Audit Report

1.Audit Summary			
Company name	Vion Enschede B.V.	Site Code	1598805
Site name	Vion Enschede B.V.		
Scope of audit	Deboning, cutting to specification of beef. Slicing, injecting, curing and packing of beef in bulk (chilled, dolavs and bags in crates) and in consumer packaging (chilled, vacuum).		
Exclusions from scope	none		
Justification for exclusion	na		
Audit Start Date	2021-03-23	Audit Finish Date	2021-03-25
Re-audit due date	2022-03-25	Head Office	Yes

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	2019-11-05		
Certificate issue date	2021-04-21	Certificate expiry date	2022-05-06		

Number of non-conformities		
	Fundamental	0
	Critical	0
	Major	0

2. Audit Results

	Minor	6

3.Company Details

Address	Het Lentfert 74 7547 SP Enschede		
Country	The Netherlands	Site Telephone Number	
Commercial representative Name		Email	No email
Technical representative Name		Email	

4.Company Profile

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

Shift Pattern	dayshift
Subcontracted processes	No
Other certificates held	SKAL, IFS PIA, ISO9001 (multisite)
Regions exported to	Europe Choose a region Choose a region Choose a region Choose a region Choose a region
Company registration number	NL 305 EG
Major changes since last BRCGS audit	Changes in employees and functions. Extra disinfection and other measurements because of corona.

4.Company Profile

VION Enschede B.V. is a site of VION Food Group in which beef is cut and produced to specification for retail and industry. This beef plant is together with the one other Dutch beef plant, led by the German VION Beef group. The third Dutch meat plant in Leeuwarden is closed past summer, leading to a shift in supply of beef.
VION Enschede is bought summer 2010 as a former cattle slaughterhouse, this is still there and maintained but close for operation. The production consists of two halls for production and several cells for storage. There is an area for receiving and dispatching hanging goods and an area for receiving and dispatching goods in bulk.

About 320 employees, including the ones in the offices. Production employees work in one shift (about 90 employees via agencies/subcontractors) mainly in production.

There is a small team leaded by the operation Director Beef with maintenance workers, a sales team, finance manager, two on QA and two persons on HR.
Main activity is the deboning and packing of fresh beef for retail organizations and meat industry. There are 3 type of products (so 3 HACCP studies): slice (which can be injected), minced meat and bulk. There are cutting lines and packaging lines and a fresh meat line. On site (m2) is app m2 in use by factory and some m2 for offices, utilities and maintenance. Of m2 not all is in use as the former slaughtering house is partly closed.
Retailers are the main customers (Western Europe with a focus on North Europe: Sweden and Denmark), but also meat industry in Western Europe mainly The Netherlands.
The production is organized from 6.00 till 16.00 in one shift. All finished products do need a heating step by the consumer or customer. Beef to be used for not heated products is released only on positive release.

This audit should be performed in October 2020, but because of the coronavirus it is later done. The next audit is in principal planned as previous (November 2021)

5.Product Characteristics

Product categories	03 - Raw prepared products (meat and vegetarian) Category Category Category				
Finished product safety rationale	Chilling (temperature <7°C, <2°C), salting, vacuum packing				
High care	No	High risk	No	Ambient high care	No
Justification for area	Appendix 2 applied. All products have to undergo full cooking step prior to consumption, for 1 product a challenge test for Listeria is done (this product was not a Listeria growing source as outcome, see report for details). Smoking process step is not considered as a sufficient heating step				

5.Product Characteristics	
Allergens handled on site	None Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	Organic, Simmentaler
Product recalls in last 12 Months	No
Products in production at the time of the audit	Beef quarters, labelled beef, sliced beef, minced meat

6.Audit Duration Details			
On-site duration	20 man hours	Duration of production facility inspection	10 man hours
Reasons for deviation from typical or expected audit duration	na		
Next audit type selected	Announced		

Audit Duration per day			
Audit Day	Date	Start Time	Finish time
1	2021-03-23	8.45	17.05
2	2021-03-24	8.45	17.00
3	2021-03-25	8.45	13.00

	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
operational Manager Beef	X		X	x
Sales manager	X			X
, Quality Manager	X		X	X
, QA	X	X	X	X
Bedrijfsleider Retail	X	X	X	X
Controlling	X			X
ıanager deboning	X	X		X
manager retail	x	x		x
ıanager TD	x	x	x	
, HR Officer			X	X
QC employee			x	x
several operators, maintenance employees		x		

GFSI Audit History

Date	Scheme/Standard	Announced/Unannounced

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
1	1.1.2	The food safety culture plan is not connected with other programmes which are also related to food safety culture. "People matter" is part of the Vion central strategy, a programme is in place. Vion Operating System, VOS, (a lean system) in which all departments are involved; also weekly a translator is on the site for the employees to ask questions about work or private related issues with the goal to feel home here.	Policy has been adjusted to include the existing points for the food safety culture. It is discussed daily during the huddle in various departments. Procedure beleid Vion enschede 2021 is ready.	It is discussed daily during the huddle in various departments. It will be included in the policy and will be assessed annually during the management review. It will be part of the reassessment	A food safety culture procedure was established by the QA department. Different parts of this culture were implemented but there was no connection between the different departments. There was only the huddle and not the Tier consultation. Through Tier consultation will all departments be connected from Vion.	2021-04-19	closed

Major							
2	2.2.1	Fallen meat from the floor was brought to a special place. Somebody else was tiding up this meat. But the person who was bringing the meat, was without washing hands / changing clothes brining back that meat (with touching the meat to heir workwear)	The person helping during the day of the audit was new to this department and had not yet completed fallen meat refurbishment training. The procedure for fallen meat has been re-explained and assessed to the responsible person	Daily during the SSOP check this will be checked by the person in charge of the department. Several times a year the QA and HR department will meet and discuss the training plan. All employees will be assessed as to whether they still need to undergo training.	The colleague has been given a new position from employee to Foreman. Training should have been given for this new position. QA was not aware that there had been a change of function in which the training should have been given	2021-04-19	closed
3	4.4.2	In the PRE SSOP (daily start up checks) was not seen that at 2 places from the receiving department kit was losing.	The sealant seams have been removed and replaced with new ones. The person in charge of the department has received practical training from the QA department on pre ssop control. All construction-	The technical department will conduct a monthly tour of the production in which all technical deviations are recorded and remedied.	During the pre ssop check, the Foreman checked a lot for cleaning and disinfection. In doing so,	2021-04-19	fully closed

Major							
			technical points have also been included		he supervised the structural condition less, so that the sealant seams were not registered on the pre ssop check		
4	4.9.3.2	There was overseen that a face shield was damaged and that red-white tape (warning for 1,5 m corona distance) was losing fibres. These subjects were no part of the glass / plastic checks/ or seen in the SSOP.	Face shield is immediately replaced. Red/white tape has been removed and will not be replaced.	Parts have been added to the Formulier glas en hardplastic register (F-ENS-NL-10031) Four times a year with the mandatory tour also will be checked for the completeness of the list for inspection glass and hard plastic.	Parts were not added to the check form.	2021-04-19	fuly closed
5	4.10.3.4	During the metal detection demonstration, the operator did not check the used meat with the metal samples later	Colleague was immediately addressed about the deviation during the check. This has been supervised by	Training metal detection has been	Due to the presence of a large number of	2021-04-19	fully closed

Major							
		on / before without a sample in the detector.	the person responsible for this department.	expanded with a photo training. Training has been given again.	persons during the audit, this person has been nervous and the procedure was not carried out properly During the metal detection check 2 weeks earlier, the execution went perfectly.		
6	4.14.9	At the action list of pest control a lot of actions were open (from October 2020 on). Most of them should be closed, but this was not recorded. So that was no evidence that the corrective	All outstanding points were handled, but not processed in the online system. This has since been adjusted.	After each audit, the list of recommendations will be communicated internally to the responsible departments. As soon as the points have	Due to changes at , there has been no proper follow-up in recording the open points.	2021-04-19	fully closed

Major							
		actions were carried out in a timely manner.		been dealt with, a notification will be sent to QA. will adjust this in their system and during the subsequent inspection this will be checked by someone from	The points were dealt with, but not recorded.		

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

Comments on non-conformities
Comments

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 company demonstrated an effective food safety management system, which is maintained to meet legal, food safety and customer requirements. Process controls and product measures are handled properly. All procedures are linked to this system and actions are followed up by root cause analysis and corrective actions (+ verification). This system was introduced past year but did not grow because of weak financial position. No resourced available to invest, just to maintain. Reallocation on resourced is planned coming months with new focus on retail and foodservice.
Policy is signed off by operational manager dd 15/1/21, objectives and KPI's are defined local and are related to the Vion Central Policy (based on food safety, traceability and product integrity, sustainability, animal welfare, human safety and customer satisfaction, all these objectives were verified by the company (and the auditor, sample checked for "complaints costs").
The company h)as a management team which meets monthly. Formal communication meetings are held at several levels within the organisation; MT 1x/4 weeks, Production meetings 1x/2 weeks, HACCP 4x/year (Production, QA, HR, TD). Minutes of meetings are kept. Seen several minutes of MT/Production/HACCP team meetings.
The management review, dated , 1 July 2021, is kept at a yearly base, seen evaluation over July 2019 – June 2020 with minor nc's identified. The reassessment report together with the management review contains the verification of the HACCP system including the required details like CCP evaluation, complaints, the review of the objectives, training activities, and the preventive and corrective actions. It is reported in the VION Operating System Style in the HQ mandated format. The management review contains also evidence for continuous improvement (e.g. reduction of complaints). Each quarter there is also a review on specific items such as complaints, microbiological results and KPI's. Seen report Q3, Q4 Q1, Q2 2020 (and Q1 2021)
The Food safety and quality culture plan is included in the x-matrix but the connection with the bigger picture is missing, see MINOR (examples: there are more programmes which are related to food safety culture. "People matter" is part of the Vion central strategy, a programme is in place. Vion Operating System, VOS, (a lean system) in which all departments are involved; also weekly a translator is on the site for the employees to ask questions about work or private related issues with the goal to feel home here).
The evaluation of these culture related plans is part of the management team meetings (and records are made in the minutes, seen from Q1 2021).

Non-conformities identified at the previous BRC audit are effectively corrected and did not reoccur.

Confidential reporting system are in place, central arranged. Over 2020 central a review is done, no concerns raised for location Enschede.
BRC issue 8 standard copy available on site. No BRC logo uses/ no problems seen with the BRC logo.

MINOR: Food safety and culture plan and the other food safety culture programmes and actions are not connected with each other.

1.2 Organisational structure, responsibilities and management authority

The organisation chart (P-ENS-NL-10020 March 2021) shows the organisations' structure and is supported by job profiles with responsibilities and authorities. Deputation is arranged and clear to all personnel. To implement the VOS into production departments guiding on huddle, mmm, communication and discipline the communication chains are described. Communication described in procedure P-ENS-NL-10032.
The management team is formed by operational manager and department managers, most present in the opening and closing meeting of the audit. Haccp team is installed and meets 4x/y.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification

2 The Food Safety Plan – HACCP

The HACCP system is implemented and maintained. A VION central PRP and CCP plan is the basis for the local HACCP plan (P-FOOD-10000m regularly updated). The hazards are part of this document (incl. microbiological (esp. pathogens, with Salmonella as higher risk (therefore temperature at receiving is a CCP), chemical, physical (incl. radioactivity/ radiological hazards).

The HACCP system of the site is developed by a multi-disciplinary team. HACCP team is trained and experienced.

The verification and management review contains the HACCP reassessment (e.g. CCP's, audits, hygiene inspections, complaints, changes in legislation, review of process diagrams. HACCP team meeting is 4x / year, seen minutes dd 3/12/20.

Each identified hazard was reviewed and given a risk rating 1 to 9 (severity and likeliness of a hazard occurring = 3 x 3 matrix). A decision tree is used. A set of flow diagrams is part of the HACCP documentation, the steps are: Process steps in sequence: Receipt (CCP temperature), storage, cutting, metal detection, injecting (option) / slicing, packing, storage and dispatch (CCP temperature on outgoing and returns). The processes are shown on flow diagrams for each process. Checked during the audit for deboning and retail (packing). Also, a minced meat line is part of the production, The production of minced meat with 2 mincing machines, a portioning machine and vacuum packers.

Last version from the central procedure, P Food 10000, is from 23/11/2020 (Changes in HACCP system are planned for Q2 2020 (new MAP and replacement of skin pack machine).

flow diagrams are checked (records in the verification report). During the audit several flow diagrams were checked, e.g. packaging and slicing.

At this moment the following CCP apply with the critical limits (all related to temperature of incoming or outgoing product):

- CCP1a Temperature incoming meat/organs: Meat can come in as hanging meat, or in dolavs which is called,
- CCP 2 temperature returned products.
- CCP 3 Temperature of outgoing meat/organs.
-

Critical temperature limits are: Organ meats: <3 °C, vacuumed organs: <2°C; Meat: <7°C), vacuumed meat: <6°C. CCP monitoring has been defined and documented; records of CCP's were checked during this audit. Eg The CCP's temperature checks are done on 5 places for delivery of fresh hanging meat.

Also, there are some 20 specific control measures on various prerequisite and operational processes: personal hygiene, metal detection, household plan, identification and traceability, pest management, training, etc.

The local HACCP plan is last updated July 2018. It is made with input of the central HACCP plan (P Food 10000). No alterations in CP's or CCP's. Reassessment / verification taken up in the quarterly management review . This verification (reassessment) of the HACCP system is done 24/8/20.

Validation of the CCP is done at central level, report is part of the central management system (quality online) 3/1/2/20.

MINOR about working method of fallen meat (cross contamination)

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

The documented system is defined and available via Quality-on-line. All key functions have direct access. Also several other software systems are applicated to manage information, HR has its own manual (also HQ managed).

3.2 Document Control
Procedures have names by which they can be recognised. P-VION (apply to all VION plants); P-FOOD (apply to all VION Food plants); P-NLFOOD (apply to all Dutch VION plants); P-ENS-NL (applies to VION Enschede). There are P for procedure and instruction and F for forms and some other types ass MMI's
3.3 Record completion and maintenance
Records are kept for 3 years (max shelf life fresh 35 days). Several records are checked, also as part of the vertical audit and during production.
3.4 Internal audits
There is a schedule for the internal audits according to procedure 'interne audits' (P-VION-10011) carried out by trained auditors of other VION companies. The audit frequency is based on risk of activity to the business, the operation and the customers (4 x a year performed, due corona 1 audit from October was delayed to Jan 21). So, several times per year the production site in Enschede and involved departments are audited announced and once a year unannounced 18/2/2020 and 9, 10 sept 2020). Other reports were seen from 9 Feb and 28 July 2020. Seen records of audits dd (by Vion central auditor). A hard copy of internal audit reports is maintained. Conformities and non-conformities are listed with corrective actions. Announced and unannounced internal audits are performed by several VION auditors being QA mangers from other VION sites. Both conformity and non-conformity is reported resulting in demonstrable follow up of actions. Furthermore, there is a scheme of inspections in SSOP forms and Pre SSOP forms indicating a high amount of daily (hygiene) inspections at the shop floor by the department managers. These inspections are monthly done by QA together with the operation department (as factory inspections).
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 at VION Food Nederland on all goods except carcasses (packaging, services, pest contractor, cleaning, transport, etc.). All (other) suppliers are approved by the central VION office and entered into the list of approved suppliers (S-MMI-10011) before they can be used. Carcass suppliers are audited regularly by VION (the quality manager of Vion Enschede), and corrective actions are recorded. Based on risk assessment all suppliers are low risk, only organic sliced meat is medium risk (at least 1 audits is done by the supplier), this is also an outcome of the integrity assessment. Last audit by QA Enschede was seen, from 6/5/20). Of all carcasses it is known were they are born, bread and slaughtered. Carcases are bought by VION Intercompany, externally by contract, and on the free market from preferred suppliers. Raw material also bought from agents / brokers and identity of slaughtering house and carcass is always in place. Minimal a GFSI certificate is needed (more examples were seen this visit), also a questionnaire is needed. Mostly also a huge client is approving the suppliers (audits are done together with Vion Enschede). Documents of these audits were seen for supplier and Non food is central purchased, all information was available during the audit.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures
At the warehouse department incoming raw materials, packaging materials and their specifications are checked visual and on temperature (CCP). Records are created seen on checklist F-ENS-NL-10018. Microbiological parameters are analysed by external lab . Also, supplier audits are done, generally audits are arranged VION central. (QA manager of VION Enschede is highly involved in the implementation of the QA system in VION Leeuwarden, key supplier of VION Enschede.) Meat supplies are monitored onsite as every hook with beef is weighted, visual checked at delivery and recorded, temperature is measured. Seen registrations on F-ENS-NL-10003, at receipt of carcasses during the audit.
3.5.3 Management of suppliers of services
All service suppliers are managed by VION Food NL in Boxtel (HQ). Suppliers are monitored onsite by eg; Inspection regarding outsourced cleaning on forms regarding pre-SSOP's and trailer checks at dispatch, for transport suppliers. Relevant data is available, checked during the vertical audit.
3.5.4 Management of Out sourced processing
NA (Transport, storage and plate-freezing is done by subcontracted suppliers who are certified to GFSI standard. Roemaat in Harreveld (certificate BRC Food). Plate frozen products do not come back on the site of Enschede).
3.6 Specifications
Specifications for raw materials, packaging materials, cleaning agents and finished product are defined and managed by the involved QA and maintenance department. Maintenance for cleaning agents, equipment to be in contact with food, lubricants and other technical aids. QA for packaging, additives, and raw materials. Several specifications seen in vertical audit.: - raw material hind quarter from supplier Vion location - DoC and specification from foil from - DoC from - final product specification from Entrecote. Specifications of finished goods are kept by the sales department and available in dedicated parts of IT, also visible to production. Specifications of ingredients and other materials are kept by Vion central. Including 3 yearly review. All specifications are digital available.

3.7 Corrective and preventive actions

VOS 2.0 (Vion Operating System) is used to manage corrective and preventive actions on the shopfloor. There is plan to restart again with this. At the moment only the huddles are implemented (more times a day meeting on the shop floor by the white boards). Within some months this will be extended (again) with the mmm's (Multi Moment Measuring), TIER meetings (a level above the Huddles). A major nc in any audit can lead to an "A4-" or "A3-verbeterplan" meaning a controlled method of managing non conformities. Details of corrective actions and closing out are kept including root cause analysis as seen for complaints.
From internal audits an action list is in place.

3.8 Control of non-conforming product

The procedure for non-conforming product is checked during the audit and records any incidents of non-conformity. If meat falls to the floor, special educated operators can tide up this meat on a special table as documented in P-ENS-NL-10004. All fallen meat incidents have to be reported on the SSOP-checklists.
Non-conforming products are categorised to CAT 1 or CAT 3. Blocked products are accompanied by form F-ENS-NL-10021. Returned products are handled according P-ENS-NL-10008.

3.9 Traceability

A traceability procedure is in place to operate the trace system: All raw- and packaging materials, intermediate and finished products receive an unique lot code. At all stages of production, the materials and products are traceable. All individual product packs are identified with a production code (line - week - day - hour) and shelf date.
Trace test was based on art 2862, Entrecote, 2,5 kg, customer . transported start at 23/12/21. All relevant information was retrieved. Specifications (incl. from packaging) and calculation documentation and all incoming goods on supplied to were demonstrable.
Mass balance was correct and available within 4 hours. CCP and CP records were available.
Records presented were: invoices of raw material; records of incoming goods control and process control (including CCP temperature checks and CP metal detection); stock lists; productions schedules and efficiencies. Also, other records concerning training and prerequisite programs (including pre SSOP and SSOP forms), microbiological results.

The yearly company test was done 23/7/2020 to final product, 24/3/2020 to ingredients.

Recall procedure P-ENS-NL-10017 was followed and evaluation included. Positive/negative release procedure is installed.

3.10 Complaint handling

Complaints are received from local sales offices and from headquarters and managed in an IT system called (No direct contact with the client.) All complaints which are considered to be attributable to the process/ product are communicated and investigated by the quality manager (categories: safety; labelling; processing/cut). Complaints are investigated with regard to root cause analysis. Actions towards suppliers and internal processes could be demonstrated.
All complaints are trended and reviewed centrally per VION plant. Complaints and retours together are expressed in €/1.000 ton or €/amount of orders and discussed quarterly as a KPI's in MT.
There are no complaints on food safety, several on foreign bodies and on integrity (wrong labels etc).
There were no complaints from authorities. Most complaints are on weight loss which is considered a complaints. The target on food safety complaints is 35/quarter of the year and on integrity complaints 10/quarter. Also, a target on complaint follow up (no open complaints of more than 14 days set to 3/quarter).

Over last period in the management review 2019-2020: in total45 complaints were received in 1 year. 10 about foreign bodies (plastic and paper, no metal complaints). In depth 2 compliants were assessed during this audit.
3.11 Management of incidents, product withdrawal and product recall
There is a general recall procedure at VION concern (P-FOOD-10015 Crisis management) which covers the process and which is applicable for all operations. Also, local Procedure Recall and Crisis management P-ENS-NL-10017 applies. A combined traceability/ recall is reported on 17 Sept '20.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.4	no outsourced processing

4. Site standards
4.1 External standards
There are no potential risks associated with the site that may affect product safety or integrity. It is located at an industrial area. It is in good repair and well maintained.
4.2 Site security and food defence
Site boundaries well defined and security (external facility provider) in place with check for visitors and lorry drivers. Separate storage takes place for cleaning chemicals, lubricants and waste. Two entrances for pedestrians and one for vehicles. There is a documented policy of the security included in F-ENS-NL10040 Risico management beheersplan Product en procesintegriteit (TACCP study) which is reassessed in the yearly management review.
4.3 Layout, product flow and segregation
The production and storage zones have been defined and based upon a risk assessment all zones are "Low risk areas" and "enclosed product areas". Personnel flows, material flows, services and equipment are placed such as to minimise the risk of product contamination. No high risk, high care or ambient high care production. All produced products do need a heating or preservation step before consumption (except beef for a client which demand injected beef steaks, a challenge test for Listeria is documented).
4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas
The fabric and internal condition of the site was suitable and satisfactory for the processes. Walls, ceilings and floors were generally suitable. Storage of packaging materials and maintenance material is separated

from production. Some condensation, no risk to product was observed. Measures on condensation removal applied.

MINOR about losing kit at receiving department.

4.5 Utilities – water, ice, air and other gases

All utilities for water, ice and heating devices (cutting department) are within the maintenance system. Water quality of the mains is monitored: at least half yearly water analysis is done on E. Coli, enterococci and TC 22 degree. A water distribution plan is available; this is in computer software which also regulates the temperature.
Machinery appears to be in a good state of maintenance. No steam or ice (except frozen CO2). The company monitors on presence of Legionella and other. Compressed air is maintained by an external partner, which is on hours of working and not at planned intervals and specification compressor oil
".
There is placed a filter (half yearly replaced) in use at the end of an air pistol (used at the start of the process, to inject air in a part of the carcass to make cutting easier). The specification of that filter was in place.

Within some months there will be started with MAP-packaging.

4.6 Equipment

In general all equipment was observed suitably designed and in good shape as to minimize potential product contamination. Relevant documents (incl. DOC for conveyor belts) were available at the technical department.

No new equipment acquired for production past year.

4.7 Maintenance

Preventive maintenance system is in place in excel with tabs per equipment section. Monthly monitoring and recording on a simple paper folder. Daily start up checks are recorded on F-ENS-NL-10033 by maintenance engineers on all departments. Also is daily checked if all maintenance tools are complete, clean and not damaged.
There is a monitoring and registration system for the temperature in cooling / freezing cells and production areas. Maintenance gets an alert, on the telephone, when temperature is beyond limits.
Calibration of the temperature equipment is outsourced and well controlled.

Workshop are kept tidy.

Hygiene clearance process after maintenance is signed off by TD and chef of the department. Records are checked by the auditor

Since March 2021 a new maintenance manager arrived, one of his goals is to get the maintenance planning and performance in a software tool.

4.8 Staff facilities
There is a well arranged area for staff facility. Outdoor clothing and shoes are stored separately from work wear. For man two separate rooms and for woman one room is available. Every person has 2 lockers. Rest room and catering facilities are provided for staff. Before using the cantina relevant clothing has to be left in the changing room. The production and storage zones have been defined and based upon a risk assessment all zones are "enclosed product" or "Low risk" areas because all finished products do need a heating step before consumption. Hand-washing facilities (with hand-free soap tap operation and air dryers) is provided at entry point to production areas. Before entering production areas sole washing and hand disinfecting equipment is installed. Smoking is only allowed in a separated area away from production and canteen near the changing rooms.
4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas
4.9.1 Chemical control
Control of chemicals on site was demonstrated. Pre SSOP and SSOP instructions are in place to control contamination. Control of chemicals on site is organized by separate (locked) storage facilities for e.g. cleaning chemicals, nitrate and nitrite and lubricating oil.
4.9.2 Metal control
Knifes are provided in sets. In the SSOP there is signed off that no knifes are missing. Visual checks on knives and needle breakage is done at start up (Pre SSOP). In the trace test seen SSOP and Pre SSOP registrations from the date of the test.
4.9.3 Glass, brittle plastic, ceramics and similar materials
Quarterly glass audits do take place on F-ENS-NL-10031. Seen daily SSOP records in the vertical traceability test of several departments by RB. MINOR about missing some subjects in hard plastic/ glass checks and daily SSOP
4.9.4 Products packed into glass or other brittle containers
NA
4.9.5 Wood
No wood is allowed at the production departments, were open product is present. Only at the end of the packing equipment wooden pallets are allowed in the packing department as well as carton layers and boxes.
4.9.6 Other physical contaminants
Carcasses on blue robes for easy detection. Only pens who are metal detectable are allowed. Cleaning gear with colour coded per area. Seen clean working areas with no built up of redundant materials. Blue metal detectable pens are in use.

4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of foreign-body detection and removal equipment
On detection of foreign bodies 4 metal detectors are in place and an x-ray is in place (to select the fat percentage). Validation is completed in the past, limits and rejection scheme is available.
4.10.2 Filters and sieves
Na
4.10.3 Metal detectors and X-ray equipment
Metal is controlled as a CP and recorded on F-ENS-NL-10023 in cutting department and on F-ENS-NL-10036 in skin pack department. Based upon risk analysis one metal detector device is placed in the cutting department, one in the sorting and labelling department. After these departments, meat can be injected and / or sliced and packed, and there are also two metal detector devices in the packing department. The x ray device is behind the detector in the cutting department but for fat% measurement. No removal or detection of foreign bodies with the Xray. Metal detection is arranged as a system with an alarm and a belt stop at the production lines. Tests are done with 3 types testing rods in the cutting department: Fe 10,0 mm; Non FE 7,1 mm; RVS 316 8,7 mm, and in the packing department: Fe 4,0 mm; Non FE 4,0 mm; RVS 316 4,0 mm. Testing is every hours (skin pack) and also at start and the end of the production day. Regular testing is demonstrated as well as recoding results. MINOR about not doing the metal detection conform procedure.
4.10.4 Magnets
na
4.10.5 Optical sorting equipment
Optical sorting in use for quality parameter fat measurement. No foreign bodies detection applied.
4.10.6 Container cleanliness – glass jars, cans and other rigid containers
na
4.11 Housekeeping and hygiene
A cleaning program v32 dd 20/4/2020 has been agreed with a third party and covers equipment, plant, buildings and services (with daily / weekly / monthly cleaning frequencies). Low frequent cleaning schedule (ceilings, walls above 2,5m, evaporators) assessed also. These detail the chemicals to use, precautions to take and method of cleaning. A list of cleaning chemicals is in place. Also a calibration on dosing unit is executed e.g. 11/1/2021. Rotating cleaning program is in place twice a week to avoid and prevent lime scale. Nine stages are recognised in cleaning: precleaning, foam cleaning, periodical cleaning, disinfection, periodical disinfection, rinsing, manual cleaning, disassemble, assemble. Daily end of production checklists are recorded to communicate with and production. Daily start up checks (pre SSOP's) demonstrate visual and agar measurements. An internal facility team supports handling of waste and staff facilities (detergent, gloves, paper towels). The boxes and crates are washed elsewhere (arranged by . On a monthly base records of swabs are sent by There is a washing machine for the washing of knifes and a circulation system to avoid cross contamination.

4.11.7 Cleaning in place (CIP)
na
4.11.8 Environmental monitoring
Weekly agar control by 30 plates/week, residue tests are also done weekly. The effectiveness of the cleaning and disinfection process is followed by hygiene audits (pre-SSOP). Swabs for CFU, pathogenic bacteria like Listeria and residue tests are taken regularly. Concentration measuring of cleaning agent is yearly exercised and outsourced. Trends are all plotted in monthly reports and in quarterly management review.
4.12 Waste
Different types of waste are defined. Correct collection and identification is demonstrated. Legal handling of categorised meat (Cat. 1 and Cat. 3) is collected by a licensed company. Other waste is collected on call separately. Furthermore, waste from foil, and general waste.
4.13 Management of surplus food and products for animal feed
Containers, crates etc. for Cat. 1 and Cat. 3 materials are well labelled.
4.14 Pest management
Pest control is subcontracted to company (contract 2016-03-24). Visit frequency is 8 times per year. Flying insect traps (EIV's) are checked 4 times a year. Seen site maps with traps allocated, yearly verified. Quality in depth inspections are executed twice per year, seen QA inspection and PRI ("pest risico inventarisatie") dd 26 Nov 20. Some advises were given, these were listed. Some infestations were reported over last year (all outside). Specs are present on the website. No toxic traps inside the premises. Once a year the EIV light bulbs are renewed. A trend analysis is in place in the software tool. Corrective actions from the inspections and visits are very well kept, but not managed in a timely manner: MINOR about not having up to date the list of corrective actions.
4.15 Storage facilities
At the production facility several cooling areas have been defined. Control of temperatures is established (only cooled) including temperature alarm settings and controlled by an external service supplier.. Alarms are monthly tested and recorded (every month another area), appr. 20 monitoring devices PT1000 are in use. Also, meat can need some days/weeks for ripening, this is done at the location Enschede itself. A separate area of the building (the newest part of the building, former production area) is applied for the storage of packaging and supporting materials. No outside storage.
4.16 Dispatch and transport

Dispatch and release of products is based upon temperature measurements at CCP level (meat temperature). This is managed by Vion headquarters (Distrifresh B.V. Boxtel, BRC S&D certified).
There is an overview of approved transporters seen this visit, this includes a sample plan for agars per transporter in combination with the Vion location (done on yearly base). Required is that the supplier of the trailer is certified (BRC/ IFS S&D or questionnaire).
Trucks are inspected at hygiene and temperature before loading. Results of this inspection are recorded at the CP control forms.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
4.3.9	No temporary structures.
4.5.3	No non potable water used for initial product cleaning.
4.9.4, 4.9.5	Products packed in flexible plastic
4.10.2	No filters and sieves applied
4.10.4	No magnets applied to control / prevent product contamination. Method not suitable for this sector.
4.10.6	No packaging in glass jars, cans and other rigid containers.
4.11.7	No CIP cleaning applied. Brine storage tanks are cleaned using manual flushing programs.
4.13.1	No customer-branded surplus food.
4.15.5	No outside storage

5. Product control

5.1 Product design/development

Process improvements are done based upon investment projects. The product development process is centrally organised within the VION Food organisation. There are no product claims other than organic. Also legislation VO 1760/2000 on "country of birth, breed and slaughter" applies. No validation past year.

For 2021 a replacement of the flow pack line, central vacuum system and a new MAP machine is planned.

5.2 Product labelling

Process improvements are done based upon investment projects. The product development process is centrally organised within the VION Food organisation. There are no product claims other than organic. Also legislation VO 1760/2000 on "country of birth, breed and slaughter" applies. No changes/ validation since last audit.
There are no cooking instructions related to food safety. For the injected beef steak which can be not fully heated, a challenge test for Listeria was done. In the report from the specialised agency in Listeria challenge tests (lab) from Dec 2019 was stated that this product is not a growing source for Listeria (shelf life is tested for 28 days after contamination with Listeria).

5.3 Management of allergens

No allergens onsite. Risk of allergens is part of the risk analysis. Measurements are arranged in hygiene rules and visitor rules.

5.4 Product authenticity, claims and chain of custody

A vulnerability study(= VACCP) is made by headquarters and transposed to the site. Procedure food fraud (P-ENS-NL-10056)and risk assessment food fraud (P-ENS-N-10057) was seen. Review is done in the HACCP re- assessment which is part of the yearly management review.
Carcasses bought from (own) slaughtering houses are scaled as low risk suppliers. For Enschede one supplier delivers sliced (organic) meat. This supplier is rated as middle risk.
Another IP product is Simmentaler Rind (from south Germany).
Several supplier audits have been performed, according plan and on supplier approval.
Segregation and correct identification is established for organic beef (Skal (certifcate exp date 31/12/2021) Skal number 028065), but during the audit no organic beef processing could be audited.
GMO's are not on site (raw material specifications). Furthermore VION Enschede has a declaration on IFS PIA audit (June 2020) on verification of authenticity and transparency certified by LRQA. Simmentaler and organic meat were both assessed in that report. And for both mass balances are done at least 4 times a year.

5.5 Product packaging

Packaging materials are stored separately from production materials and partly used packaging is covered prior to returning to the storage area. Dedicated and trained employees on packing handling on batch recording and change over. Product contact liners applied are coloured. In use are plastic bags in several sizes and colour and for vacuuming and normal packing. Foils for and labels with and without glue layers.

5.6 Product inspection and laboratory testing
5.6.1 Product inspection and testing
Product testing on site is with an x-ray on fat content. Also pH, brine, and weight is inspected. Sub contracted analyses (microbiological, chemical) are carried out by a laboratory operating in accordance with ISO 17025 . There is no lab on site. The scheduled program of testing microbiology conform P-Food-10008 is demonstrated. This procedure complies with VO 2703. Trend analyses is made over periodic, prepared by Merieux.
5.6.2 Laboratory testing
Seen COA's micro biological results for pooled product on salmonella and Listeria. In the vertical audit were raw materials on which TC, Entero's, Listeria, Salmonella also is tested. Testing on for fresh product and product on expiry date. Results for sample Minced Meat, production date 23/12/20 on Aerobic mesophilic count, Enterobacteriaceae, Salmonella, E. coli, Listeria monocytogenes, Coag. Pos, Staphylococen is within limits. Analysis by external laboratory All samples are weekly done (ca 12, from 5 product groups) . shelf life tests are planned (weekly for injected products, results are seen (Listeria, TC and Enterobacteriaceae or more parameters if required by customer), several results were checked this audit. Trend analysis are in place (provided by the lab), corrective actions are documented.
5.7 Product release
Product release is based upon product temperature measurements of the beef at 5 places (CCP) before loading. For selected clients there is a positive release on microbiological values (Listeria absent, E. coli O157 absent).
5.8 Pet Food
na

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.2.3	No nutritional claims made.
5.3.2 to 5.3.8	No allergens on site.
5.6.2.2	No laboratory on site.
5.6.2.4	No laboratory on site.
5.8	No pet food

6. Process control

6.1 Control of operations

Processes are reflected in the Process control plan. Process control is based upon the HACCP study, legal and customer requirements. Documented starts up checks are applied as pre SSOP's and during the day SSOP are reported. Records checked on the audit day and in the vertical audit.
Organic is produced at the start of the day but during the audit no organic beef was produced. Excel sheets are used to communicate and account for production values and identification of batches. Screens in production cutting areas show batch number and supplier.
In the retail department curing, tumbling and slicing takes place and good process control was seen.
X-ray equipment is started up (incl. calibration) by TD every morning (and software is protected with a code)

6.2 Labelling and pack control

At the packing department several checks are done to control that products are packed in the right packaging. Labels have to be checked at the beginning and the end of each batch. The checked labels are attached to the records of packing checks. Records checked on the audit day and in the vertical audit.
There are labels on fresh meat in primary packaging as vacuum foils and bags and there are labels on packed, slices, injected or processed meat. Also labelling applies on boxes, creates and other secondary packaging.
This visit, no label check/ product changeover was seen, but in the records the changeover was clearly to follow for e.g. the change over from organic meat parts to not organic minced meat (24/3/20)

6.3 Quantity, weight, volume and number control

Quantity control is done via scales at the packing department and at expedition for bulk. Planned daily checks take place as well as regular external measurements. All products are weighed and mass balances are used to check correct appliance.
E-weighing is done at the packing department and is described in F-ENS-NL-10001. Licence is in use since 27-04-2011 of Most goods in packing area are on e-weight. Also some type of meat can be packed with the nominal weight on the label
Injection quantity is recorded on F-ENS-NL-10025 and 10026 to record machine adjustments and monitor weight increase. Injection was in operation during the audit and weight and temperature were measured and within limits.

6.4 Calibration and control of measuring and monitoring devices

Calibration procedures ensure relevant equipment is identified and regularly calibrated on calibration form F-ENS-NL-10020.
There is a monitoring and registration system for the temperature in cooling / freezing cells and production areas. Calibration of the temperature equipment is outsourced.
Temperature devices (hand thermometers CCP and CP related) and scales (legal issue) were sampled and found calibrated 6 times a year. Seen: up to date overview calibration of all hand thermometers.

Daily all weighing equipment is checked with a weight (F-ENS-NL-10009). Yearly the balances are external calibrated by Metal detectors are calibrated by ' Seen report Metal detector 22/4/20 on correct detection material. Also the records of calibration were seen from temperature equipment in the cellars.
The inline X ray (fat measurement) is calibrated daily by TD.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
6.2.4	No on-line vision equipment used.

7. Personnel

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

The HR department has its own Quality Manual, also centrally for VION locations. Training is a relevant part of the Manual. For temporary personnel, for flex, for key personnel. Records are maintained in personnel files and in an excel-sheet (seen overview 2021 ytd)
There is evidence of introduction training for new starters and refreshment training of employees. Personnel hired via an agency is currently a challenge as scarily available. Each agency has a job coach to assist and guide its personnel so many coaches in the house, all trained on hygiene policies and safety policies as well. HQ is responsible for contracts with agencies. Competence training had taken place for the staff sampled (food safety and quality).
A good overview of given training per person is in place. All employees do have to pass a test (after an instruction/training video) on the hygiene rules before starting the contract. This HACCP training (HACCP toets) is every two year repeated. Seen personal training records for several key personnel on Metal detection, HACCP toets, Instruction "Werken bij Vion voor Flex", CCP temperature, Training SSOP, Internal auditor/"Interne audit training" by LRQA 2015-07-09, HACCP update course.
There are two xlsx -files to demonstrate education and training on competencies and on training: "Invoeren opleidingsoverzicht" and "Personeelsmatrix".
The induction-film and training is available in 6 languages (Dutch, Polish, Slovakian, Hungarian, German and Rumanian).

Records were sampled and available e.g. for (metal detection), (new started TD manager, HACCP test), CCP receiving and GS metal detection (he was related to the MINOR, but training was recently performed).
Also was checked for n the HACCP team that he was trained.

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

Hygiene regulations: available in 4 languages (Dutch, German, English and Polish).
All personnel are instructed on the documented hygiene standard, prior to commencing work, this includes temporary personnel, visitors and contractors. The wearing of any jewellery is not allowed. Instructions on changing before and after lunch breaks are clear. Coats are taken of and coatracks available.

Effectiveness of the hygiene procedures for personnel is part of the SSOP system. Blue plasters are batch wise tested.
7.3 Medical screening
Employees, visitors and contractors have to complete a health questionnaire prior to entry to any production areas. Procedures are established for personnel to notify management of infectious conditions they may be suffering from or been in contact with. The site makes all visitors, new starters and contractors aware of the need to report infectious disease during the intake by the porter before entering the site. The health and safety service physician signs declarations for each personnel under contract of VION Enschede. Persons who are suffering from relevant infectious diseases are not allowed to enter the production facilities. Personnel should report the use of medicine to their direct leader according the house rules in the contract. Dutch law ensures basic income in case of absence due to illness.
7.4 Protective clothing: employees or visitors to production areas
Housekeeping policy defines acceptable clothing and their individual cleaning. Visitors and contractors are supplied with protective clothing as required. For employees: white clothing (coats, overalls, tops and trousers) is provided. Trousers and coats and some staff have long coats. All sleeves hair nets and bear snoods are in use. Safety shoes/boots also provided. For visitor's coats, shoes/boots and hairnets are provided. The laundering of protective clothing is outsourced to a contracted and specialised laundry The wearing of sleeves, aprons and work coats isn't allowed during eating and smoking.

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
Click or tap here to enter text.
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		