Audit Report

Global Standard for Food Safety Issue 8: August 2018

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	n/a		
Audit Finish Date	2019-11-05		
Re-audit due date	2020-11-11		

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	2018-11-06		
Certificate issue date	2019-12-02	Certificate expiry date	2020-12-23		

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

3 Company Details

Address	Het Lenfert 74 7547 SP Enschede		
Country	The Netherlands	Site Telephone Number	+31 53 486 4444
Commercial representative Name		Email	Email
Technical representative Name		Email	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, CoC CBL, 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 BRC audit	External issues as price fall of beef has created shortage in supply and shift in focus to retail activities. Less deboning and more retail activities. A shortage in personnel has led to an increase of numbers of agencies, with focus on management of all agency supplied workers.

4 Company Profile

Company Description

VION Enschede B.V. is a site of VION Food Group in which beef is cutted 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 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. Some 200 employees work in one shift (about 150 employees via more then currently 10 agencies/subcontractors) mainly in production. There is a small team of 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 (9500 m2) is app 5300 m2 in use by factory and some 1200 m2 for offices, utilities and maintenance. Of 5300 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.
Due to absence of manager operations and manager Supply Chain the company is led by de Sales manager and the General manager Beef NL. Two highest on site (Manager Performance Centre Beef and the Director Operations Beef) are absent during the audit due to known reasons. They are deputized by General manager Beef and Sales Manager. All other members of MT and others joined opening and closing meeting.

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. 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 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 quarters, labelled beef, sliced beef, injected beef.

6 Audit Duration Details

On-site duration	16 man hours	Duration of production facility inspection	7 man hours
Reasons for deviation from typical or expected audit duration	18 ours were calculated but reduced to 16 hours because of a mature system and good results in the past.		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-11-04	08.30	16.30
2	2019-11-05	08.30	16.30

	Auditor (s) number	Name	Role
Auditor Number			
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
General Manager Beef	X		X	
, Sales manager and operational manager a.i.	X		X	X
Quality Manager	X		X	X
QA	X	X	X	X
Bedrijfsleider Retail	X	X	X	X
Controlling	X		X	X
Afdeling manager retail	X	X		X
HR Officer			X	X
, Foreman reception carcasses		X		
Foreman deboning		X		
Foreman bulk packing		X		
Foreman dispatch		X		
operator meat curing		X		
, Foreman Maintenance		X		
Packing operator		X		
accountmanager			X	

BRCGS Food Safety

Lloyd's Register LRQA

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	1.1.2	Food safety and culture plan does not describe clear actions and no timeframe is made. **CLOSED TO BE VERIFIED**	There's been a new procedure P-ENS-NL-10052 Procedure verbeterplan voedselveiligheidscultuur	This procedure will be implemented in 2020. See timetable	Seen Appendix 1 with timetable and comprehensive plan	2019-11-29	
2	1.1.4	Management review not complete as paragraph on complaint has incorrect objectives and results and paragraph on internal audits is not complete. Verification of correct administration not executed. **CLOSED TO BE VERIFIED**	Described complaints of foreign body or labeling are based on a written memo send to customers; internal audits are described in Q1 and Q3 2019. Verification will be done by Finance Control.	Together with Vion central QA a format specially for beef will be realized. This format will be implemented in Q1 2020 for Vion Tilburg and Vion Enschede. This report will be completed by QA and verified by Management Team from concerning plant. .	Seen Appendix 2 with adjusted Management review	2019-11-29	
3	3.1.2	QA manager does (already for a longer time) not have access to (document management system) due to ICT problems. **FULLY CLOSED**	ICT problems for access are solved by IT specialist Vion Enschede	Procedure activeren designer na een Office update	Seen Appendix 3 with method of correction and correction	2019-11-29	
4	3.5.1.1	No root cause analysis presented after an acceptance of goods from Italians	HACCP certificate received no GFSI; no more deliveries from this supplier because of no	Every Friday list of planning suppliers for next week is send to	Seen Appendix 4 with production by week	2019-11-29	

Minor							
		suppliers who is not GFSI certified. **CLOSED TO BE VERIFIED**	GFSI certificate and bad mibi results	QA. This document is checked by QA and after approval signed and send back to planning.	and suppliers signed of by QA manager		
5	3.5.2.1	Boxes not identified as primary packaging material and no batch control on boxes besides packing notes. **FULLY CLOSED**	The current procedures are reviewed and adjusted. P-ENS-NL-10009 F-ENS-NL-10022 F-ENS-NL-10061	Will be checked by QA during internal audit and recall test.	Seen Appendix 5-6-7 in which altered procedure P-ENS-NL-10009 Tracing packing materials; Form F-ENS-NL-10022 Receiving packing material and Form F-ENS-NL-10061 on labels control for Retail.	2019-11-29	
6	3.6.1	Folder on raw material acceptance criteria has app 25 items which all are outdates (from 2012) Not clear on which criteria goods can be accepted as perceived is 10 days after production. No verification possible. Also slaughtering date is recorded on F-10016 and production date is perceived. **CLOSED TO BE VERIFIED**	The specification of the raw materials will be updated. There will be monitored for several days after slaughter on expedition.	QA department will check all specifications once a year.	Seen Appendix 8 Specification on "Dikke Lende Gevliesd" v2	2019-11-29	
7	3.7.1	Actions in the HACCP team are closed out without solution or answers. **CLOSED TO BE VERIFIED**	List with actions is changed only rows with completed are green coloured	List with actions will be registered by HR and will be verified by QA	Seen Appendix 9 with list with actions in correct status and colour.	2019-11-29	

Minor							
8	6.1.3	X-ray installed to monitor fat content of batches. After this control extra human monitoring on meat quality whereby results are altered and do not comply with test results of sorting machine. **FULLY CLOSED**	The extra control on the meat after the X-ray machines is moved and the control is know before the X-ray machine.	The head of this department, daily review, and if there is any deviation, these are communicated to the QA department	Seen Appendix 10 with picture of changed workplace.	2019-11-29	

Comments on 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 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 on "Beleid & Doelstellingen signed off is seen bij operational manager dd 28-01-2019, KPI's are defined local and from HQ. The company has 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 is kept at a yearly base, seen evaluation over July 2018 – June 2019 with minor nc identified. The reassessment 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 2018 Q1, Q2 2019.
The Food safety and quality culture plan is included in the x-matrix but limited detailed (see minor).
Non-conformities identified at the previous BRC7 audit against the Global Standard for Food Safety are effectively corrected and did not reoccur. The Manager Beef NL was the highest on site to attend the opening meeting. He deputised the Manager Performance Centre Beef and the Director Operations Beef.
Confidential reporting system are in place.
BRC issue 8 standard copy available on site. No logo uses.

Minor 1: Food safety and culture plan does not describe clear actions and no timeframe is made.
Minor 2: Management review not complete as paragraph on complaint has incorrect objectives and results and paragraph on internal audits is not complete. Verification of correct administration not executed.

1.2 Organisational structure, responsibilities and management authority

The organisation chart (P-ENS-NL-10020 v6 dd 24-06-2019) 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 dd 24-06-2019
The management team is formed by Director and managers, most present in the opening and closing meeting of the audit. Haccp team is installed and meets 4x/y.

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-10000). The HACCP system of the site is developed by a multi-disciplinary team.

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 28-6-2019 and 31-08-2019. HACCP team is well trained and experienced.

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, in operation during the audit. The production of minced meat with 2 mincing machines, a portioniser and vacuum packers.

At this moment the following CCP apply with the critical limits (all retalted to temperature of incoming or outgoing product):
1a Temperature incoming meat/organs: Meat can come in as hanging meat, or in dolavs which is called CCP1a, temperature returned products is called CCP2. 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 treacibility, pestmanagement, training, etc.

The local HACCP plan is reassessed in july 2018. It is made with input of the central HACCP plan. No alterations in CP's or CCP's. Reassessment taken up in the quarterly management review seen in the review of Q2, 2019.

3. Food safety and quality management system

3.1 Food safety and quality manual

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

Minor 3: QA manager does (already for a longer time) not have access to (document management system) due to ICT problems.

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 Work instructions for employees are available in 4 languages. Local sites have to organise their own manual within the manual.

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. The scheme is not altered after the new BRC requirements but the definition on what is an Internal audit is altered so now the preparations audit on FDA visit and

NVWA visit is also added to the program. Several times per year the production site in Enschede and involved departments are audited announced and once a year unannounced. Seen records of audits dd 14-01-2019 and 22-08-2019. 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.

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 (MMI) before they can be used. Carcass suppliers are audited regularly by VION and corrective actions are recorded. In past year the amount of carcass suppliers is decreased due to a shift in strategy. Situation on internal focus is shifted so now more acquisition in the eastern and southern part of Europe is done. Site VION Leeuwarden ceased slaughtering operation.
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 in place.

Minor 4: No root cause analysis presented after an acceptance of goods from Italian supplier who is not GFSI certified.

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 andon 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.

Minor 5: Boxes not identified as primary packaging material and no batch control on boxes besides packing notes.

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; (Morning) 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

Transport, storage and plate-freezing is outsourced to subcontracted suppliers who are certified to GFSI standard. in (certificate BRC Food). Further transport is arranged by HQ.

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.:

- (incl declaration on allergens status)
- Technical data sheet
- DoC
- DoC

- Basis Productspezification art 3040

(Specifications of finished goods are kept by the sales department and available in dedicated parts of IT, also visible to production. Seen list PLU lijst DK Enschede.xlsx on all articles to be sold to Denmark including pricing and labelling. Seen list of all approved chemicals including MSDS on F-ENS-NL-10052.

Minor 6: Folder on raw material acceptance criteria has app. 25 items which all are outdates (from 2012) Not clear on which criteria goods can be accepted as perceived is 10 days after production. No verification possible. Also slaughtering date is recorded on F-10016 and production date is perceived.

3.7 Corrective and preventive actions

VOS 2.0 (Vion Operating System is used to manage corrective and preventive actions. Also results of controls and audits are scheduled and can by incorporated in the mmm's (Multi Moment Measuring), Huddles, TIER meetings. 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 several complaints.

Minor 7: Actions in the HACCP team are closed out without solution or answers.

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 3040 2,5kg shipped 27-08-2019. All relevant information was retrieved. Specifications and calculation documentation and all incoming goods on from 21-22-23/08/2019 supplied to were demonstrable.
Mass balance was correct and CCP records available (batch order
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), micro biological results.
The yearly company test is not executed as a real recall took place in December 2018 on private label product with E. coli O157. This was followed up by LRQA in January 2019. 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 and on integrity complaints 10/quarter. Also, a target on complaint follow up (no open complaints of more then 14 days set to 3/quarter.)

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 2018-12-10.

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 which is reassessed in the management review after Q2-2019.

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 who produces filet americain; this beef is on a positive release procedure.)

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.

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: half yearly water analysis. 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 ".

4.6 Equipment

In general all equipment was observed suitably designed and in good shape as to minimize potential product contamination. Relevant documents were available at the technical department. No new equipment acquired 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.
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 2019-08-27.
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 2019-08-27 of several departments by
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.
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 in 2017 an x-ray is acquired which is in operation. Validation is completed so 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 skinpack 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 of FB. 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 (skippack) and also at start and the end of the production day. Regular testing is demonstrated as well as recoding results. Seen record of testing on 26-08-2019 on F-ENS-10023 and on 27-08-2019 on F-ENS-10036.
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 v20 dd 30-1-2018 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. In June 2019 there was a shift from chemical supplier and a list of cleaning chemicals is in place per old eand new. Also a calibration on dosing is executed in June 2019. 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 transporter). 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. 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 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 2019-07-27. Some advises were given as 7 point for imrvement were listed and followed up. Some infestations were reported over last year (all outside). Corrective actions from the inspections and visits are very well kept and managed in a timely manner. Specs are present on the website. No toxic traps inside the premises. Once a year the EIV light bulbs are renewed.
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). There's a list of approved transport companies as prescribed by headquarters. All GFSI approved. Trucks are inspected at hygiene and temperature before loading. Results of this inspection are recorded at the CP control forms.

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.

5.2 Product labelling

Product is labelled in all stages of storing: at entrance per quarter, in crates, boxes, plastic, dolav. Instructions per labelling activity are in place. If labelling errors and mistakes take place these are reported in the complaints category 'Integrity'.

5.3 Management of allergens

No allergens onsite.

5.4 Product authenticity, claims and chain of custody

A vulnerability study is made by headquarters P-NLFood-10211 and transposed to the site. Carcasses bought from (own) slaughtering houses are scaled as low risk suppliers. For Enschede one supplier delivers sliced meat. This supplier is rated as middle risk. Several supplier audits have been performed, according plan and on supplier approval.
Segregation and correct identification is established for organic beef (Skal nummer 028065), but during the audit no organic beef in the building.
GMO's are not on site (raw material specifications). Furthermore VION Enschede has a declaration on Chain of Custody on verification of authenticity and transparency certified by LRQA.

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 10-2018 to 9-2019, prepared by

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 also is tested. Testing on for fresh product and product on expiry date. Results for sample Minced Meat 8-12% production date 27-08-2019 nr 21184151 on Aerobic

mesophilic count, Enterobacteriaceae, Salmonella, E. coli, Listeria monocytogenes, Campylobacter is within limits. Analysis by external laboratory

6.7 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).

6.8 Pet food

NA

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.

Minor 8: X-ray installed to monitor fat content of batches. After this control extra human monitoring on meat quality whereby results are altered and do not comply with test results of sorting machine.

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.

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 NMI. After last years audit now all goods in packing area are on e-weight.
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. Seen: hand thermometer used at impedition 15246999 valid until 1-1-2020.
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 calibrated 25-02-2019 on correct detection material.

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 2019 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). Records were sampled and available eg . on 5-11-2018 and 14-10-2019. 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).

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.

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 all to have cuffs. 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.

8. High Risk, High Care and Ambient High Care Production Risk Zones
8.1 Layout, product flow and segregation in high risk, high care and ambient high care zones
NA
8.2 Building fabric in high risk and high care zones
NA
8.3 Maintenance in high risk and high care zones
NA
8.4 Staff facilities for high risk and high care zones
NA
8.5 Housekeeping and hygiene in the high risk high care zones
NA
8.6 Waste/Waste disposal in high risk, high care zones
NA
8.7 Protective clothing in the high risk high care zones
NA

Details of non applicable clauses with justification	
Clause/section reference	Justification
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
5.2.3	No 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
6.2.4	No on-line vision equipment used.

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

Module 11: Meat supply chain assurance	
Scope	
11.1 Traceability	
11.2 Approval of meat supply chain	
11.3 Raw material receipt and inspection	
11.4 Management of cross-contamination between species	
11.5 Product testing	

11.6 Training

Module 12: AOECS Gluten-free Foods	
Scope	
12.1 Senior management	
12.2 Management of suppliers of raw materials and packaging	
12.3 Outsourced production	
12.4 Specifications	
12.5 Management of gluten cross-contamination	
12.6 Management of incidents, product withdrawal and product recall	
12.7 Labelling	
12.8 Product inspection and laboratory testing	

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018				
Item no.	Clause	Module item	Conforms (Y/N) or Not Applicable (N/A)	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		