Audit Report

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 Start Date	2021-04-08	Audit Finish Date	2021-04-09
Re-audit due date	2022-05-10	Head Office	No

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

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	A	Previous audit date	2020-05-20		
Certificate issue date	2021-05-05	Certificate expiry date	2022-06-30		

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

3.Company Details

Address	Enschotsestraat 28 5013 BD Tilburg		
Country	The Netherlands	Site Telephone Number	
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

Shift Pattern	no
Subcontracted processes	No
Other certificates held	ISO9001; Organic; IFS PIA; BLK
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 BRCGS audit	Start made with new building

4.Company Profile

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 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 people (including subcontracted personnel). The production takes place in one shift. The surface is K sq. meters and the used quality system is based on two HACCP-studies. www.vionfoodgroup.com.. Al the production processes are planned in one day because extra protection was needed for the auditor (Covid – 19).

5.Product Characteristics

Product categories	01 - Raw red meat Category Category Category				
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 regimeJustification for area				

5.Product Characteristics

Allergens handled on site	Milk 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	BLK Organic
Product recalls in last 12 Months	No
Products in production at the time of the audit	Beef carcass (own slaughter and from 2 other slaughtering houses), deboned technical parts of hindquarter and forequarter. Cuttings to specification packed in boxes, crates, vacuum and big boxes. By-products: liver, heart, tongue, offalls, semi-processed by products: scalded stomachs

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 Day	Date	Start Time	Finish time
1 (start date)	2021-04-06	7.00	15.00
2	2021-04-07	7.00	15.00
3	2021-04-08	7.00	15.00

	Auditor 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	
s, QA Manager	X		X	X
), QA Manager	X	X	X	X
I, Foreman slaughtering department		X		X
Foreman slaughtering department		X		
Maintenance manager			X	
/ HR Manager			X	
maintenance employee		X	X	

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced
2020-05-20	BRCGS Food	Announced

Non-Conformity Summary Sheet

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

Critical			
No.	Clause	Detail	Ant. Re-audit date
-	-	-	

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Major							
-	-	-	-	-	-	-	-

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	1.1.2	Objectives have been formulated for food safety and quality culture but a SWOT analysis could not be showed from where those objectives are formulated.	Planning for realization SWOT analysis process was discussed, planned documented and signed for agree by plantmanager and commercial manager. (Dated 2021-04-21). Time table: Stage 1 (May/July 2021) Stage 2 (Aug / first part sep) Srage 3 (second part sep and first part Okt). Closed : point will be followed up the next BRCGS Food audit.	Yearly update SWOT analysis by management team. Conclusions can be used for planning yearly documented targets/ objectives for the organization.	This part of process was not fully covered and administrated by the organization.	2021-04-30	
2	2.7.1	In process steam and ice are used (For direct product contact). This process	Document procesbeheersplan P-TIL-NL-10127 version 16	Indirect production processes (in relation to food) must have	Attention description in procedure	2021-04-30	

Minor							
		(making steam and ice) is not indicated in the risk assessment ("Procesbeheersplan"). Available are micro analyses for the water (used for making steam and ice) and food grade products are used, however this is not evaluated in the Risk assessment ("Procesbeheersplan")	d.d. 22-04-2021 Vion Tilburg is completed with processes producing/using steam and ice in relation food contact. Seen P-TIL-NL-10127 version 16. Fully closed.	more attention from all related managers/departments. All related processes must be part of this procedure.	was most focused to direct production process, not to the indirect processes.		
3	3.2.1	CCP5 is not present in risk assessment ("Procesbeheersplan"). P-TIL-NL-10127 verssion 15 dated 2021-03-19. However, procedures and limits etc. are present at the implementation level, but these are not stated in the overall plan. With this, the CCP is present and implemented in process, but this is not shown correctly in terms of document management.	Document procesbeheersplan P-TIL-NL-10127 version 16 d.d. 22-04-2021 Vion Tilburg is completed with CCP 5. Seen P-TIL-NL-10127. Fully Closed.	More attention during updating and release of new procedures by related persons/ QA managers.	During updating procedure the wrong field/file was selected/used during copying. Important information CCP 5 what already was part of this procedure was lost and not seen during release process new version.	2021-04-30	

Minor							
4	4.4.2	In room E13 it was seen that there are some "cracks" in the floor and in Cell E01 a part of the repair of the floor is coming loose.	Cracks room E13 are repaired. Seen picture of repair of E13 and workorder for repair floor E01 (planed for 2021-04-29/2021-05-05). Closed : point will be followed up the next BRCGS Food evaluation. .	Better planning identified technical related non conformity's by technical department.	This non conformity was not noticed before so not into planning.	2021-04-30	
5	4.3.3	The sterilizer unit in Cel E13 did not reach the correct temperature (>82 C) the temperature was 67.6 C. After the supply was turned on, it appeared that it could reach the correct temperature. At the time of the audit, there were no production activities on this position.	Updating SSOP F-TIL-NL-10122 checklist department afsteekruimte, koel en boutencellen with this unit into E13. Attaching the way of working, control and critical limits. Seen instruction for new way of working (only on themperature if there are activities in this area) Seen training given and seen picture of sterilization unit with right temperature (86,2 C (>82 C).	Training related department manager in relation to new version F-TIL-NL-10122. Only during activities into "Onthouderscel E13" this unit must be controlled and verified.	The unit into E13 is most of the time not active and sometimes only used a small part of the total production time.	2021-04-30	

Minor							
			Fully Closed				
6	4.14.9	A Pest control, system for follow-up points for improvement is not guaranteed, seen that pest control provides "advice" and that Vion Tilburg also makes improvements on a number of points, however the demonstrable follow-up of the points is not organized in a system.	All advices (improvements) are listed and part of document used during "technical meeting" between QA, TS and plantmanager. All improvements are discussed, risk-analyzed noticed and if needed planned into new used excel document. Seen new system to organized the advices from the pest control company. Fully Closed	The created system will be used into the future, information concerning improvements will be available.	No correct "system" for follow up.	2021-04-30	
7	6.1.1	In the packaging department observed that there are packed tail pieces (vacuum packed), the label states that these should be stored between 0-2 C. Temperature measurement is done during the audit and the temperature of the tail pieces, with a production	Short term: Products will not returned from cool section to packing department for completing the pallets with product. So temperature product is secured. Seen new way of working (Short term) with this way of	Long term: Management team Vion Tilburg makes decision that this part (pallet- places during collecting boxes of products) of the packing department must be fully cooled	Way of working into this area was based at effectiveness collecting and not based at food risk (temperature). Is discussed	2021-04-30	

Minor							
		date of 02-04-2021 (moment of review was 07-04-2021), showed a temperature of 3 °C, the department temperature has a set temperature of 6 ° C with an alarm value of 10 ° C.	working the tempetature is secured because the themperature on the other department is in line with the label. Fully Closed	into the future. Realization is planned for Q3 2022.	with some MT members, short and long term action was planned and decided.		
8	6.1.3	Seen that one leg of the carcass came into contact with the platform, this is not allowed.	Carcass correction directly. The contact place was removed and destructed. Instruction department managers that position before must use rope (food-Grade) for "lifting" the front-leg (shin) in case long carcass. Seen during the audit a direct corrective action and seen proof of instruction given on the correct way of working.	Instruction department managers that position before must use rope (food-Grade) for "lifting" the front-leg (shin) in case long carcass. See proof attachment minor 8.	Worker was noticed the long carcass to late and/or was not correctly trained.	2021-04-30	

Minor							
			Closed : ;point will be followed up the next BRCGS Food audit.				

Comments on non-conformities
na

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit due date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The Director operations demonstrated commitment by explaining the policy (2021-01-20) 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.

Food safety food culture :
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 (27-01-2021). The documents has several tabs on food safety, on human safety, on operational figures and on costs. VION has a general Speak up (confidential reporting system) arrangement for all sites. No Speak up (confidential reporting) calls where seen for location Vion Tilburg.
There is also defined a food safety and quality culture plan is available and seen implementation of the food safety plan. X-gram is system for monitoring of those objectives seen objectives: .

- Nr 41: Goals are : on yearscore A (End Q4)
- Nr 42 : Satifaction of client on 7 (End Q4)
- New building (End 2021 / beginning 2022)

The yearly verification includes quarterly verifications (Q3 2020, Q4 2020, Q1 2021) and the total. This includes the follow-up of the objectives. Also monthly follow up of objectives is reported to the management team (seen minutes of meeting 27-01-2021) and 12-02-2021. The objectives for 2020 have not all been reached..
The Q1 2021 verification report was discussed in detail (Dated 27-01-2021).
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.

The resources offered are adequate.

The recertification audit will take place on or before the audit expiration date.

Senior management was in attendance. See list 'Present at audit'

No incorrect use of Logo seen.

It has been established that the 9 minor deviations from the previous have been adequately resolved.

Minor NC:

Objectives have been formulated for food safety and quality culture but a SWOT analysis could not be showed from where those objectives are formulated.

1.2 Organisational structure, responsibilities and management authority

An organisation chart reflects the organisational structure (Nov 2020). 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 Ref	Justification
-	-

2 The Food Safety Plan – HACCP

The company's food safety control system is based on the Codex Alimentarius HACCP principles: an assessment is made of microbiological, chemical 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 (seen week 11 2021). 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. Radioactivity is also part of the risk assessment no risk evaluated.

Verifications done conform P-TIL -10127 29 March 2021 revision 15

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 -10127 29 march 2021 revision 15

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. The yearly verification is part of the quarterly reports for the period P-TIL -10127 29 march 2021 revision 15 (This is included a verification of flow diagrams). Q1 2021 report was discussed for actual results. Verification included also food defence and incidents/recall procedure.

Seen validatie new building 2021-01-12 and validation on the food defence 05-03-2021.

Minor NC:

In process steam and ice are used (For direct product contact). This process (making steam and ice) is not indicated in the risk assessment ("Procesbeheersplan""). Availabe are micro analyses for the water (used for making steam and ice) and food grade products are used, however this is not evaluated in the Risk assessment ("Procesbeheersplan"")

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

3. Food safety and quality management system

3.1 Food safety and quality manual

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.
Minor NC:

CCP5 is not present in risk assessment ("Procesbeheersplan""). P-TIL-NL-10127 reision 15 dated 2021-03-19. However, procedures and limits etc are present at the implementation level, but these are not stated in the overall plan. With this, the CCP is present and implemented in process, but this is not shown correctly in terms of document management.

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 trainingsrecord Internal Auditor (2015-07-09) and and (2015-07-9)). Seen were the calendars of 2020 (fulfilled and 2021. There is a schedule for the internal audits according to procedure 'interne audits' (P-VION-10011). In 2020/21 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 2020-12/16 2021-02-11(5 Minor NC's are reported following minor nc nr 4 2021-03-04. by (with focus on fundamentals BRCGS). The results of the audits sampled comply with the requirements but no proof of covering all topics.
Hygiene inspections are also done seen PRESOPP and SSOP Over period Q1 2021 Seen week 7 and 11 2021.

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 ' ' system in The Netherlands is arranged that no cattle is slaughtered without correct identification on birth and breeding.

Suppliers (Included Brokers) 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 (Included Brokers) divided in Food/meat, Ingredients, Packaging, sourcing suppliers as cold stores and transport, service suppliers. No exemptions are seen, if

for High risk no GFSI certificate available than a audit is done. Seen evaluatie P-TIL-NL-10199 rev4 date 2020-03-20. Evaluation is part of the reporting system.

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.

(Meat supplier) IFS Food (2021-11-06), BRCGS Food exp date 11 aug 2021. 2021-08-15. Looked at supplier for "Smart packaging Solution",

Supplier evaluation done on 4-2-2021

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 BRCGS 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 "Levend rund" P-RDV-NL-10032 rev 4 . Specification end product "start" < Specification packaging dated 2020-10-13.

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.

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)
- 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 schemes as Organic and IFS PIA . 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 artikel "Ribstuk 3 kg +5 rib" in total kg production date 26/27-10-2020.
The beef products of this batch were traced forward towards the customers supplied and products still in stock (freezing house), 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.

Trace test done: 2020-09-20
Recall test : 2021-03-17

3.10 Complaint handling

Complaints are received by the sales department (in Tilburg) (P-TIL-NL-10229 rev 1 dated 29 march 2021) directly from customers and via sales offices. Any complaint which is considered to be attributable to the site is reported, communicated and investigated. 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 2021: 64, 124, 73. They are related to foreign bodies (hard plastic, soft plastic and metal). Seen complain dated 2021-3-10 (complain with metal in product (slachthaak) with corrective action.

Q1 2021: 1315 complains (0,4% - 0,8%) this is a normal trend.

3.11 Management of incidents, product withdrawal and product recall

There is a VION crisis and recall management procedure (P-FOOD-10015) / P-TIL-NL-10087 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. Seen recall test done 17-03-2021 No recalls since last BRC audit.

Details of non-applicable clauses with justification	
Clause/Section Ref	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 good 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-NL-1024 dated 11 May 2020 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 2021.

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 2021-03-01
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, for 2022 a new building will be in use and new routings will be used.

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.

At the moment of the audit a old part of the factory is going down to make room for a new part. The new part must be in operation end this year or beginning 2022.

Minor NC:

In room E13 it was seen that there are some "cracks" in the floor and in Cell E01 a part of the repair of the floor is coming loose.

Minor NC:

The sterilizerunit in Cel E13 did not reach the correct temperature (>82 C) the temperature was 67.6 C. After the supply was turned on, it appeared that it could reach the correct temperature. At the time of the audit, there were no production activities on this position.

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 / 14-05-2020 (change of filter). No gasses are applied.
Water analyse 4 times a year seen results 11-03-2021.
Steam production 15-02-2021

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.

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. Workshop is outside the production area so no direct risk for contamination to production for routing seen) 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.

Seen check (calibration) on pt100 (temperature measurement) done on 30 sep 2020.

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 anc .
Seen overview on chemicals used : Overview chemicals for cleaning and deinfection

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 done on 2021-01-19.

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.

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.
A 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 (No CCP) 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-100228) and Plan total 23 Mrt 2021 version 1. 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. Seen overview off the results ot the cleaning activities: (results 2020-2021) version 23-06-2020. Seen agar results week 11 2021 result 0,08 and week 12 2021 result 0,20.
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 (Conform P-TIL-NL-10228 rev 1) : seen results 23-03-2021 No pos. results in 2020 YTD 2021.

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), y (bones), Almere (category 3, feed).
Seen waste overview P-TIL-NL-10208 v6 dated 26-03-2021
Seen cat material records sample taken : 2021-04-08 (10829963 / 16360713) (Cat 1 material

4.13 Management of surplus food and products for animal feed

na

4.14 Pest management

Pest control is contracted to company (since Jan 2020), Seen pestcontro 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 29-12-2020. 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. No infections seen during this audit

Seen inspection done on 29-12-2020

Technische inspection (QA inspection) done 12 nov 2020.

Minor NC:

A Pest control, system for follow-up points for improvement is not guaranteed, seen that pest control provides "advice" and that Vion Tilbug also makes improvements on a number of points, however the demonstrable follow-up of the points is not organized in a system.

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.
External freezing storage are in use. Seen for freezing BRCGS certificate valid until 2021-10-01 (Extended certificate because of Covid 19). .

Details of non-applicable clauses with justification	
Clause/Section Ref	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: THT are available in P-TIL-N-10122 V3. is +10 days.
Seen shelf life test on Micro conform plan P-Food-1008 rev. 13 seen THT eind THT dated production 18-01-2021 / 28-01-2021. 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 : 29-03-2021 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 (1x/y by LRQA(once a 2 year) 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 (Once in 2 year).
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). (verification is done once a year and will be done in May 2021.
BIO and BLK2* are used seen cerification on those

- BLK2* Certificate done 13 okt 2020exp date 31 dec 2021.

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:

- › BRCGS packaging certifiates certificate exp date 6 may 2021 DIC 02-03-2017
- 2003 S.L. BRCGS packaging v6 certificate exp date 2021-12-19.
- . BRCGS Packaging v6 certificate exp date 2021-07-11

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 (KDS) 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
Seen example of approval slaughtering date 29-03-2021 (Lab analyse STEC also seen a not approved possitief release dated production date 01-03-2021

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 is used (for example used for positief release seen results of 2021-03-29.

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.
Seen procedure for positief release procedure P-TIL-NL-10132 dated rev 6 1 mrt 2021.
Seen example of approval slaughtering date 29-03-2021 (Lab analyse STEC also seen a not approved possitief release dated production date 01-03-2021.

5.8 Pet Food

Na – no Pet food production

Details of non-applicable clauses with justification

Clause/Section Ref	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 8) 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 NC:

In the packaging department observed that there are packed tail pieces (vacuum packed), the label states that these should be stored between 0-2 C. Temperature measurement is done during the audit and the temperature of the tail pieces, with a production date of 02-04-2021 (moment of review was 07-04-2021), showed a temperature of 3 °C, the departmenttemperature has a set temperature of 6 ° C with an alarm value of 10 ° C.

Minor NC:

Seen that one leg of the carcass came into contact with the platform, this is not allowed.

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 production from one artikel to a other with check on label and change in label from this process (done during the audit 2021-04-07). (Seen from slaughtering Belgium to Dutch) change of labels in production. (P-TIL-NL-10084 revision 8 27 jan 2021)

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). Seen Calibration on Pt100 done on 30 sep 2020 ( ) and calibration on metal detector serialnr (Line 3 snippers) dated 15 feb 2021. Temp measurement (CCP) expedition 2102338 done on 5 march 2021 due date 5 mach 2022 (Serial nr).
Based upon sampling this method is demonstrated.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification

7. Personnel

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

There 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 07-05-2020 / 07-05-2020.
A competence matrix is in place with evidence that relevant personnel are trained in the slaughter department. A training plan for 2021 is available. Seen also training given to flex employee 18-03-2021.

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, 2020-09-21". 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 2020-09-21 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 Ref	Justification

Template control	Food	Version	1.0

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
Click or tap here to enter text.
8.3 Maintenance in high-risk and high-care zones
Click or tap here to enter text.
8.4 Staff facilities for high-risk and high-care zones
Click or tap here to enter text.
8.5 Housekeeping and hygiene in the high-risk high-care zones
Click or tap here to enter text.
8.6 Waste/Waste disposal in high risk, high care zones
Click or tap here to enter text.
8.7 Protective clothing in the high-risk high-care zones
Click or tap here to enter text.

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

9 - Traded Products
9.1 Approval and performance monitoring of manufacturers/packers of traded food products
Click or tap here to enter text.
9.2 Specifications
Click or tap here to enter text.
9.3 Product inspection and laboratory testing
Click or tap here to enter text.
9.4 Product legality
Click or tap here to enter text.
9.5 Traceability
Click or tap here to enter text.

Module 11: Meat supply chain assurance	
Scope	Click or tap here to enter text.
11.1 Traceability	
Click or tap here to enter text.	
11.2 Approval of meat supply chain	
Click or tap here to enter text.	
11.3 Raw material receipt and inspection	
Click or tap here to enter text.	

11.4 Management of cross-contamination between species
Click or tap here to enter text.
11.5 Product testing
Click or tap here to enter text.
11.6 Training
Click or tap here to enter text.

Module 12: AOECS Gluten-free Foods	
Scope	Click or tap here to enter text.
12.1 Senior management	
Click or tap here to enter text.	
12.2 Management of suppliers of raw materials and packaging	
Click or tap here to enter text.	
12.3 Outsourced production	
Click or tap here to enter text.	
12.4 Specifications	
Click or tap here to enter text.	
12.5 Management of gluten cross-contamination	

Click or tap here to enter text.
12.6 Management of incidents, product withdrawal and product recall
Click or tap here to enter text.
12.7 Labelling
Click or tap here to enter text.
12.8 Product inspection and laboratory testing
Click or tap here to enter text.

Module 13 FSMA Preventive Controls Preparedness Module

Version 2 July 2018

Clause	Module item	Conforms Y/N	Comments
13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant.		

	Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is		

	exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		
13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).		
13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures		

	and responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		
13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.		
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).		

13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.		
13.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and		

	number of samples • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
13.1.16	Devices used to verify preventive controls must be calibrated.		
13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food		

	safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
13.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.		
13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they		

	must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		
13.1.21	Where a hazard requiring a supply-*chain-applied control* is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
13.1.22	Supplier approval must be documented before receiving and using raw materials and *ingredients*. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		
13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter		

	at an adequate frequency.		
13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		

13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.		
13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant vulnerabilities and actionable process steps • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates		

	the following key criteria (at a minimum): • 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.		
13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the strategy		

	significantly minimizes or prevents the vulnerability.		
13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.		
13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions		
13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to		

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

	becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence		
13.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.		
13.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility		

	for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.		
13.4.1	Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used. A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.		
13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver,		

	it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.		
13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.		
13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary		

	specifications provided by shipper.		
13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.		
13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper		
13.4.7	Contracts with carriers shall specify that the carrier implements a		

	training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems • Responsibilities of the carrier		
13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.	NA	
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.	NA	
13.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following:	NA	

	• Principles of food hygiene and food safety Produce safety standards applicable to an individual's job		
13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment	NA	
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.	NA	
13.5.4	A supervisor shall be identified with	NA	

	responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.		
13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.	NA	
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.	NA	

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.	NA	
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.	NA	
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.	NA	
13.5.10	Agricultural water testing may be performed by the site	NA	

	(or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), "*Method 1603*: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007)," December, 2009 or equivalent method.		
13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize	NA	

	infiltration of pathogens into produce.		
13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.	NA	
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.	NA	
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	NA	
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.	NA	
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	NA	

	studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts. Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria: • Target test (i.e., Listeria spp. or L. *mono*) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) The plan shall describe aseptic methods for	NA	

	sample collection and testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent).		
13.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts. The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono. If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process: • Resample positive surfaces and the surrounding area to determine the extent of contamination • Clean and sanitize the affected and surrounding areas • Resample and re-test to confirm the elimination of Listeria spp. or L. mono • Conduct finished	NA	

	product testing as appropriate • Take additional action to prevent recurrence and to prevent adulterated food from entering commerce		