Audit Report

Global Standard Food Safety Issue 8

1. Audit Summary			
Company name	Vion Enschede B.V.	Site Code	1598805
Site name	Vion Enschede B.V.		
Scope of audit	Deboning and cutting to specification of beef. Curing, slicing, mincing, marinating, and tumbling of beef, bulk packed in dolavs or bags in crates, (consumer-) MAP or vacuum packed.		
Exclusions from scope	NA		
Justification for exclusion	none		
Audit Start Date	2023-01-16	Audit Finish Date	2023-01-18
Re-audit due date	2024-03-24	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 Programme	Unannounced
Previous audit grade	A		Previous audit date	2022-03-24	
Certificate issue date	2022-04-21		Certificate expiry date	2023-05-06	
Number of non-conformities			Fundamental	0	
			Critical	0	

2. Audit Results

	Major	0
	Minor	10

3. Company Details

Address	Het Lentfert 74 7547 SP Enschede		
Country	Netherlands	Site Telephone Number	
Commercial representative Name		Email	vionfood.nl
Technical representative Name		Email	@vionfood.nl

4. Company Profile

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

Shift Pattern	Dayshift, 2 shifts or shifted day shifts
Subcontracted processes	No
Other certificates held	Skal, IFS PIA, ISO9001 (multi site)
Regions exported to	Europe Choose a region Choose a region Choose a region Choose a region

4. Company Profile

	Choose a region
Company registration number	NL 305 EG
Major changes since last BRCGS audit	Changes in employees and functions. Slicing machine was installed slice to calibrated beef pieces instead of manual slicing.

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 employees, including the ones in the offices. Production employees work in one shift (about 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, QA manager and 2 QA/QC employees and HR manager supported by coaches.
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): Cutting to 1st slices meat products (technical parts, fresh bulk packed in crates or dolavs or most vacuum packed in foil), sliced products (which can be marinated/ tumbled), fresh packed in crates, vacuum packed, skin packed or map packed and minced meat production to be packed vacuum or MAP. 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 basic in one shift and when needed this can be expand to a 2-shift operation. In special situations shifted shifts are implemented as some employees start a bit later and work until about 7PM (as example expedition, employee to manage dispatch). All finished products do need a heating step by the consumer or customer, no ready to eat products are produced.

5. Product Characteristics

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

5. Product Characteristics

Finished product safety rationale		Chilling (temperature <7°C, <2°C), marinated, cured, fresh, map and 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			
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, and different types of beef e.g. Weylander and Simmentaler			
Product recalls in last 12 Months		No			
Products in production at the time of the audit		Beef halves, quarters, labelled beef, sliced beef, cured beef (vacuum and fresh), minced meat (vacuum and MAP packed), sliced marinated beef (CU packed) skin packed, labelling of pre-packed beef.			

6. Audit Duration Details

Total audit 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	2023-01-16	08.00AM	5.00PM
2	2023-01-17	08.00AM	4.45PM
3	2023-01-18	08.00AM	11.45AM

Audit Team	Auditor number	Name	Role
Lead Auditor			Lead Auditor
Second Auditor	-		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
Operation manager	x	x	x	x
Qa manager	x	x		x
QA employee			x	
Sales manager			x	
HR			x	x
Team leaders deboning, retail, maintenance manager, facility manager:		x	x	x
Employees packing, deboning, cleaning, expedition, maintenance and more		x		

GFSI Post Farm Gate Audit History		
Date	Scheme/Standard	Announced/Unannounced

Document control			
CB Report number	RQA1032600 517494		
Template Name	F834 Food Safety Audit Report Template v11		
Standard Issue	8	*Template issue date*	2022-02-15
Directory allocation	Food	*Version*	1.0

Non-Conformity Summary Sheet

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

Critical			
No.	Clause	Detail	Re-audit 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
1	2.10.2	The records of CCP's are signed and verified (also signed). - Not all signatures were clearly, not to be identified and connected with an authorised employee. - The list with signatures and the related authorised/trained employees, was not demonstrably updated since 2010. - During the audit on 2022-01-18 the CCP temperature check of incoming goods was not performed as the employee was not trained (employee # had unloaded and accepted the incoming meat products that morning, but was not demonstrably trained for the related CCP	2.10.2.a) Quality department is able to identify the signatures and will take action if the employee is not authorized. Concerning CCP registration forms have been modified, no longer the signature of operators is requested, but the name only. **See evidence.** 2.10.2.b Still during the audit the temperature was measured and registered by the employee who took in the goods (he has the necessary experience as he used to work in the warehouse finished product). **See evidence**	2.10.2.a We will not ask for signatures of operators anymore on CCP registration and other forms as well, as it's not necessary. Only for approval of the records we will ask for a signature of the teamleader / department manager and the QA responsible. The list of signatures has been renewed only for the team leaders/department managers and QA responsible employees. **See evidence** 2.10.2.b Concerning employee has been requested to receive incoming goods and perform the CCP temperature check on the incoming goods in	2.10.2.a List with signatures was not updated through the years because it was not formalized and put in the quality management system (not subject to the periodic review). 2.10.2.b Occasionally purchased dressed cuts (raw material for retail department) is received outside of working hours of the finished	2023-02-13 Fully closed	

Minor							
		check on temperature, so he did not perform this check)		case there's no trained warehouse employee present at that time. has been trained on the CCP Temperature on 26-01-2023. **See evidence.**	product coldstore. No back-up was arranged for intake and authorized CCP temperature check of the incoming goods.		
2	3.4.1	During 2022 3 internal audits spread over the year were demonstrably performed (1 BRC8 self-assessment on documentation and 2 internal audits) instead of 4 audits were demonstrably performed specific for site Vion Enschede. Beside this, the audit program was not demonstrably risk associated and the scope of both internal audits was broad and general described (scope description: "HACCP, prerequisite requirements, food defence, food fraud, ISO9011,	Our planning schedule has been modified in such a way that 4 internal audits are scheduled in 2023 which cover all aspects of BRC. **See evidence**	In our new audit planning we have scheduled 4 internal audits which cover all aspects of BRC. One of the audits will be a complete check on all aspects of the BRC 9 standard carried out on several random weeks during the year.	Besides the 3 internal audits Vion Enschede was internally audited on the audit standard and was audited by other customers and the nVWA on hygiene and food safety. All these audits for sure covered all aspects of BRC, but unfortunately we failed to	2023-02-13 Closed to be verified on site	.

Minor							
		BRC/IFS, legislation, IKB BLK, QS, IFS Pia and organic"). This resulted in the fact that some of the reports showed less depth and it was not fully clear if these audits (each audit max 1 day) were covering all aspects of the quality and food safety system.			document these as part of our internal audit system.		
3	3.8.1	The rework operation procedure of non conforming product (e.g. Leak vacuum pack, weight not ok) was not fully clear implemented: - Block forms were not always used - Records of the decision on the use or disposal of the product were not always included - Responsibilities were not always fully clear - Blocked product (non conforming products) which are supposed to be re-worked, cannot be recorded in the management system	During the audit we explained that side streams of (packed) meat are either repacked, reworked as raw material or are sold as a specific article to some customers with less quality requirements. All materials in the cold storage and production were identified with batch traceability information, however blocking forms were not used consistently. After the audit we started using the blocking forms.	With approval of our site manager the blocking procedure has been modified. The procedure now describes all rework streams we have and defines more clearly the way of working for each stream and responsibilities. The blocking form will be applied according this procedure and the responsible employees will be trained on the procedure. **See evidence.**	The procedure regarding non-conforming product was not detailed enough describing the site-specific rework streams in Enschede. Also responsibilities have not been clear and no specific training of the blocking procedure took place in the past.	2023-02-13 Closed to be verified on site	

Minor							
		Modules, so these products must be clearly direct labelled.					
4	3.9.3	The company performs several trace tests per year on request of clients. These tests are used as trace tests also. In general these tests do not all show a clear summary of the findings /evaluation. During the traceability test initiated by the auditor, the traceability of primary packing material was not fully clear, records were missing. Beside this, handwritten documents related to labelling /traceability (e.g. country of origin) raw material batches used showed a mistake which resulted in an inefficient trace which took a lot of time. In the end, the trace cold be completed in time.	a.) The trace test for a internal audit in December-January was formalized using a new format for traceability testing. This format gives a clear summary of the findings with evaluation. **See evidence.** b.) We have introduced a picking-list for the warehouse on which the operators, who pick the materials) have to register the batchcode of primary packaging and the amount picked. **See evidence** c.) The concerning batch tracing document for raw materials has been modified to prevent mistakes. Besides that our QA Assistant will check these forms on a daily basis and report any mistakes to be corrected immediately. **See evidence**	a.) We have made up and introduced a trace test template to be used from now on when performing trace tests according our audit schedule. In this format also mass-balance is requested for raw material to finished product (and vice versa) including primary packaging. b.) Project has started a few weeks ago implementing . is a warehouse system with FEFO stock control and batch tracing for batch-managed non-food articles. With we will be able to trace batch-managed articles (primary packaging) including mass-balance. **See evidence**	a.) We did not use a specific template for performing traceability test before. Besides that in our audit schedule the trace tests (upstream and backstream) were not specifically mentioned. For 2023 this has been corrected. b.) For non-food articles up till now there's been no automated warehouse management system with stock control	2023-02-13 Closed to be verified on site	

Minor							
				c.) The concerning batch tracing document for raw materials has been modified to prevent mistakes. Besides that our QA Assistant will check these forms on a daily basis and report any mistakes to be corrected	and batch tracing. c.) As we still have a manual system for tracing on the retail we are dependent on the correct writing of people. This was not checked thoroughly on a daily basis.		
5	3.10.1	Not all complaints are documented correctly following the procedure. This way the information provided in the Management review and other trend analyses and information used to reduce recurring complaint levels (general overview) was found incomplete: - the complaints are stored in 2 systems: and . The complaints recorded in were	All 2023 complaints which have not been registered in yet, are registered now by Sales Support in this system. In our Excel database, in which we register complaints and direct complaints which require investigation, we make reference to the complaint number now. **See evidence**	A new complaint procedure has been introduced describing our new way of working and assuring that all complaints are registered in **See evidence**	The corporate complaint procedure has not been implemented thoroughly and completely at Vion Enschede in the past. .	2023-02-13 Fully closed	

Minor							
		not included in the general overview Complaints received of clients without original shipment number, can only be closed outside the system. This way they are not visible for the QA department and are not include in the general overview of complaints.					
2023-02-13 Fully closed		Attention is needed for identification of containers of chemicals/ fluid: - In chemical storage was seen a filled chemical container and some hand spray units were not labelled, no identification of the fluid inside of the cans /container was demonstrable. Outside stored in the near of the food gas storage, an unlabelled container with fluid was seen.	a.) In chemical storage the chemical container and the hand spray units, which were filled with a dilution of 0,1% disinfection [illegible], have been labelled accordingly. **See evidence.** b.) The unlabelled container outside near the food gas storage contains plain water and has been identified accordingly. **See evidence.**	The concerning areas have been included in our ARBO audit schedule.	The employees who have been working with these chemical did not report the fact that the containers / hand spray pumps were not identified. Also these areas have not been part of our Hygiene-ARBO check schedule.	2023-02-13 Fully closed	
7	4.11.1	Attention is needed for the following elements to maintain in a clean and hygienic condition	4.11.1.a) After the audit our cleaning company instructed to clean this belt. The pollution was identified as (discoloured)	4.11.1.a This issue was discussed with the department manager and teamleaders. When	4.11.1.a) Concerning block belt transports packed product.	2023-02-13 Fully closed	

Minor							
		and checked correctly before starting: - Blue block belt before sticker unit (closed packed products) line 2 Retail packing showed dried meat parts - Gray bins with packing material, supplied from the dry storage area, was covered with dust - Chemical container in hygiene sluice (production entry) was found to be dirty inside and mould growth was seen - Black crates in deboning area were not fully cleaned at the outside, sticker residues were seen - Sterilization water (to clean the knifes at expedition for unloading carcasses), temperature was not constant > 82°C (78-82°C)	hotmelt, not dried meat parts. **See evidence** 4.11.1.b) The grey bins in storage have been cleaned. **See evidence** 4.11.1.c) After the audit this non conformity was reported to our cleaning company after which the chemical container was cleaned thoroughly. The cleaning coordinator from now on will check on weekly basis if this container has been cleaned. **See evidence** 4.11.1.d) After the audit we have made inventory of the black crates in storage and removed all sticker residues. The responsible teamleader and department manager of the storage area have been retrained on the SSOP and quality specification for crates. **See evidence** 4.11.1.e) The sterilisator was thoroughly cleaned and descaled to improve it's reliable functioning. Besides that the flow rate of refreshing the water was lowered. **See evidence.**	objects in the packaging (dry) area get (too), this must be reported to QA with the pre-SSOP or SSOP Checklist. QA will then instruct CSU to clean it. 4.11.1.b In our SSOP Checklist for the non-food storage area we have included inspection point 12 'cleanliness of primary and secundairy packaging. **See evidence** 4.11.1.c In the cleaning frequency table of our facility department we have specifically mentioned that each time when empty cans are exchanged for full ones (which is at least weekly) the responsible facility employee must perform a check on cleanliness of the storage container. When it is not clean they have to report this through the pre-SSOP or SSOP form so QA is informed and can take	The packaging (dry) area) is not cleaned b but must be cleaned by the Vion employees (removing stickers, glue etc.). As they cannot wet clean the belt stayed dirty (without risk on product contamination). When the belt is too dirty with potential contamination of the packaging this should have been reported to QA. 4.11.1.b The responsible employee did not notice the dust and thus failed to report and clean it. 4.11.1.c The chemical container was being cleaned but not with a sufficiently high frequency. This		

Minor							
				immediate action. **See evidence** 4.11.1.d In our SSOP Checklist for the retail we have included inspection point 8 'cleanliness of primary and secundairy packaging. **See evidence.** 4.11.1.e In our SSOP Checklist for incoming carcasses area we have included a extra check on the temperature of the sterilisator to monitor it's performance during the day. **See evidence.**	stayed unnoticed during the SSOP Checks, the responsible facility employees did not pay enough attention to it. 4.11.1.d According to the quality specification for crates the crates with sticker residues should have been refused at intake. Our teamleader for the non-food area did not take the right action. 4.11.1.e The sterilisator has a water supply for refreshing the water / keep it filled on the right level during the day. After the audit our technical department discovered the flow rate was too high. When this supply is too		

Minor							
					high the heating capacity is too low and the right temperature will not be reached.		
8	4.11.3	The verification of the cleaning performance is not fully performed following the procedure: The cleaning performance of contact surfaces and processing equipment is checked on daily basis. Once a week this verification is performed also by sampling by rodac plates. In case of unacceptable levels of micro results, resampling was not always demonstrable to verify corrective actions.	The three objects with unacceptable scores on micro testing with contact plates were cleaned extra thoroughly the next day and re-tested the day after. **See evidence**	From now on we will follow our procedure 100% and will communicate unacceptable levels of of micro results after contact plating with our cleaning company. They must reclean thoroughly the next day and we will retest those objects afterwards. Also in our agar results sheet we applied conditional formatting. Any score higher than 29 will be highlighted red to signal bad results. **See evidence.**	Due to the fact our micro results on raw material and processed meat almost never exceed the internal standard there's been insufficient attention to the follow-up of bad agar results.	2023-02-13 Closed to be verified on site	
9	4.12.2	At the retail department, waste collection was performed in normal crates with blue inner liner, instead of specific Cat. 1 marked crate.	The waste, as noticed during the audit, was deposited in a collection crate (also a normal red crate with blue liner) identified as Cat. 1 waste. Of course this is not according procedure. Directly after the	We have made MMM (Multi Moment Measurement) stickers which we will place on the machines and other workplaces where Cat.1 waste is released /	During the SSOP this should have been noticed and reported on the check form. This has	2023-02-13 Fully closed	

Minor							
			audit the normal red crates have been replaced by the Cat.1 grey crates. **See evidence.**	collected. This visualizes the correct usage of the Cat.1 crates and makes directly visible if the procedure is not followed (input for daily SSOP Check). **See evidence.**	been discussed with the production manager and teamleaders of the Retail.		
10	6.2.3	At the retail department, labelling procedure/check of organic minced meat was not fully correct performed, not fully clear, during audit day 2: - the 'pack date" of minced meat BIO batch was not correct (prınted pack date on the label was the day before packing,16 Jan 2023 which must have been 17 Jan 2023) - during the trace test was seen that a wrong batch number of raw material was documented (see also minor on 3.9.3). The info of the raw material (with defined country of origin) was not verified with info printed on the label. This indicated that verification of label	a.) On the forms (production form minced meat / label check form) of concerning production we made a correction regarding the wrongly coded packaging date, which should have been 17-01-2023, to assure traceability. **See evidence.** b.) The recording of a wrong batch number of raw material is now prevented by changing the registration form and a daily check by QA department (on material number / country of origin). We refer to the evidence of point 3.9.3.	Both employees who recorded the wrong information have been warned.	Both mistakes are human mistakes. As our process is not automated a mistake like this can happen, but we haven't been able to detect this in time due to lack of control / clear registration forms which stimulate correct recording.	2023-02-13 Closed to be verified on site	

Minor							
		information against used raw material was not performed fully correct.					

Comments on non-conformities
-

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit 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).
Policy is signed off by operational manager dd 2022-11-01, 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").
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, dated, 2022-03-25, which was evaluated last audit. The latest quarterly management review, dated, 2022-09 was seen, until Q3 2022. Each quarter there is also a review on specific items such as complaints, microbiological results and KPI's. 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. The management review contains also evidence for continuous improvement (e.g. reduction of complaints). It is reported in the VION Operating System Style (VOS) in the HQ mandated format.
The Food safety and quality culture plan is included in the x-matrix, goals are attached and defined on training, awareness and understanding food safety culture. "People matter" is part of the Vion central strategy, a programme is in place. Vion Operating System, VOS, (a lean system) is implemented in almost all Vion locations. Vion Enschede is in the middle of this project plan to implement VOS for this Vion Location. Vos will help processes on improvements and also is part of the food safety culture plan, to further increase FS awareness. The meeting structure is implemented in several huddles, meetings Tier 1, tier 2 and 3.
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 are part of the management team meetings, which are documented.
A regular system audit is performed by the NVWA 2022-09-29 (specific topic traceability and integrity) No issues.
Most non-conformities identified at the previous BRC audit are effectively corrected and did not reoccur beside minor NC on 3.4.1.

Confidential reporting system are in place, central arranged. Over 2022 central a review is done, no concerns raised for location Enschede. QA manager is informed on quarterly basis on notifications for this location, no issues were reported.
BRC issue 8 standard copy available on site. No BRC logo uses.

1.2 Organisational structure, responsibilities and management authority

The organisation chart (P-ENS-NL-10020 2022-05-20) 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 and the Tier 1-2-and 3 meetings have been started to implement. Communication described in procedure P-Food-10044

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-10000 PRP's and additional CCPs' and CP's is 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, recently updated as a new Q manager has started for this organization and also new production manager was installed. 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 2022-03-11 and 2022-10-20. Procedure P -ENSNL-10006 2023-01-06 describes HACCP team of location Enschede has a multidisciplinary team incl. responsible for VACCP/TACCP.

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, two portioning machines and a Map /vacuum (skin) pack machine and vacuum packers.

Last version from the central procedure, P Food 10000, is from 2021-11-17, local P-Ens- NL-10011 2022-08-02 (MAP packing is implemented).

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 / technical parts of others than Vion locations.
- 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. E.g. The CCP's temperature checks are done on 5 places for delivery of fresh hanging meat.

In general good control was seen on CCP's. Steady group of employees performing the measurements, corrective actions taken correctly. However, during reception of vacuum-packed meat, deviation on CCP measurement: **Minor NC 1 on 2.10.2** on CCP recording.

Beside CCPs, there are about 20 specific control measures (CP's)on various prerequisite and operational processes: personal hygiene, metal detection, household plan, identification and traceability, pest management, training, etc.

The local HACCP plan (process beheersplan) is last updated 2022-06-24 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.

Validation of the CCP is done at central level, report is part of the central management system (quality online)

Documentation and record keeping is verified. Results of verification are recorded and communicated to the HACCP food safety team. Seen minutes of meeting 2022-01-28, 2022-03-11, 2022-07-01, 2022-10-22 and next meeting was planned for 2022-01-26.

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 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 of ass MMI's

3.3 Record completion and maintenance

Record completion and maintenance are in good condition and retrievable. Records retained for 3 years (max shelf life fresh 35 days). List of controlled documents is available and stored securely (electronic) and is backed up on regular basis. 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. This planning was drawn up March 2022. The audit frequency is for each company almost the same. Not clear is if the planning is based on risk of activity to the business, the operation. Yearly the production site in Enschede and involved departments are audited announced and once a year unannounced. These audits are performed by several Vion demonstrable qualified internal auditors. Both conformity and non-conformity are reported resulting in demonstrable follow up of actions. seen reports of 2022-06-08 and 2022-11-15 The third internal audits was a BRC self-assessment . In Jan 2023 a BRC gap analyses was performed by HQ on BRC9 general documents.

For 2022 there were only 3 IA moments seen. Beside this, the audit program was not demonstrably risk associated and the scope of both internal audits was broad and general described (scope description: "HACCP, prerequisite requirements, food defence, food fraud, ISO9011, BRC/IFS, legislation, IKB BLK, QS, IFS Pia and organic").

This resulted in the fact that the reports showed less depth, and it was not fully clear if these audits (each audit max 1 day) were covering all aspects of the quality and food safety system. **Minor NC 2, on 3.4.1** Motivation minor NC: The document audit performed in Jan 2023, was not counting for 2022, so 4 audits in 2022 was not achieved. However, lot of inspection rounds were held also by the new QA manager (since his start in May 2022) which are not recorded as internal audits but which show demonstrably improvements.

In addition to the internal audit programme, there is a separate program for documented inspections. SSOP's are performed on daily basis per department indicating a high amount of daily (hygiene) inspections at the shop floor by the responsible employees. These inspections are monthly performed by department managers together with the operation department (as factory inspections) as verification (as factory inspections), seen reports of 20022-10-13, 2022-09-13, 2022-6-16. Glass rounds are performed 4x year. Seen report 2022-12-22, 2022-09-18 and 2022-06-21. Beside these inspections 4x year additional environmental inspections (incl. outside area) were seen incl. follow up of corrections and corrective actions.

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 division Beef 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, and corrective actions are recorded.
Based on risk assessment all suppliers are low risk, only organic sliced meat is medium risk (at least 1 audit is done by the supplier), this is also an outcome of the integrity assessment.
Of all carcasses it is known where 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. Meat supplies from external companies 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.
Documents of the external suppliers # and # were seen, all ok and up to date. Intercompany (Vion) suppliers are not included in this monitoring program as analyses are shared intercompany, low risk. The visual inspection and CCP monitoring at reception take place the same as for external deliveries.

The site does not receive live animals.

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 of (clothing), (pestcontrol) (cleaning) and Distrifresh (transport) Netherlands), Group logistics arranges the transport within Europe, this process is controlled and checked by ISO9001 process. A list with approved cold stores is available, all listed companies are conform GFSI requirements certified. Catering services are managed by own employees.

3.5.4 Management of Out sourced processing

NA no outsourced processes: Transport, storage and plate-freezing is done by subcontracted suppliers who are certified to GFSI standard. E.g. in and 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 Rumpen from intercompany supplier
- Spec's form labels of #
- Black crate (CBL11) from Doc and spec
- DoC and specification and
- Filter compressor
- Final product specification from minced meat art
-
-

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. Where the company is manufacturing customer branded products, an formal agreement of
the finished product specification is managed by Vion Central. 3 Yearly review of specifications supported by All specifications are digital available.

3.7 Corrective and preventive actions

A documented system is used to manage corrective and preventive actions on the shopfloor.

There is plan to restart again with this and to work with the VOS system. Once a week operation management meeting and 1x 2 weeks QA meeting. The huddle white boards are implemented, and these daily morning meetings are implemented). Process is running to extend this system in the mmm's (Multi Moment Measuring), TIER meetings (a level above the Huddles).

Corrective actions and preventive action system is up to date. The handling of these non-conformities is according requirements: An internal major nc (of Internal audit or inspection) 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. Internal audits actions are listed and demonstrably followed up and verified during next on site audit.

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 (CAT 3 is degraded to cat 1). Blocked products are accompanied by form F-ENS-NL-10021. Returned products are handled according to P-ENS-NL-10008. Seen blocked product batch # which was sorted out (Ire-work-0, 100% weight and label check. Not all non-conforming product was marked with a "red block form". Some were marked with a white form incl. a description of the non-conformity. On this form also is not always clear what the purpose will be: re-work or sorting out (correction). **Minor NC 3 on 3.8.1**

3.9 Traceability

A traceability procedure P-Food-10015 2022-02-23 is in place to operate the trace system: All raw materials and ingredients, 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 Minced meat 1500gr for # Sa produced 2022-09-22 UBD 2022-09-30, produced that day 2x 720 kg. Most of the relevant information was retrieved. Specifications (incl. from packaging) and calculation documentation and all incoming goods on supplied to were demonstrable. Rework was not applicable on this batch.

Records presented were almost all provided on paper which makes the trace not easy. Documents were seen as: invoices of raw material; records of incoming goods control and process control (including CCP temperature checks and CP metal detection), e-weight checks, MAP gas checks, label checks; stock lists; productions schedules and efficiencies. Also, other records concerning training and prerequisite programs (including pre SSOP and SSOP forms), microbiological results.

Mass balance was correct and available within 4 hours, but on document level this was a challenge. No standard format was used, so it was not always clear which documents must be used for this trace test (which was also seen during review of the trace tests performed by the company itself)

However, on one form related to this production a wrong raw material batch number was recorded. The company showed that it was impossible that this batch was used. Other records also related to the production of this batch showed the real batch which was used. So at the end, the traceability /mass balance was ok.

Beside the document issue on the batch number, the traceability of primary packing material was not ok. This trace was not recorded and could not be shown. Beside this, no other issues found during the product traceability and all documents showed control over the system for food safety by the organisation. Food contact materials legalization is fully implemented. **Minor Nc 4 on 3.9.3**

The company implemented a basic traceability system: traceability of raw material and ingredients.

The yearly company mock recall test was done 2022-03-18. Bottom-up test was performed on 2022-08-09 on [redacted] top-down test was performed on 2022-12-19 on Rump steak 125 gr. For # [redacted] all ok.

These tests were most of the time performed on request of clients. Therefore the conclusion was not always easy to find (provided most of the time by email), but was seen.

Conclusion: traceability system is working properly. Mass Balance is complete. Packaging is also traceable. Verified records of CCP's, OPRP's and PRP's.

Recall procedure P-ENS-NL-10007 was followed and evaluation included. Positive/negative release procedure is installed.

3.10 Complaint-handling

Procedure P-Ens-NL-10024 17-03-2020
Complaints are received from local sales offices and from headquarters and managed in an IT system caller [redacted]. (No direct contact with the client as this is managed by HQ.)

In 2022 63 FS related complaints per quarter, target <60, just above the target. Complaints like past shelf life, mould on the meat, metal complaint, plastic piece, most of them B to B complaints. Not all complaints were legitimate.

In 2022 37 Integrity (labelling) complaints were received per quarter Target <60 (e.g. wrong label or UBD/coding)

Beside these FS and integrity related complaints, also other complaints were received like leakage of vacuum packing (most of them caused by sharp bones) and losses in weight.

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, seen documented in MR over 2022 until Q3.
There are no serious complaints on food safety (no withdrawals/ recalls), several on integrity (wrong labels etc) and some on foreign bodies. There were no complaints from authorities.

The number of complaints is stable against past years.
Within the Vion company, the performance of Vion Enschede (with focus on complaints) is AAA (" adequate" status, which is good.)

Not all complaints are documented correctly following the procedure. This way the information provided in the Management review and other trend analyses and information used to reduce recurring complaint levels (general overview) was found incomplete:

- the complaints are stored in 2 systems: and . The complaints recorded in ' were not included in the general overview

Complaints received of clients without original shipment number, can only be closed outside the Fobis system. This way they are not visible for the QA department and are not include in the general overview of complaints. **Minor NC 5 on 3.10.1**

Seen complaints in a dump document out of , handled complaints until Dec 16 2022.

In depth assessment during the audit of complaint in eviewed, connected complaints of #. , one of the biggest clients of the company, complaints on deviations in reception (entrance control check at on Kg/ quality). RCA, and good communications was seen, incl actions defined to improve.

Complaint assessed of (# :) 2022-12-23 as petrification of pieces of the " platte bil", complaint in of (#) and return goods from (# , 2022-01-13.

Complaints were followed up, communication documents were provided and assessed.

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.
Recall and withdrawal procedures are including the activities, the list of contact persons and the replacement scheme, as well as a checklist, and overview of specialist to consult, and the national recall scheme from the authorities.
Scenarios are discussed in the manual regarding incidents. No withdrawals applicable since the last audit.
Permanent contact person is always available in the organisation.
The recall notification letter of LRQA has been included in the procedure, stating that the Certification Body will be informed within 3 days of the event of a recall.
Also, local Procedure Recall and Crisis management P-ENS-NL-10017 applies. A combined traceability/ recall test was reported on 2022-03-18, ok

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
3.5.4	no outsourced processing

4. Site standards

4.1 External standards

Suitable located building containing enough space. No adverse activities in the surrounding area. Site is suitable maintained and well equipped; makes a logical and safe way of processing possible.

The factory is situated in a light industrial area, well maintained external areas. No special risk identified. Total area of the plant is with a fence. There are no potential risks associated with the site that may affect product safety or integrity. Building and area are 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, last review as input for MR, 2022-03-11 during HACCP meeting) 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 marinated beef steaks, a challenge test for Listeria is documented).

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

Suitable flow is implemented. In general a modern building fabric, well maintained through the years. Good facilities. Flat finished walls, suitable for processing and packaging activities. Floors are well designed and in good condition. Well maintained ceilings/constructions with a good access to suspended ceilings. Protected glass, no windows could be opened in the processing areas.
Doors in good condition, external doors are well fitted and kept closed when not in use.
Suitable protected strip lights, including protected electric fly-killer devices.
No temporary fixtures have been noticed. Raw material intake and storage, production, packaging and storage are separate areas. There are no lines present that require equipment to extract dust. All staff has access to all departments via one entrance with brushes for shoes and hand disinfection connected to a gate. This is fully automated. Separate rooms are in place for raw material intake, storage of packaging materials and weigh up area and expedition. There are no identity preserved goods applicable. No dedicated production lines are applicable. The washing of equipment is done separated in time from

production and crates are washed externally. No high-risk areas applicable only enclosed areas and low risk areas. Good condensation control (ceilings) in areas as packing areas was seen conform P-Ens-NL-10060 2022-01-25.

4.5 Utilities – water, ice, air and other gases

All utilities for water 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. Seen good results of samples taken 2022-01-20. 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.
For MAP-packaging installation is applicable and used gases are food grade, gasses stored in tank units, locked, stored conform requirements.

4.6 Equipment

Equipment installed is suitable and designed for the intended purpose. Equipment is specified, tested and commissioned before commercial use. Equipment which is in direct contact with food is suitable for food contact and meets legal requirements where applicable. Relevant documents (incl. DOC for conveyor belts, food grade 2020-01-30) were available at the technical department. Validation seen of new slicing machine. Equipment made of stainless steel. Seen validation incl. DOC of the equipment in Retail dep. in use (portioning / sawing e.g. T-bones) object , in use since 2022-11-04, ok

4.7 Maintenance

The maintenance planning and performance is implemented ir. Monthly monitoring and recording of planned maintenance and other maintenance. Daily start up checks are recorded on F-ENS-NL-10033 by maintenance engineers on all departments, as pre view before start up, to be sure all equipment is ready for production and to prevent start up delay.

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. Chilled areas are controlled by SKADA system. Latest calibrations and checks of the PT-1000 performed on 2023-01-11. Air compressors are maintained regular, air is filtered and conform requirements 2022-09-22.

Greasing plan for food grade and non – food grade grease demonstrable (risk based approach). A detailed overview of required maintenance and lubrication was shown. Effective plan and follow up. Lubrication with food grade oils (see element 3.6).

Workshop are kept tidy.

Hygiene clearance process after maintenance is introduced with and chef of the department. Records are checked by the auditor.

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 outside, as this facilitating smoking is no longer allowed inside the building following Dutch law since Jan 2022

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

All chemical containers (with cleaning chemicals, clearly labelled) are separated stored. Cleaning chemicals are stored in a locked room with restricted access. MSDS sheets are available on the spot. Mobile satellites to dose the chemicals are installed. All approved chemicals are suitable for food production areas. Only trained persons have access to these chemicals.
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.

In the chemical storage a filled chemical container and some hand spray units were not labelled, no identification of the fluid inside of the cans /container was demonstrable. Also near the food gas storage outside, an unlabelled container with fluid was seen. **Minor NC 6 on 4.9.1.1**

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. Staples, paper clips and drawing pins are not used

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 and during the on-site audit. No glass incidents took place since the last audit.

4.9.4 Products packed into glass or other brittle containers

NA Products are not packed into glass/brittle containers

4.9.5 Wood
No wood is allowed at the production departments, where 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 plasters 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 metal detectors are in place at deboning area and packing are for retail, also an x-ray is in place (to select the fat percentage). Validation is completed in the past, limits and rejection scheme is available. Checks are documented and performed by trained employees. This was seen during the trace test and during the on-site audit.
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 vacuum (skin) pack department for retail. Based upon risk analysis metal detector devices are placed in the cutting department, also in the sorting and labelling department. After these departments, meat can be 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 performed 1 x hour (skin pack, vacuum and MAP) and also at start and the end of the production day. Regular testing is demonstrated by trained employees as well as recoding results.
4.10.4 Magnets
NA No magnets are used into the process
4.10.5 Optical sorting equipment
Optical sorting is used for quality parameter fat measurement. No foreign bodies detection applied.
4.10.6 Container cleanliness – glass jars, cans and other rigid containers
NA No containers are in use. No products packed into glass/brittle containers.
4.11 Housekeeping and hygiene
A cleaning program 2022-08-04 (Bestek) has been agreed with a third party) and covers equipment, plant, buildings and services (with daily / weekly / monthly cleaning frequencies). Cleaning and

disinfection described in P-Ens NL-10032 2022-07-19. 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 and calibration on dosing unit is executed. 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).
However, some equipment was not cleaned well, e.g. belt in the retail packing area, see **Minor NC 7 on 4.11.1**

The cleaning performance of contact surfaces and processing equipment is checked on daily basis. Once a week this verification is performed also by sampling by rodac plates. In case of unacceptable levels of micro results, resampling was not always demonstrable to verify corrective actions. **Minor NC 8 on 4.11.3**

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 CIP is not applicable.

4.11.8 Environmental monitoring

Environmental monitoring program is in place, P-Food-10009 2022-03-03, typical sampling areas, organisms being assessed, frequency of testing, procedures for out of specification results are identified and verified.
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 (aprox 2x month), Seen results of cutting department 2023-01-23, 2023-01-05, and also of retail department 2023-01-05,all ok, no detection. 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

Procedure P-Food-10021 storage waste and cat material was seen. Waste is identified, collected and removed regular during the day from the production areas. Most waste is stored in marked containers in the production and on the premises before it is being disposed of. However in the retail department was usage of a normal meat crate seen to collect Cat 1 material. **Minor Nc 9 on 4.12.2.** No accumulation of waste seen during site tour. Different types of waste are defined. Cat 3 is degraded to Cat 1, which is legal handled and collected by a licensed company . Other waste is collected separately by . Furthermore, waste from foil and general waste. Container with collected cat 1 material is stored inside in a separate room to avoid pests and risk on contamination. Wastewater is disposed in the municipal sewage canal after fat has been drained into a grease trap that is emptied regularly and collected by a licenced company.

4.13 Management of surplus food and products for animal feed

4.14 Pest management

Pest control is subcontracted to company ... (contract 2016-03-24). Visit frequency is 8 times per year. Seem last inspection report 2022-11-21, extra visit report was seen of 2022-10-25 on check on cockroaches, hoyhoy traps are placed in changing rooms. This situation is controlled, no issues. 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, seen QA inspection 1x year 2022-09-26 and PRI 1x year ("pest risico inventarisatie") dd 2022-02-03. Some advises were given, these were listed and followed up demonstrably. Specs of used rodents (non tox) are present on the website of . No toxic traps used inside the premises and also outside. Once a year the EIV light bulbs are renewed. Corrective actions from the inspections and visits are very well kept and managed in a timely manner. A trend analysis is in place in the software tool. The inspector of is licenced util 2028-01-21.

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 control forms of which samples were seen of past weeks and during trace test of # , ok.

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 the flow pack line MAP packing was introduced, validation was seen and completed.

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) , accreditation), 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).
Labelling according to legal aspects as required by the company, several checks done during production tour. Raw materials are special labelled in the racks and on the individual product bags. Shown were good results for the product of the vertical traceability test.

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 2021-04-20) and risk assessment food fraud (P-ENS-N-10057 2022-06-21) 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. No high risks identified.
Several supplier audits have been performed, according to plan and on supplier approval, this was verified for Simmental, , all ok
Segregation and correct identification is established for organic beef (valid Skal certificate, Skal number 028065), but during the audit no organic beef processing could be audited.
GMOs are not on site (raw material specifications). A Pia audit was performed June 2022, verification on authenticity and transparency, certified by LRQA. Organic meat was also assessed in that report, incl. mass balances are done at least 4 times a year, ok

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. In general, suitable packing procedures and materials with relevant (food contact suitability/migration) specifications. Blue contact liners are used for bulk packing fresh; intermediate storage in special octa bins – with blue inner bags.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

oduct 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

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 2022-03-17 on Aerobic mesophilic count, Enterobacteriaceae, Salmonella, E. coli, Listeria monocytogenes is within limits. End of shelf life test results seen of biefstuk , 19 days seen results of 2022-02-25 (prod. date 2022-02-04). Analysis by external laboratory

All samples are weekly done (ca 12, from 5 product groups). Trend analysis are in place (provided by the lab), corrective actions are documented. No deviations seen.

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, label check/ product including changeover was seen on minced meat products for (art no . . ≠), and during the trace test. The records of the changeover were clearly to follow, renewed label check and line clearance was observed. However, during the 2nd day of the audit was seen that during labelling of minced meat (art no . for client :) was labelled with the production date of the day before. **Minor NC 10 on 6.2.3**

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 2011-04-27 of NMI. Most goods in packing area are on e-weight. Also some type of meat can be packed with the nominal weight on the label. The e-weight system used for retail products (:) was not fully clear in case underweight was measured.

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 and yearly calibration report of the standard “mother” thermometer device 2022-02-28.
Calibration of the chemical dosing systems used for cleaning equipment is managed by the cleaning company .
Daily all weighing equipment is checked with a weight (F-ENS-NL-10009). Yearly the balances are external calibrated by , seen scale retail 2022-11-05. Metal detectors are calibrated by . Seen report Metal detector 2022-03-17 on correct detection material. Also the records of calibration were seen from temperature equipment in the cellars which are monitored on temperature 24/7.
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 2023 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).
Day 0, a guided tour is performed, to introduce the company and it habits, incl. the induction-film and training (provided in 12 languages). A good overview of given training per person is in place.
After that, 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” of by LRQA 2012-08-28, HACCP update course. There are two xlsx -files to demonstrate education and training on competencies and on training: “Invoeren opleidingsoverzicht” and “Personeelsmatrix”.
Recently the VOS team of Enschede was trained in Grmany (on another Vion company by a Vos trainer). This, to handle the VOS system for improvement purposes on daily basis.

All workers (including contracted workers) are trained in Food defence. Principles of Food hygiene and food safety, Health and personal hygiene and Produce safety standards. All personnel engaged in activities relating the production has followed relevant training. Verified training records including CCP/ HACCP training, allergens, food defence and food fraud) and cleaning.Training will be given once every year. In case of new employees these will be trained prior to enter the production area by the QA manager himself. Employees sign for the house rules prior to start working as well.

Seen records of flex- and permanent employees , no issues, all ok.

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 all are batch wise tested, last in used batch seen tested on 2022-03-16.

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

For employees: white clothing (coats, overalls, tops and trousers) is provided. Trousers and coats and some staff have long coats. Also sleeves hair nets and bear snoods are in use incl. mouth masks (still preventive because of Covid-19 and Flue going around).

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, gloves and work coats isn't allowed during eating and smoking.

Housekeeping policy defines acceptable clothing and their individual cleaning.

Visitors and contractors are supplied with protective clothing as required, and sign for hygiene rules.

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

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
Not applicable
8.2 Building fabric in high-risk and high-care zones
Not applicable
8.3 Maintenance in high-risk and high-care zones
Not applicable
8.4 Staff facilities for high-risk and high-care zones
Not applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not applicable
8.7 Protective clothing in the high-risk high-care zones
Not applicable

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
Not applicable
9.2 Specifications
Not applicable
9.3 Product inspection and laboratory testing
Not applicable
9.4 Product legality
Not applicable
9.5 Traceability
Not applicable

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 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 BRCGS section 2.10.		
13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRCGS 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.		
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.		
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		
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		

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.		
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.		
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.		
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.		
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.		
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.		
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.		
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.		
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.		
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.		
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.		
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.		
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.		
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.		
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).		
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		

14.1 Additional Specifier requirements

14.1 Traceability

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14.2 Environmental Monitoring
Click or tap here to enter text.
14.3 Product inspection and laboratory testing
Click or tap here to enter text.
14.4 Protective clothing: Employees or visitors to production areas
Click or tap here to enter text.