BRCGS | Food Safety

Lloyd's Register

Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	Vion Tilburg BV	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	2020-05-20		
Re-audit due date	2021-05-19		

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

Head Office	Yes

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	A	Previous audit date	2019-05-19		
Certificate issue date	Select a date	Certificate expiry date	Select a date		

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 00 345 number
Commercial representative Name		Email	-
Technical representative Name		Email	-

4.Company Profile

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

Shift Pattern	no
Subcontracted processes	Choose an item
Other certificates held	ISO9001; Organic; IFS PIA; BLK
Regions exported to	Europe Asia North America Choose a region Choose a region Choose a region

4. Company Profile

Company registration number	NL 87 EG
Major changes since last BRCGS audit	Management change / Covid-19 protocol changes since last BRCGS audit

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. The location Tilburg is NVWA approved (NL 87 EG). VION Tilburg B.V. produces beef products and slaughter by-products and offal's (like organs, processing of stomachs (scalding) and the processing of first stage of natural casing (cleaning/ heating of bovine intestines)). The cattle is bought by VION Rundvee BV at the general mostly Dutch market. Currently since several months also veal is produced so less impact on shortage of cattle to slaughter. The capacity of slaughtering is about 400 calves, 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 in addition claves are slaughter a few times per week. Furthermore, which is not a change to previous year 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 ɔeople (including ɜubcontracted 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. Because of the Covid-19 issues this audit is planned on 18-20 May 2020. The audit due date was 2020-05-19. Also the program of the audit is changed. Al the production processes are planned in one day because extra protection was needed for the auditor (Covid – 19).

5. Product Characteristics

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

5.Product Characteristics

Finished product safety rationale		Cooled red meat and by-products/offals. 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 is 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		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 Choose an allergen			
Product claims made e.g. IP, organic		Product claims made e.g. IP, organic			
Product recalls in last 12 Months		Choose an item			
Products in production at the time of the audit		Products in production at the time of the audit			

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	none		
Next audit type selected	Announced		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2020-05-18	7.00	15.00
2	2020-05-19	7.00	15.00
3	2020-05-20	7.00	15.00

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

Present at audit				
Note: the most senior operations manager on site should be listed *first and be present at both* opening & closing meetings (ref: clause 1.1.11)				
Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Site manager	X		X	X
/ Sales manager	X		X	X
QA Manager	X		X	X
QA Manager	X	X	X	X

Present at audit				
, Foreman slaughtering department		X		X
., Foreman slaughtering department		X		
/ Maintenance manager			X	
, Head deboning and cutting department		X		
/ HR Manager			X	
/ Head slaughtering department				X
, maintenance employee		X	X	
Foreman dispatch		X	X	

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced

Non-Conformity Summary Sheet

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

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

Major							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan**	**Root cause analysis**	**Date reviewed**	**Reviewed by**
1	1.1.4	In annual report Vion Tilburg (July 2018 / June 2019) evaluations are performed on various points, not all points are followed by a conclusion / evaluation on this process. As an example in customer feedback (4.1), there is a trend that is "down", this has been explained during the audit but is not seen in the document showed (evaluation / conclusion is missing).	The annual report is yearly published together with HACCP reassessment. All relevant pages are completed with possibility for add information / evaluation and conclusion.	Is now part of the central procedure.	VION QA central document did not have the structure (each page) for adding this information. Only total action list is part of report.	2020-06-11	FULLY CLOSED
2	2.10.2	A form is used on CCP 1/4 to check whether a recheck is necessary on the CCP, for this there is a possibility to indicate this with Yes / No on the document. During the trace test	Form with working method was updated at 9-6-2020 into .	No 100% clear instruction at related . form and or not full understand by related worker(s).	No 100% clear instruction at related . form and or not full understand by related worker(s).	2020-06-11	CLOSED point will be followed up the next BRC evaluation.

		showed that this is not always necessary to indicate this. However, the procedure / working method is not clear in this.					
3	2.14.1	A change has been made to the production process, as a result of which the flow diagrams and risk analysis have also been adjusted. However, no validation report has been drawn up on this change.	Validation report is made.	Involved workers/employees have instruction that validation process must be done at every important/ related food safety issue.	Validation was based on daily practice and continue flow of process information. But not implemented as "secured" administration process.	2020-06-11	FULLY CLOSED
4	3.7.3	For internal and external audits there is a method to follow up improvement measures (3.1 reassessment) in a number of other places within the organization, such overviews are also available, but a (total) overview at management level is not available, as a result of which control of improvement points could not be demonstrated.	Model for registration improvement processes by MT is made. .	The organization will start using this model after first MT meeting if design, tasks, work method and responsibilities are discussed, trained	MT meetings using action list, but no conform model for registration improvement.	2020-06-11	CLOSED : point will be followed up the next BRC evaluation.

5	3.11	At the end of 2019 there was a serious issue with regard to the cleaning that is provided by an external company), this became visible through Vion Tilburg's own verification program (agar checks) after which various actions were taken. However, no report has been made of this incident where, among other things, it has been stated what caused it and what measures were taken and whether it was efficient. In practice, however, it appears that this has been done but is not centrally recorded.	Relevant page QA report is completed with possibility for adding information / evaluation and conclusion. .	In case of structural noncompliance actions will be uploaded as A3 approve plan or discussed into MT	No full administration from done improvement related to non-conformities R&D process.	2020-06-11	FULLY CLOSED
6	4.6	In a slaughtering line on the inspection platform, it was found that a drain was clogged, so that the water flows from the drain instead of being	Repair this technical non-conformity.	Re-train involved workers concerning SSOP and Pre-SSOP procedures	Not seen during daily controls by all related workforce.	2020-06-11	FULLY CLOSED

		drained to the sewer when using the washing facilities.					
7	4.6	On carousel for product packaging, cover plates are placed on an accessible platform to prevent possible product contamination, however these plates do not connect sufficiently, which creates cracks, which in turn allows contamination.	Repair this technical non-conformity.	Not seen during daily controls by related workforce.	Not seen during daily controls by related workforce.	2020-06-11	CLOSED : point will be followed up the next BRC evaluation
8	4.9.3	It was established in litigation that the risk of contamination of plastic is not sufficiently guaranteed. Considering that e.g. release warning stickers in the dirty slaughter line that the e2 crate with meat (with the carousel chip) was damaged. In both cases it was not established that there was a direct risk of product contamination.	Warning stickers are ordered and replaced for new.	SSOP forms deboning F-TIL-NL-10076 and packing area F-TIL-NL-10121 are updated with daily actual control for intensive use plastic materials. Involved workers are trained and training is registered.	Warning stickers already seen but not replaced. Risk intensive use plastic crates during repeatedly work not noticed.	2020-06-11	CLOSED : point will be followed up the next BRC evaluation.

9	4.9.6.1	In production (cutting room) a dolaf with product was under the overhead conveyor, so there is a risk of product contamination (not seen during the audit).	Turning point overhead conveyor with risk (food-grade) fat contamination was updated/repaired by technical service.	Not seen during daily use by all related workforce.	Not seen during daily use by all related workforce.	2020-06-11	FULLY CLOSED

Comments on non-conformities

Additional Modules / Head Office Non-Conformity Summary Sheet

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

Major							
No.	Requirement ref.	Details of non-conformity	Corrective action taken	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Proposed preventive action plan**	**Root cause analysis**	**Date reviewed**	**Reviewed by**

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The Director operations demonstrated commitment by explaining the policy (2020-05-13) and objectives. He is also a member of the HACCP team and leading the daily operational meetings. He could not attend opening or closing meeting and was deputised by all other members of the management team.
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. Mission, policy and actions included. It is filled 4x per year and is also the management review as in 1 of 4 (after Q2) verification on HACCP plan is included. The documents has several tabs on food safety, on human safety, on operational figures and on costs. VION has a general Speak up arrangement for all sites.
There is also defined a food safety and quality culture plan is available and seen implementation of the food safety plan. Social responsible plan 2020.

- Goal for 2019 / 2020 was IFS PIA assesment (score 85%)
- Goal for 2020 implementation IFS PIA points are scedueld.
- Because of Covis-19 other goals are alson standin but will be revieuwd when ther is a "normal" situation.
- Goals are : ɔn vearscore A
- Satifaction of client) on 7
- Satisfaction of client on "very good"

Minor NC:
In annual report Vion Tilburg (July 2018 / June 2019) evaluations are performed on various points, not all points are followed by a conclusion / evaluation on this process. As an example in customer feedback (4.1), there is a trend that is "down", this has been explained during the audit but is not seen in the document showed (evaluation / conclusion is missing).

The yearly verification includes quarterly verifications (Q3 2019, Q4 2019, Q1 2020) and the total. This includes the follow-up of the objectives. Also monthly follow up of objectives is reported to the management team The objectives for 2019 have not all been reached. The reconstruction of new offices, rerouting of packaging materials is not pursuit due to financial constraints. Alteration of processing of intestines is finished to produce semi-finished product as a base for natural casing production.
The Q1 2020 verification report was discussed in detail.
Company is kept informed via HQ and via authorities permanently onsite. Also, they are aware of consequences of reoccurrence of non conformities of previous audits.

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). Deputation is included in a scheme created by HR and therefor not in the same format as other documents. On operational level the procedures defines details about decisions and follow-up. In production an experienced team operates daily business.
Details of non-applicable clauses with justification

Clause/Section 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 as indicated by HQ structures. 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. The allergen milk is acknowledged due to slaughtering of cows/presence of udder.
Flow diagrams are prepared and available in All process steps were shown. The accuracy of the flow diagrams is onsite verified in the summer period. Key processes identified in the scope are the slaughtering of cattle, the cutting to specification of beef and the slaughter by products and offal's. Some 40 PRP's are identified temperature control of storage cells, identification of cattle, beef and packed beef; microbiology on water and on product; training; metal detection and knife management.
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 cattle (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.
Seen Procedure procesbeheeplan P-TIL -10126 march 2020 revision 14

Minor NC:
A form is used on CCP 1/4 to check whether a recheck is necessary on the CCP, for this there is a possibility to indicate this with Yes / No on the document. During the trace test showed that this is not always necessary to indicate this. However, the procedure / working method is not clear in this.

Minor NC:
A change has been made to the production process, as a result of which the flow diagrams and risk analysis have also been adjusted. However, no validation report has been drawn up on this change.

An overall process control plan is defined. This includes CCP's, CP and general control measures. Metal detection is a CP as some 40 other controls are.

The yearly verification is part of the quarterly reports for the period July 2018- June 2019. Q1 2020 report was discussed for actual results. Verification included also food defence and incidents/recall procedure.

Details of non-applicable clauses with justification

Clause/section 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 Document Control

Documents within are managed by the QA manager

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. Retention period for paper and digital archive is > 5 y

3.4 Internal audits

There are schedules of internal audit made available by HQ against documented procedures, carried out by trained independent staff (VION sister company employees). Seen were the calendars of 2019 (fulfilled and 2020. There is a schedule for the internal audits according to procedure 'interne audits' (P-VION-10011). In 2019 several audits on other topics are included in the scheme to fullfilll the 4 internal audits per year. Eg the "Preinspections third countries" by HQ are included and animal welfare audits are included. Seen report of internal audit dd 7-11-2018 by (with focus on fundamentals BRC). The results of the audits sampled comply with the requirements but no proof of covering all topics (seen minor 2). Some conformity is reported, 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 material and packaging

Purchasing and supplier approval is a corporate quality department responsibility (at VION central office – VION Food). All suppliers (non cattle) are monitored and followed up. Supplier approval is based on risk assessment and analysis. Cattle suppliers is monitoring per animal as the I&R system in The Netherlands is arranged that no cattle is slaughtered without correct identification on birth and breeding.
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 divided in Food/meat, Ingredients, Packaging, sourcing suppliers as cold stores and transport, service suppliers.
Tilburg has its own Procedure purchasing of 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 3: Identity of manufacturer of packing material bought from wholesaler vdW is not demonstrable.

3.5.2 Raw material and packaging acceptance, monitoring and management 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. An overall VION report reflecting all transport companies for the year 2020 is available in an MMI. This is also in place for the cold storage suppliers.

3.5.4 Management of Out sourced processing

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. Storage : Seen BRC status 24-08-2020

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. Assessed was the spec on finished good specification "Levernd rund" P-RDV-NL-10032 rev 4 . Specification end product "start" Artnr 250 03-04-2020, specification packaging materials VPK packaging .

3.7 Corrective and preventive actions

A list of non-conforming situations is kept and discussed in the Management team of 11 persons (6 production, maintenance, sales, HR, QA, general manager. Input is from audits, complaints and reported deviations. Deviations are reported, root cause and corrective actions defined, follow-up and verifications are reported.

Minor NC:

For internal and external audits there is a method to follow up improvement measures (3.1 reassessment) in a number of other places within the organization, such overviews are also available, but a (total) overview at management level is not available, as a result of which control of improvement points could not be demonstrated.

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 (see minor 3).

Internal trace testing is done several times per year as for several schemes as Organic and COC.. And extra testing is related to customer initiated tests. Reported Recall and Tracing (forward, backwards, mass balance, timing and team assembling). During the audit a trace test is initiated by the auditor. Tracing of batch tails production 2020-02-20. The beef products of this batch were traced forward towards the customers supplied and no products still in stock, correct mass balance could be shown. 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.

Recall test done: 20-sep 2019
Recall test : 25-10-2019

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 4000per year which is a again a decrease to last year. This is calculated per order line is the %. Several PI's are set on complaints in 4 categories: on food safety; order/quotation/invoice, production, transport, labelling/packaging. Within this group the majority are commercial complaints (colour differences, not confirmed/ incomplete orders). Food safety per Q1 2020: 64, 124, 73. They are related to foreign bodies (hard plastic, soft plastic and metal). Seen complain metal in product and reaction to client. Seen overview on client level seen march 2020.

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 2019) and the procedure is reviewed yearly by HQ. No recalls since last BRC audit.

Minor NC:

At the end of 2019 there was a serious issue with regard to the cleaning that is provided by an external company , this became visible through Vion Tilburg's own verification program (agar checks) after which various actions were taken. However, no report has been made of this incident where, among other things, it has been stated what caused it and what measures were taken and whether it was efficient. In practice, however, it appears that this has been done but is not centrally recorded

Details of non-applicable clauses with justification

Clause/section 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 are. Site registration Nr. EG. 87 NL.

4.2 Site security and food defence

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 (CCTV). 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).
The VACCP/TACCP is conform Procedure procesbeheeplan P-TIL -10126 march 2020 revision 14. Risk for food defence is possible because off the activities of the company (Slaughterhouse), a fence is placed and 24 hous security is in place for food fraude the analyse is made also conform P-TIL-10126 march 2020 revision 14 and no direct risk are seen. But attention is there for animals coming from Belgium. The verification is done on a yearly base and is done Q1 2020.

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. Seen lay out map : seen plan dated 2020-02-05
Low risk open product areas are defined. The BRC FS8 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 (4 times a year by external lab
The compressed air system is controlled by regular filter inspections and preventive renewal (each half year) / 14-05-2020 (change of filter). No gasses are applied.
Ice analyse 14-02-2020
Water analyse 4 times a year seen results 19-03-2020.

4.6 Equipment

The used equipment is suitable for its purpose. Use of well-known brands of equipment for food applications. Past year no relevant new equipment is installed.

Minor NC:
In a slaughtering line on the inspection platform, it was found that a drain was clogged, so that the water flows from the drain instead of being drained to the sewer when using the washing facilities.

Minor NC:
On caroucel for productpackaging, cover plates are placed on an accessible platform to prevent possible product contamination, however these plates do not connect sufficiently, which creates cracks, which in turn allows contamination.

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 because of Covid-19 it is seen that external companies are not allowed to come within the production hours. . 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

4.9.1 Chemical control

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

4.9.2 Metal control

A knife handling policy is in place. Seen procedure "Messenregime snijzaal P-TIL-NL-10129 dated 30 okt 2015 rev.2.

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 times a year the check is done : pictures are taken and communicated to the Technical department, seen check doen 2020-05-07 (Q1 2020).

Minor NC:

It was established in litigation that the risk of contamination of plastic is not sufficiently guaranteed. Considering that e.g. release warning stickers in the dirty slaughter line that the e2 crate with meat (with the caroucel chip) was damaged. In both cases it was not established that there was a direct risk of product contamination.

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.
4.9.6 Other physical contaminants
Pens are metal detectable and in use. Minor NC In production (cutting room) a dolaf with product was under the overhead conveyor, so there is a risk of product contamination (not seen during the audit).
4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of 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. Registration and corrective actions could be demonstrated. Since a few months X-ray detection is in place to analyse on fat content.
4.10.2 Filters and sieves
na
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. Records and corrective actions could be demonstrated. The metal detector at the packing station detects on 4,0 m Fe, 4,8 mm nFe and 6,0 mm SS.
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. Past year several cleaning activities are taken back to keep personnel employed.
Some machines and areas are cleaned by own rained personnel (vacuum packing machines and intermediate storage areas for beef carcasses).
Cleaning schedules of are available ('Reinigings- en desinfectieschema' P-TIL-NL-10081) and Plan total 1-5-2020 version 2. 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 plac

4.11.7 Cleaning in place (CIP)

na

4.11.8 Environmental monitoring

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.
Listeria swaps are taken every week 6 samples : seen results 13-05-2020 No positifs results in 2019 YTD 2020.

4.12 Waste

Waste containers are available throughout production areas and are emptied regularly to prevent an accumulation of waste. No trademarked materials applicable. 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).
Seen cat material records sample taken : 2020-00-20 (Cat 1 material

4.13 Management of surplus food and products for animal feed

na

4.14 Pest management

Pest control is contracted to new company (since Jan 2020), Seen pestcontro EVM1961091301 exp date 09-12-2024. Service contracts are available to specify the requirements and contractual obligations of the pest control contractor. The company has a contract on the pest control of rodents, cockroaches, crawling insects and flying insects. The frequency of control is 12x/y for rodents, insects. Maintenance of EFK is 4x/y and an in-depth pest control survey is done once a year, seen the report of 4-12-2018. 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.
Seen inspection done on 14-05-2020.

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 off site freezing storage facilities. VION Tilburg reviews the performance of these transport companies each year. The cold store was included in the tracetest during the audit.
The content of the contract complies with the requirements. General handling procedure and temperature control (CCP) is applicable. Product is loaded via covered bays.
Seen audit done by BRC 24-08-2020.

Details of non-applicable clauses with justification

Clause/section reference	Justification
4.10.2	Filters and sieves
4.10.4	Magnets
4.10.5	Optical sorting equipment
4.10.6	Container cleanliness – glass jars, cans and other rigid containers
4.13	Management of surplus food and products for animal feed

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.
Seen shelf life test on Micro conform plan P-Food-1008 rev. 13 seen THT "snippers vacuum eind THT dated 03-02-2020. Good result.

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 (seen risk assessment dated : 14-03-2020 P-TIL-NL-10127 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 IFS PIA audits included in the evaluation of the risk assessment and vulnerability assessment (2x/y by LRQA) in which risk assessment on vulnerability is present. Part of the training concerns how to act in case of doubts. IFS PIA audit is done in 19/20 Feb 2020.
Seen Food Fraud procedure P-TIL-NL-10224 revision 11 May 2020. And seen risk assessment P-TIL-NL-10223 on food fraude done (12 May 2020).
BIO and BLK2* are used seen cerification on those

- BLK2* Certificate d done 23 feb 20218 exp date 15 macht 2021.

Bio (Skal), cwertificatenr 1255480 31 Dec 2020.

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.
Seen DOC of packaging material:

- VPK packaging N.V> BRC packaging certifiates certificate exp date march 2021 DIC 02-03-2017 (vacuum packaging) BRC packaging certifcated march 2021 and DOC 15-11-2019.

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. Finally post mortum approval by veterinarian.
All analyses (microbiological tests of products, GMP analyses – hygiene programs, water analyses) are based upon a sampling plan and in line with EU VO 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.
Seen results of
If there are results of positief release results : 14-05-2020 : EDE-18578978-0 on STEK (stx 1 and 2 eas Escherichia / salmonells : all not present. If it is for RTE positif ttan it is not used for RTE products.

5.6.2 Laboratory testing

Internal swab incubating, testing and results are counted at the office of the QA manager. No laboratory onsite.
External lab is used ISO17025 is used (for example used for positief release seen results of 2020-02-19.

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).
Seen the procedure for return products P-TIL-NL-00048 rev 6
Seen procedure for positief release procedure P-TIL-NL-10132 dated rev 3 19 apr 2019.

5.8 Pet Food

Na – no Pet food production

Details of non-applicable clauses with justification

Clause/section reference	Justification
5.6.2.2	No lab onsite

6. Process control

6.1 Control of operations

The site demonstrated a sufficient control of operations. In the slaughtering line permanent external supervision by authorities is present. 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. Seen verification on CCP F-TIL-NL-10042 (revision 7) a Minor NC is given on the filled in of this document
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.

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. Seen chage over in procuction from Bio to requlair and change in label from theis process (done during the audit 2020-05-19)

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. Test weight is a daily operation and recording on Pre SSOP eg 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 controlled in Weighing equipment (legal requirement) is calibrated once in three years.
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.

Details of non-applicable clauses with justification

Clause/section 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. Refreshment competency training (on food safety, quality and food defence) had taken place for the staff on 09-06-2020. CCP's control was done in line with the documented requirements. Seen training correctly in place. (Seen records of training given on CCP for GH 04-02-2019 / TD 04-02-2020.
A competence matrix is in place with evidence that relevant personnel are trained in the slaughter department. A training plan for 2020 is available. A new model of competence appraisal is rolled out on several VION plants currently, in the coming month in VION Tilburg.

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 booklet Flex NL is available (Veiligheidinstructies Uitbeen/Snijzaal Vion Tilburg " "Werken bij Vion 05-2018 and code of conduct . 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. There is seen a deviation (brought up internally) in the slaughtering line on correct removal of clothing during canteen visits. This is acknowledged and a plan is made to improve. 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/section reference	Justification

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones

8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones

na

8.2 Building fabric in high-risk and high-care zones

na

8.3 Maintenance in high-risk and high-care zones

na

8.4 Staff facilities for high-risk and high-care zones

na

8.5 Housekeeping and hygiene in the high-risk high-care zones

na

8.6 Waste/Waste disposal in high risk, high care zones

na

8.7 Protective clothing in the high-risk high-care zones
na

Details of non-applicable clauses with justification	
Clause/section reference	**Justification**

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

Module 11: Meat supply chain assurance	
Scope	
11.1 Traceability	
11.2 Approval of meat supply chain	

11.3 Raw material receipt and inspection
11.4 Management of cross-contamination between species
11.5 Product testing
11.6 Training

Module 12: AOECS Gluten-free Foods

Scope	

12.1 Senior management
12.2 Management of suppliers of raw materials and packaging
12.3 Outsourced production
12.4 Specifications
12.5 Management of gluten cross-contamination
12.6 Management of incidents, product withdrawal and product recall
12.7 Labelling

12.8 Product inspection and laboratory testing

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018				
Item no.	Clause	Module item	Conforms (Y/N) or Not Applicable (NA)	Comments
1	13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
2	13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
3	13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize		

		accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
4	13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
5	13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
6	13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		
7	13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).		
8	13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard)		

		such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
9	13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		
10	13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.		
11	13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRC sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).		
12	13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90		

		calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.		
13	13.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
14	13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
15	13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method		

		• Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
16	13.1.16	Devices used to verify preventive controls must be calibrated.		
17	13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
18	13.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
19	13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.		
20	13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		

21	13.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
22	13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		
23	13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.		
24	13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles		

		used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
25	13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.		
26	13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant vulnerabilities and actionable process steps • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
27	13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum):		

		• Scale and severity of threat if a contaminant is added to product • Degree of physical access to the product • Ability of an attacker to successfully contaminate product—including consideration of an inside attacker A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.		
28	13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.		
29	13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.		
30	13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation		

		• Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions		
31	13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation strategies. Verification procedures shall include: • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities		
32	13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility becomes known		

		• Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence		
33	13.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
34	13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.		
35	13.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.		
36	13.4.1	Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used. A documented procedure shall describe cleaning and storage practices of all vehicles and		

		transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.		
37	13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.		
38	13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.		
39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.		
40	13.4.5	Where the site receives temperature controlled product immediately following		

		transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.		
41	13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper		
42	13.4.7	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems • Responsibilities of the carrier		
43	13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite		

		records shall be retrievable within 24 hours.		
44	13.4.9	The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.		
45	13.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following: • Principles of food hygiene and food safety Produce safety standards applicable to an individual's job		
46	13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment		
47	13.5.3	One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.		
48	13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual		

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

		Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.		
54	13.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007)," December, 2009 or equivalent method.		
55	13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.		
56	13.5.12	Dropped produce (i.e., produce that comes in contact with the		

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

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

		prevent adulterated food from entering commerce		