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	2019-05-08		
Re-audit due date	2020-05-19		

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	2018-05-17		
Certificate issue date	2019-07-01	Certificate expiry date	2020-06-30		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	10

3 Company Details

Address	Enschotsestraat 28 5013 BD Tilburg		
Country	The Netherlands	Site Telephone Number	+31 0 13 462 08 00
Commercial representative Name		Email	
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	No
Other certificates held	ISO9001; Organic; CoC v3; 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 BRC audit	Decline in slaughtering and production due to shortage of cattle. Temporary staff is halved.

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.

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 regime.*				
Allergens handled on site	Milk Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen *Choose an allergen*				
Product claims made e.g. IP, organic	Organic, BLK				
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	20 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)	2019-05-06	7:00	16:00
2	2019-05-07	7:00	16:00
3	2019-05-08	7:00	11:00

	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
– Direto Operations			X	
Production Manager	X		X	X
QA Manager	X	X	X	X
Foreman slaughtering department	X	X		X
Foreman slaughtering department		X		
/ Maintenance manager	X		X	X
Head deboning and cutting department	X	X		X

/ HR Manager	X		X	X
/ Sales manager	X		X	
/ Head slaughtering department	X			X
maintenance employee		X	X	
/ Foreman dispatch		X	X	
– Employee facility department		X		
– Forewoman packing department		X		
– foreman packing department		X		
- Stable employee		X		
– Controller			X	

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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 (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

Minor							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	3.2.1	Form created by sales to record requirements indicated by customer does not belong to the documented quality manual. Form is in use in the dispatch area (2 forms for 2 customers to record dates, batches and temperatures). *Formulier opgesteld door* afdeling verkoop om klanteisen te registreren is niet opgenomen in het QA handboek (QOL). Het formulier is in gebruik op afdeling expeditie (2 formulieren voor twee klanten betreffende registratie datum, batchnummers en temperaturen).	Forms formalized / uploaded as QOL document. Formulieren zijn geformaliseerd en opgenomen in QOL. **FULLY CLOSED**	RCA: Not implemented because information is also in other systems Vion Tilburg available. Oorzaakanalyse: Niet ingevoerd doordat informatie ook in andere systemen van Vion Tilburg beschikbaar is. PPA: Documents related to food quality/security items will be *communicated and uploaded in* QOL. Preventieve actie: Klantverzoeken betreffende documenten gerelateerd aan kwaliteit/veiligheid zullen worden gecommuniceerd en worden opgenomen in QOL.	See attachment: Proof minor 1	2019-06-03	
2	3.4.1	Not demonstrable that all activities are included in the internal audit program eg supplier approval and maintenance department no findings reported past year. Past *year 3 internal audits conducted,*	All activities and findings must be reported completely. QA manager Vion Tilburg will control new internal pré-audit reports before acceptation. *QA central instructed*	RCA: Internal auditor wrote no complete report findings. Only sign X that department was visited. Oorzaakanalyse: De interne auditor rapporteerde niet al zijn *bevindingen.* Alleen een X dat	Instruction QA central for all auditors was done. See attachment: Proof minor 2A, 2B, 2C.	2019-06-03	

		4 not yet demonstrable. Het is niet aantoonbaar dat alle activiteiten onderdeel zijn van het interne audit programma. Bijvoorbeeld klanteisen en technische dienst omschrijven/bevatten geen gerapporteerde bevindingen het afgelopen jaar. Er hebben afgelopen jaar 3 interne audits plaatsgevonden, de vierde is nog niet aantoonbaar.	internal auditors concerning this minor. Last (4) internal AW audit report is available. Alle activiteiten en bevindingen moeten volledig worden gerapporteerd. De QA manager zal nieuwe interne pré-audit rapporten eerst controleren voor acceptatie. Tijdens het Centrale QA overleg op 23-05-19 in Boxtel zijn de interne auditoren geïnstrueerd om de template van de rapportage volledig in te vullen. Laatste (vierde) AW audit rapport is beschikbaar. **CLOSED TO BE VERIFIED**	betreffende afdeling was bezocht. PPA: Auditee will control new pre-audit reports before acceptation. QA central instructed internal auditors concerning this minor Preventieve actie: Auditee zal nieuwe interne pre-audit verslagen controleren op volledigheid voor acceptatie. Tijdens het Centrale QA overleg op 23-05-19 in Boxtel zijn de interne auditoren geïnstrueerd om de template van de rapportage volledig in te vullen.	Follow up audit report possible after next internal audit (second half 2019). Instructie door QA centraal voor alle auditoren heeft plaatsgevonden. Zie bijlage: Proof minor 2A, 2B, 2C Opvolging audit rapport pas mogelijk na volgende interne audit (tweede helft 2019).		
3	3.5.1.5	Identity of manufacturer of packing material bought from wholesaler is not demonstrable. Identiteit van producent verpakkingsmateriaal via toeleverancier is	Ordering Vion central buying division for missing information identity manufacturer. Centrale inkoop afdeling Vion verzocht om ontbrekende informatie	RCA: Central buying division was unknown with BRC 8 demands. Centrale inkoop niet op de hoogte van BRC 8 eis. PPA: Central buying division was informed and started directly with collecting requested information.	See attachment: Proof minor 3A, 3B	2019-06-03	

		niet aantoonbaar.	identiteit producent. **FULLY CLOSED**	Supplier packaging material has a BRC / S&D certificate. Preventieve actie: Centrale inkoop organisatie is geïnformeerd en gelijk gestart met verzamelen verzochte informatie. Leverancier van het verpakkingsmateriaal beschikt over een geldig BRC / S&D certificaat.			
4	3.6.1	No specifications available for packing material used in the slaughtering line and for spray used to mark cattle in the stable. Geen specificatie beschikbaar van verpakkingsmateriaal (slachterij) en voor spuitbus om vee te merken in de stal.	Request for specifications is transmitted to suppliers and received. Verzoek informatie specificaties is toegestuurd aan leverancier en ontvangen. **CLOSED TO BE VERIFIED**	RCA: materials and ordered without demand or request concerning specification. Oorzaakanalyse: materiaal en spuitbus besteld zonder eis / verzoek betreffende specificatie. PPA: Organization will start action that people who order materials must be informed concerning relevant information manufacturer. Preventieve actie: de organisatie start heeft de personen welke materiaal bestellen welke in contact kunnen komen met product opnieuw geïnstrueerd dat hier een geldige geschiktheidsverklaring bij	See attachment: Proof minor 4A and 4B, 4C.	2019-06-03	

				aanwezig dient te zijn.			
5	3.7.2	No procedure in place to handle failures. Several methods in use to close out failures but no general method applied to demonstrate correct follow up. Not all actions on the action list of weekly MT are closed out demonstrably and verification on effectiveness of corrective measure is not demonstrable. Several 'whatts app' messages in use to communicate failures. Close out and verification not included in the procedure. Geen procedure aanwezig om afwijkingen op te volgen/ behandelen. Er worden diverse methoden gebruikt om fouten te voorkomen maar er is geen algemene methode om correcte opvolging aan te tonen. Niet alle acties op de actielijst van het wekelijkse MT zijn aantoonbaar gesloten. Verificatie en effectiviteit van de corrigerende maatregelen is niet aantoonbaar. Er worden diverse "whats app"	Procedures "Corrigerende en preventieve maatregelen" P-TIL-10088, Procescontrole P-TIL-NL-10119 and Pre-SSOP P-TIL-NL-10090 are in place but must be updated. Actions and results MT will be better registered (since week 21). Use of Whatts app is only visual reminder for failures registered at the QOL documents. If organization is introducing digital controlling by Foods Connected this will be solved. Procedures "Corrigerende en preventieve maatregelen" P-TIL-10088, Procescontrole P-TIL-NL-10119 en Pre-SSOP P-TIL-NL-10090 zijn aanwezig maar worden gecontroleerd en geactualiseerd. Acties en opvolging resultaten van MT worden vanaf week 21 beter geregistreerd. Gebruik van Whats app is	RCA: less attention for administration processes indirect production processes. Oorzaakanalyse: minder aandacht voor administratieve processen voor indirecte productie processen/ werkzaamheden. PPA: More attention for indirect QA processes for total organization. Preventieve actie: meer aandacht en aanpassing indirecte QA processen door de totale organisatie.	QOL document improvement is planned for June. Follow up next audit. QOL document verbetering is gepland voor Juni. Opvolging volgende audit.	2019-06-03	

		berichten gebruikt om afwijkingen te communiceren. Afsluiting en verificatie zijn niet in procedure opgenomen.	alleen ter ondersteuning van reeds geregistreerde afwijkingen op QOL *documenten*. Indien de organisatie gebruik gaat maken van het digitale registratie systeem zal dit probleem zijn opgelost. **CLOSED TO BE VERIFIED**				
6	4.5.1	The water distribution plan is not complete. Drinking water plan is present but processing water plan is missing. Water distributie plattegrond is niet compleet. Drinkwater plattegrond is aanwezig maar proceswater plattegrond ontbreekt.	Plan water distribution will be updated with processing water. Plattegrond water distributie wordt aangevuld met proceswater. **CLOSED TO BE VERIFIED**	RCA: History shows only demands for map / plan with "Public water". Oorzaakanalyse: Historie toont alleen eisen voor plattegrond met "publiek water" (waterleidingnet) aan. PPA: processing water will be uploaded to water distribution plan. Planned realisation date is 1 October 2019. Preventieve actie: proceswater wordt toegevoegd aan drinkwaterplan. Geplande realisatie per 1-10-2019.	See attachment: proof minor 6.	2019-06-03	-
7	4.6.2	Status of compliance of food contact materials on all	Inventarisation food contact materials for all equipment	RCA: No follow up all inventarisation.	See attachment: Proof minor 7A,	2019-06-03	

		equipment is not demonstrable as some declarations are outdated and (Belt polyurethaan dd 1-2-2016) and no clear overview if all and of which equipment is included. De status van geschiktheid van uitrusting welke met voedsel in aanraking komen is niet aantoonbaar, sommige verklaringen zijn over datum (Band polyurethaan d.d. 1-2-2016) . Er geen duidelijk overzicht van alle en welke materialen dit betreft.	is created. Outdated specification is actualized. Een inventarisatie van alle uitrusting welke met vlees in aanraking komt wordt opgesteld. De "over datum" zijnde specificatie is geactualiseerd. **CLOSED TO BE VERIFIED**	Oorzaakanalyse: geen bewaking/opvolging van inventarisatie aanwezig. PPA: Inventarisation food contact materials for all equipment is created. Outdated specification is actualized. Preventieve actie: Een inventarisatie van alle uitrusting welke met vlees in aanraking komt wordt opgesteld. De "over datum" zijnde specificatie is geactualiseerd.	7B, 7C, 7D.		
8	4.8.3	A set of knifes were found in a staff locker. Equipment should not be placed in lockers. Een messenset is aangetroffen in een kleedkast. Gereedschap zou niet in kasten opgeborgen moeten worden.	Instruction is given to involved workers into the slaughter section were non-conformity was noticed. Er is instructie gegeven betreffende medewerker in de Slachterij waar deze afwijking is aangetroffen. **FULLY CLOSED**	RCA: new worker who was trained by video still store the knife holder into locker. Oorzaakanalyse: een nieuwe medewerkster welke was getraind middels video heeft haar messenset toch in haar kast opgeborgen. PPA: Instruction all workers by P&O. Preventieve actie: Instructie van alle medewerkers door afdeling P&O.	See attachment: Proof minor 8.	2019-06-03	

9	7.1.1	In the despatch area form F-TIL-NL-10147 is filled in before actual happening during the audit. Information on a batch to be off loaded is present on the form while the goods still are in the truck. Op de expeditie is formulier F-TIL-NL-10147 vooraf ingevuld. Informatie van een partij te lossen goederen staat al op het formulier terwijl de goederen zich nog in de vrachtwagen bevinden.	Re-instruction was given to involved worker and situation was part off meeting dispatch area workers. Er is her-instructie gegeven aan betrokken medewerker. De situatie is tevens besproken op het werkoverleg van de expeditie. **FULLY CLOSED**	RCA: Involved worker did not understand his earlier training. Oorzaakanalyse: betrokken medewerker heeft zijn eerdere training niet goed begrepen. PPA: Re-Instruction involved worker dispatch area. Preventieve actie: Herinstructie betrokken medewerker. Plus bespreken overleg expeditie afdeling.	See attachment: Proof minor 9A, 9B.	2019-06-03	
10	7.1.5	Training on labelling activities is not included in the competences and not clear what positions have labelling tasks and are to be trained. Opleiding van etikettering activiteiten is geen onderdeel van competenties. Het is niet duidelijk welke posities etiketteringstaken hebben en of deze zijn opgeleid.	Training labelling will be part of "competentiematrix (HR). First all positions must be evaluated or they have a relation with (influenceable) labelling tasks. Then the relation between position and person can be implemented in "competentiematrix". Involved persons must be trained for this position. Realisation week 24- 2019. Training betreffende labelling zal onderdeel gaan uitmaken van de	RCA: Labelling is part of the QOL documents (P-TIL-NL-10084) and instructed involved personal during release(es). Labeling activities was not implemented into the competences matrix from HR. Oorzaakanalyse: Etikettering is onderdeel van de QOL documentatie (P-TIL-NL-10084) en geïnstrueerd aan betrokken medewerkers tijdens vrijgave(s). Etikettering activiteiten is niet geïmplementeerd als onderdeel van de competentiematrix van HR. PPA:	See attachment: Proof minor 10.	2019-06-03	

			"competentiematrix" (HR). Eerst zullen alle posities worden beoordeeld op hun relatie met (beïnvloedbare) labelling taken. Hierna kan de relatie tussen positie en werkkrachten worden aangestuurd/gecontroleerd. Betrokken medewerkers moeten worden getraind voor deze posities. Realisatie per week 24-2019. **CLOSED TO BE VERIFIED**	HR and QA manager will investigate all positions in relation to labelling tasks. Competences will be related to position into "competentiematrix". Preventieve actie: HR en QA manager doen onderzoek naar alle posities in relatie met etikettering-taken. Competenties zullen worden gerelateerd aan positie en in competentiematrix opgenomen.			

Comments on non-conformities
No negative impact on product safety due to identified non-conformities.

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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	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

Minor							
No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The Director operations demonstrated commitment by explaining the policy 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 with 4 pillars eg training.
The yearly verification includes quarterly verifications (Q3 2018, Q4 2018, Q1 2019) 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 2018 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 2019 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. A competence matrix reveals skills per employee, see minor in 7.1.

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.

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 2017- June 2018. Q1 2019 report was discussed for actual results. Verification included also food defence and incidents/recall procedure.

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 withir are managed by the QA manager. Based upon sampling the correct versions were in place although example was found not te be correct (see minor 1).

Minor 1: Form created by sales to record requirements indicated by customer does not belong to the *documented quality manual. Form is in use in the dispatch area (2 forms for 2 customers to record dates,* batches and temperatures).

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 2018 (fulfilled and 2019. 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" bv HQ are included and animal welfare audits are included. Seen report of internal audit dd 7-11-2018 by [redacted] (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.

Minor 2: Not demonstrable that all activities are included in the internal audit program eg supplier approval and maintenance department no findings reported past year. Past year 3 internal audits conducted, 4 not yet demonstrable. .

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 [redacted] 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 2018 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.

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 [redacted] and

Minor 4: No specifications available for packing material [redacted] used in the slaughtering line and for spray [redacted] used to mark cattle in the stable.

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. The minor NC's from previous visit were discussed and the situations did not re-occur.

Minor 5: No procedure in place to handle failures. Several methods in use to close out failures but no general method applied to demonstrate correct follow up. Not all actions on the action list of weekly MT are closed out demonstrably and verification on effectiveness of corrective measure is not demonstrable. Several 'whatts app' messages in use to communicate failures. Close out and verification not included in the procedure.

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. As this BRC auditor is also the CoC auditor, in January 4 tracetest were executed as well. 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 sold dd 1-11-2018 batch and 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.

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 per 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 Q: They are related to foreign bodies (hard plastic, soft plastic and metal).

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. Sister company VION Enschede was involved in a withdrawal also affecting VIN Tilburg. This was used as a mock recall (dd 10-12-2018).

4. Site standards

4.1 External standards

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

4.2 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).

4.3 Layout, product flow and segregation

A site plan is in place with personnel flows and material/ product flows. Equipments are placed such as to minimise the risk of product contamination.
Low risk open product areas are defined. The 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 (2 times a year by external lab).
The compressed air system is controlled by regular filter inspections and preventive renewal (each half year). No gasses are applied.

Minor 6: The water distribution plan is not complete. Drinking water plan is present but processing water plan is missing.

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. An alteration in the spraying of carcasses on entrance of the cooling system is installed.

Minor 7: Status of compliance of food contact materials on all equipment is not demonstrable as some declarations are outdated and (Belt) and no clear overview if all and of which equipment is included.

4.7 Maintenance

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

4.8 Staff facilities

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

Minor 8: A set of knifes were found in a staff locker. Equipment should not be placed in lockers.

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.

4.9.3 Glass, brittle plastic, ceramics and similar materials

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

4.9.4 Products packed into glass or other brittle containers
No product packed into glass or other brittle containers
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. 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.
4.10.2 Filters and sieves
No use of filters and sieves.
4.10.3 Metal detectors and X-ray equipment
Metal detection takes place after packing of beef. Not all products can be metal detected due to size of packed volume. Procedures are in place in case the metal detector does not detect the test bullet (CP level). Metal hazard is controlled by metal checks in relation to the hazard analysis. Registration and corrective actions could be demonstrated. Since a few months X-ray detection is in place to analyse on fat content. Validation completed correctly after last years minor.
4.10.4 Magnets
No magnets used
4.10.5 Optical sorting equipment
No optical sorting equipment
4.10.6 Container cleanliness – glass jars, cans and other rigid containers
No use of glass jars, cans and other rigid containers.
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 cover

equipment, plant, buildings and services (with daily / weekly / monthly cleaning frequencies). Low frequent *cleaning schedule (ceilings, walls above 2,5m, evaporators) assessed also.*
The follow up of cleaning is done by daily visual inspections (pre-SSOP), hygiene program by means of agar and microbiological analysis (P-NL-FOOD-10031) of end products to ensure the cleaning was effective.
Review of records assessed. Cleaning was being carried out as planned. Verification takes place.

4.11.7 Cleaning in place (CIP)

No CIP.

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.

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).

4.13 Management of surplus food and products for animal feed

No surplus food ad products for animal feed.

4.14 Pest management

Pest control is contracted to (since April 2016), HQ contract. Service contracts are available to specify the requirements and contractual obligations of the pest control contractor. The company has a contract on the pest control of rodents, cockroaches, crawling insects and flying insects. The frequency of control is 8x/y for rodents, insects. Maintenance of EFK is 4x/y and an in-depth pest control survey is done once a year, 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.

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.

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.

5.2 Product labelling

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

5.3 Management of allergens

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

5.4 Product authenticity, claims and chain of custody

Organic production (SKAL) is managed by procedures and formal certification. Identity preservation is applied with the help of clear labelling and demonstrated during the visit. The company undertakes several documented mass balances a year. Procedure "Duurzame productie" P-TIL-NL-10055. Also Chain of Custody audits 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.

5.5 Product packaging

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

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Individual animals are supervised (ante mortum inspection) by a veterinarian (NVWA) during the arrival at the slaughter department. Another authority (KDS) performs the formal carcass inspection and release. CBS 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.

5.6.2 Laboratory testing

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

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).

5.8 Pet Food

Na – no Pet food production

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.
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.

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.

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 30-04-2019. CCP's control was done in line with the documented requirements. Seen induction training correctly in place.
A competence matrix is in place with evidence that relevant personnel are trained in the slaughter department. A training plan for 2019 is available. A new model of competence appraisal is rolled out on several VION plants currently, in the coming month in VION Tilburg. Labelling activities were not taken up yet (see minor 10)

Minor 9: In the despatch area form F-TIL-NL-10147 is filled in before actual happening during the audit. Information on a batch to be off loaded is present on the form while the goods still are in the truck.

Minor 10: Training on labelling activities is not included in the competences and not clear what positions have labelling tasks and are to be trained.

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. 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.

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
No High-Risk, High-Care and Ambient High-Care Production Risk Zones
8.2 Building fabric in high-risk and high-care zones
No High-Risk, High-Care Production Risk Zones
8.3 Maintenance in high-risk and high-care zones
No High-Risk, High-Care Production Risk Zones
8.4 Staff facilities for high-risk and high-care zones
No High-Risk, High-Care Production Risk Zones
8.5 Housekeeping and hygiene in the high-risk high-care zones
No High-Risk, High-Care Production Risk Zones
8.6 Waste/Waste disposal in high risk, high care zones
No High-Risk, High-Care Production Risk Zones
8.7 Protective clothing in the high-risk high-care zones
No High-Risk, High-Care Production Risk Zones

Details of non-applicable clauses with justification

Clause/section reference	Justification
4.9.3	Glass, brittle plastic, ceramics and similar materials
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
5.6.2.2	No lab onsite
8	No High-Risk, High-Care and Ambient High-Care Production Risk Zones

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

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

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

Module 12: AOECS Gluten-free Foods
Scope
12.1 Senior management
NA
12.2 Management of suppliers of raw materials and packaging
NA
12.3 Outsourced production
NA
12.4 Specifications

NA
12.5 Management of gluten cross-contamination
NA
12.6 Management of incidents, product withdrawal and product recall
NA
12.7 Labelling
NA
12.8 Product inspection and laboratory testing
NA

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018

NA

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		