reviews the performance of these transport companies each year.
The content of the contract complies with the requirements. General handling procedure and temperature control (CCP) is applicable. Product is loaded via covered bays.

Details of non-applicable clauses with justification	
Clause reference	**Justification**
4.3.5 / 4.4.4 / 4.8.4	No high-care area in line with appendix 2
4.3.6/ 4.4.4 / 4.4.13/ 4.8.5	No high-risk area in line with appendix 2
4.3.7	No ambient high-care area in line with appendix 2
4.9.3 / 4.9.4 / 4.10.6	No products packed into glass or brittle containers
4.10.2/ 4.10.4/ 4.10.5	No filters or magnets in product flow. No optical sorting equipment.

5. Product control

5.1 Product design/development

No real product design takes place at the site. No consumer end products are applicable. At central level a development procedure is available.
Cuts are tested first in the production departments and samples are discussed with the customer before a new product is accepted. Factory trials are undertaken (no tests during this visit).
Shelf life monitoring has been done in line with the plan: Vacuum packed 6 weeks at 2 °C.

Minor 7: The installation of the new x-ray equipment is not conforming validation procedure P-VION-10003. HACCP team has not formally approved (the device and the method) and no formal validation is done. Not clear which criteria the x-ray operates on and how correct measurement is to be verified. Not clear how the machine has to be cleaned as cleaning chemicals are applied are applied not following instructions of the supplier causing accuracy and safety problems.

5.2 Product labelling

Product labels are applied at different levels. Final packed products are labelled in line with the EU requirements for beef. The labels are printed just before sticking to the packaging revealing lot code, shelf life and weight. By-products are clearly labelled with name and day of production. No unidentified/unlabelled product was seen.

5.3 Management of allergens

No allergens are used, only fresh meat under current scope. An assessment is carried out at possible risks of milk from the udders in the slaughter department. Correct removal of udders was demonstrated. Precautions are taken concerning other sources of allergen contamination at the staff canteen (pull out jacket and washing hands).

5.4 Product authenticity, claims and chain of custody

Organic production (SKAL) is managed by procedures and formal certification. Identity preservation is applied with the help of clear labelling and demonstrated during the visit. The company undertakes several documented mass balances a year. Procedure "Duurzame productie" P-TIL-NL-10055. Also Chain of Custody audits includes the evaluation of the risk assessment and vulnerability assessment (2x/y by) in which risk assessment on vulnerability is present. A whistleblowing procedure is in place in the whole VION concern. Part of the training concerns how to act in **case** of doubts.

5.5 Product packaging

All packaging and supplier approval is controlled from VION central office. The central system is a part of the multi-site ISO 9001 approval. Primary packaging materials are appropriate for the intended use and stored under conditions to minimise the risk of contamination and deterioration. Product packaging material is checked against visual standards of acceptability upon arrival at site. Packaging materials specifications reveal food safe declaration (EU-directives). E.g. foil for vacuum packing, blue bags and red crates.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Individual animals are supervised (ante mortum inspection) by a veterinarian (NVWA) during the arrival at the slaughter department. Another authority ( ) performs the formal carcass inspection and release. does the qualification of the carcasses.
All analyses (microbiological tests of products, GMP analyses – hygiene programs, water analyses) are based upon a sampling plan and in line with EU 2073. All microbiological analysis are subcontracted to accredited laboratory
A microbiological monitoring program and shelf life testing program is in place ('bemonsteringsplan VION Tilburg'). The frequency of monitoring depends on the risk: carcasses own production, carcasses additional purchase, technical cuts, by-products: 1x/w microbiological analysis of TPC, entero's, Salmonella (pool), E. coli and sometimes Listeria.
Extra parameters: 1x/3 m microbiological analysis of yeasts + moulds, Pseudomonas, Staphylococcus aureus.

5.6.2 Laboratory testing

Internal swab incubating, testing and results are counted at the office of the QA manager. No laboratory.

5.7 Product release

Finished product is released unless it is blocked. Those products are only released by competent personnel and after checking all relevant production data.
Beef intended for further raw processing and raw consumption is under a positive release regime (risk assessment and customer requirement).

Details of non-applicable clauses with justification

Clause	Justification

reference	
5.3.7	No allergen free claims.
5.6.2.2	No laboratory on-site

6. Process control

6.1 Control of operations

The site clearly demonstrated a control of operations. The process is suitable for this type of production. Process conditions and methods are well looked at and revalidated. Systematic monitoring is demonstrated. During production the correct application of CCP's is monitored and verified on a day to day basis. Assessed for CCP temperature control (delivery/receiving goods), faecal contamination of carcasses and removal of spinal cord.
Process control is based upon the HACCP study, legal and customer requirements. Documented starts up checks are applied (pre-SSOP) and process is monitored by SSOP. Maintenance of the cooled areas is demonstrated.

Minor 8: During production the cutting board should be turned sometimes as indicated in company procedure. The turning does not take place anymore which is not best practice.

6.2 Labelling and pack control

All products are sold by weight. Metrology controls the balances for commercial purpose. No issues identified. Calibration of the scales is demonstrable.

6.3 Quantity, weight, volume and number control

All products are sold by weight. Metrology controls the balances for commercial purpose. No issues identified. Calibration of the scales is demonstrable. Seen the test weight in the storage department to check the floor scales.

6.4 Calibration and control of measuring and monitoring devices

The devices are tested on a daily or weekly basis (records). Procedure scale control P-TIL-NL-10115.
Weighing equipment (legal requirement) is calibrated once in three years (report March 2016).
Critical measuring equipment are thermometers (CCP related). An external yearly calibration is combined with a 2-monthly internal temperature test (0 and 100 °C).
Based upon sampling this method is demonstrated.

Minor 9: Calibration of chemicals dosing in the hygiene/cleaning devices is outsourced to external company. It is clear not all devices are included and not of all included devices figures are plotted in the file of the calibration of 11-04-2018.

Details of non-applicable clauses with justification	
Clause reference	Justification

7. Personnel

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

There is evidence of introduction training for new starters, temporary workers and contractors. Clear refreshment competency training (on food safety, quality and food defence) had taken place for the staff in 2017/2018. CCP's control was done in line with the documented requirements. Seen training on
A competence matrix is in place with evidence that relevant personnel are trained in the slaughter department. A training plan for 2018 is available.

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

The standards for personal hygiene, dress code, medicines, jewellery and medical screening have been defined and communicated to the personnel through brochure "Good business Practice, Jan 2018". Also, Code of Conduct and safety instruction are available an demonstrable training is recorded. For agency workers Flex NL v2017-09 is available. During this visit, in general, correct application of the hygiene rules was seen.

7.3 Medical screening

The medical screening is part of the intake of new employees and part of the instructions/ questions to visitors at entrance. Persons who are suffering from a relevant infectious disease are not allowed to enter the production facilities. Medicine use is set at the hygiene rules.

7.4 Protective clothing: employees or visitors to production areas

Company issued protective clothing is given to all staff and visitors. Good adherence to the dress code observed during the site evaluation. The standards for personal hygiene, dress code, medicines, jewellery and medical screening have been defined and communicated to the personnel through brochure "Good business Practice, Jan 2018". These hygiene rules are effectively enforced. Records seen.

Clean and dirty clothes are stored separately. Employees can change daily or more frequently when necessary. The clothes are externally cleaned by This is a low risk operation with visual inspection by the company.

Personal protective devices are washed daily and monitored by the company. Gloves are coloured and changed frequently.

Details of non-applicable clauses with justification	
Clause reference	**Justification**
7.4.4	No high- care or high-risk areas.

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.		