Audit Report

Global Standard for Food Safety Issue 7: July 2015

1 Audit Summary

Company name	VION Food Group	BRC Site Code	1598805
Site name	VION Enschede B.V.		
Scope of audit	Deboning, cutting to specification of beef. Slicing, injecting, curing and packing of beef in bulk (chilled, dolavs and bags in crates) and in consumer packaging (chilled, vacuum).		
Exclusions from scope	none		
Justification for exclusion	na		
Audit Finish Date	2017-11-10		
Re-audit due date	2017-11-11		

Voluntary modules included

Modules	Result	Details
Choose a module	Choose an item	
Choose a module	Choose an item	
Choose a module	Choose an item	

2 Audit Results

Audit result	Certificated	Audit grade	AA	Audit type	Announced
Previous audit grade	AA	Previous audit date	2016-11-02		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	4

3 Company Details

Address	Het Lenfert 74 7547 SP Enschede		
Country	The Netherlands	Site Telephone Number	+31 53 486 4444
Commercial representative Name		Email	@vionfood.com
Technical representative Name		Email	@vionfood.com

4 Company Profile

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

Subcontracted processes	No
Other certificates held	SKAL, CoC CBL
Regions exported to	Europe Choose a region Choose a region Choose a region Choose a region Choose a region
Company registration number	EG 305 NL
Major changes since last BRC audit	No major changes since last audit

Company Description

VION Enschede B.V. is a site of VION Food Group in which beef is manufactured for retail and industry. VION Enschede is bought summer 2010 and 30 August 2010 the production is started. From employees, about employees are working (most via subcontractors) mainly in production. Main activity is the deboning and packing of fresh beef for retail organizations and meat industry. There are 3 type of products (so 3 HACCP studies): slice (which can be injected), minced meat and bulk. There are cutting lines and packaging lines and a fresh meat line. On site (9500 m2) is app 5300 m2 in use by factory and some 1200 m2 for offices, utilities and maintenance. Of 5300 m2 not all is in use as the former slaughtering house is partly closed
Retailers are the main customers (Western Europe with a focus on North Europe: Sweden and Denmark), but also meat industry in Western Europe mainly The Netherlands.

4.Company Profile

The production is organized from 6.00 till 15.00 in one shift. All finished products do need a heating step by the consumer or customer. Beef to be used for not heated products is released only on positive release. The production building and equipment is dated October 2009. Facility buildings are older and have no direct entrance to the production building.

5.Product Characteristics

Product categories	03 - Raw prepared products (meat and vegetarian) Category Category Category Category Category
Finished product safety rationale	Chilling (temperature <7°C), salting, vacuum packing
High care: No / High risk: No / Ambient high care: No	
Justification for area	No ready to eat product
Allergens handled on site	None Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	Organic, BLK
Product recalls in last 12 Months	No
Products in production at the time of the audit	Beef quarters, labelled beef, sliced beef

6.Audit Duration Details

6 Audit Duration Details

On-site duration	16 man hours	Duration of production facility inspection	8 man hours
Reasons for deviation from typical or expected audit duration	18 ours were calculated but reduced to 16 hours because of a mature system and good results in the past.		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2017-11-09	08.30	17.00
2	2017-11-10	08.30	16.30

	Auditor (s) number(s)	Names and roles of others
Auditor Number		– Lead Assessor
Second Auditor Number	N/A	

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 1.1.9) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
, Director Operations	X		X	X
, Quality Manager	X	X	X	X
, QA	X	X	X	X
, Bedrijfsleider Retail	X	X		X
, Bedrijfsleider Uitbenen	X	X		X
HR Manager	X		X	X
Finance	X		X	X

Present at audit				
, Sales	X			X
accountmanager			X	
, Foreman reception carcasses		X		
Foreman deboning		X		
Foreman bulk packing (snipper)		X		
, Foreman dispatch		X		
, operator meat curing		X		
, Foreman Maintenance		X	X	
. packing operator		X		

Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements				
No.	**Clause**	**Details of non-conformity**	**Critical or Major?**	**Anticipated re-audit date**

Critical			
No.	**Clause**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Minor

No.	Clause	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	1.1.2	The objectives of the site do not comply with the objectives from HQ. Alignment is not demonstrated. In the quarterly review are plotted the objectives of HQ and additional objectives are observed in the site overview. **FULLY CLOSED**	The objectives of Vion Enschede are completed and comply with the objectives of HQ now	This was not observed. The objectives of HQ and Vion Enschede will be verified on comply quarterly by QA department of Vion Enschede	Seen attachment 1 on alignment of x-matrix and quarterly review	2017-12-01	
2	3.2.1	Record 10034 has to be used to verify all SSOP forms, is not in use. Another system in excel is in use to verifiy SSOP-forms. Also form 10033 in maintenance is in use dated rev 1 dated 2011 but does contain the elements of the . Correct document control not demonstrated. **FULLY CLOSED**	Record 10034 is cancelled. The SSOP forms has been changed in January 2017. There is an additional registration added. The quality manager performs a monthly check to verify. (attachment 2). F-ENS-NL-10033 is changed to QOL. This is now in use at the TD. (attachment 4).	Change of forms was not fully correct. There is a memo sent by e-mail to all executives with the explanation about the file with the name document management. (attachment 3).	Seen Attachment 2 on SSOP F-ENS-NL-10015 Skinpack; Attachment 3 Memo on document management dd 21-11-2017; Attachment 4 F-ENS-NL-10033 v2 dd 16-11-2017	2017-12-01	
3	4.11.2	The documented cleaning program does not show the current method of cleaning as there is a change in chemicals in practice not documented correctly. It is not demonstrable what is cleaned with what chemicals past weeks and it is not clear when the	There is a new registration form in which daily is registered which types of chemicals are used by (attachment 5). This form will be checked by QA. There is a new cleaning	Use of chemical not clearly communicated. During the monthly consultations with the area sales manager	Seen Attachment 5 on daily registration of chemicals (F-ENS-NL-10043) and attachment 6 the adjusted cleaning scheme	2017-12-01	

		changeover has taken place. **FULLY CLOSED**	scheme on which the right chemicals are reported (attachment 6).	of the will the cleaning plan and use of chemicals be discussed. This will start at the next consultation on 28-11-2017.			
4	5.1.1	Compliance report on Food contact materials of (ref 003/17/DL Iss 3 date Mar 2017 updated jan 2017) states that the lead free curtains do not pass the requirements for food contact material. It is not demonstrated that this issue is seen by the validation team and it is not demonstrated that this curtain has no impact on food safety. Also the criteria of validation of the machine are not demonstrable and production did not sign the validation form F-ENS-NL-10042 dd 19-10-2017. **CLOSED to be verified during next audit**	There is an new registration form (formulier checklist aankoop nieuwe machine's F-ENS-NL-10042). In this form are some topics added. Other existing topics are further expanded. Furthermore, now a signature for approval by the Managing Director is incorporated.	This was missed by the HACCP team. During the HACCP team consultation will as a standard new machines be discussed .If there are still open validations, those will also be discussed.	Seen Attachment 7 a correct compliance report of with food contact requirement and attachment 8 form F-ENS-NL-10042 the new validation signed by 5 and with more information including cleaning restrictions.	2017-12-01	

Comments on non-conformities

Voluntary Modules Non-Conformity Summary Sheet

Critical

No.	Clause	Details of non-conformity	Anticipated re-audit date

Major

No.	Clause	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

Minor

No.	Clause	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

FSMA Module Non-Conformity Summary Sheet

Critical

No.	Clause	Details of non-conformity	Anticipated re-audit date

Major

No.	Clause	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

Minor

No.	Clause	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The company demonstrated an effective food safety management system, which is maintained to meet legal, food safety and customer requirements. Process controls and product measures are handled properly. The system for continuous improvement and PDCS was demonstrable according the VION VOS method (VION Operating System). All procedures are linked to this system and actions are followed up by root cause analysis and corrective actions (+ verification).
Policy on "Beleid & Doelstellingen signed off is seen, KPI's are defined local and from HQ. The company has a management team which meets regularly. Formal communication meetings are held at several levels within the organisation; MT 1x/4 weeks, Production/HACCP meetings 1x/2 weeks (Production, QA, HR, TD). Minutes of meetings are kept. Seen several minutes of MT/Production/HACCP teams meetings.
The management review is kept at a yearly base, seen evaluation over July 2016 – June 2017. The reassessment together with the management review contains the verification of the HACCP system including the required details like CCP evaluation, complaints, the review of the objectives, training activities, and the preventive and corrective actions. The management review contains also evidence for continuous improvement (e.g. reduction of complaints). Each quarter there is also a review on specific items such as complaints, microbiological results and KPI's. Seen report Q1, Q2 2017.
Non-conformities identified at the previous BRC7 audit against the Global Standard for Food Safety are effectively corrected an d did not reoccur.

Minor 1: The objectives of the site do not comply with the objectives from HQ. Alignment is not demonstrated. In the quarterly review are plotted the objectives of HQ and additional objectives are observed in the site overview.

1.2 Organisational structure, responsibilities and management authority

The organisation chart shows the organisations' structure and is supported by job profiles with responsibilities and authorities. Yearly appraisal meetings are held. Recently a new training coordinator is installed to guide new employees and to be trained employees with training on the job. And recently a new job was created as QA officer to assist the QA manager.
The management team is formed by Director and managers, all present in the opening and closing meeting of the audit. .

Details of non-applicable clauses with justification

Clause reference	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 v11 dd 29-9-2017). The HACCP systemof the site is developed by a multi-disciplinary team. The verification/ management review contains the HACCP verification (e.g. CCP's, audits, hygiene inspections, complaints, changes in legislation, review of process diagrams. HACCP team meeting is 4x / year. HACCP team is well trained and experienced and expanded with the new QA Officer.
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, also in operation during the audit. The production of minced meat with 2 mincing machines, a portioniser and vacuum packers.
At this moment the following CCP apply with the critical limits: Temperature incoming meat/organs: Temperature of outgoing meat/organs. Meat can come in as hanging meat, or in dolavs which is called CCP1, temperature returned products is called CCP2. CCP 3 is outgoing product. 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. The CCP's temperature checks are done on 5 places for delivery of fresh hanging meat.
Also there are 20 specific control measures on various prerequisite and operational processes.
The local HACCP plan is reassessed on 4-9-2017. It is made with input of the central HACCP plan. No alterations in CP's or CCP's

Details of non-applicable clauses with justification

Clause reference	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 Documentation control

Procedures have names by which they can be recognised. P-VION (apply to all VION plants); P-FOOD (apply to all VION Food plants); P-NLFOOD (apply to all Dutch VION plants); P-ENS-NL (applies to VION Enschede). There are P for procedure and instruction and F for forms and some other types ass MMI's Work instructions for employees are available in 4 languages.

Minor 2: Record 10034 has to be used to verify all SSOP forms, is not in use. Another system in excel is in use to verify SSOP-forms. Also form 10033 in maintenance is in use dated rev 1 dated 2011 but does contain the elements of the . Correct document control not demonstrated.

3.3 Record completion and maintenance

Records are kept for 3 years (max shelf life fresh 35 days). Several records are checked, also as part of the vertical audit and during production.

3.4 Internal audit

Once a year the production site in Enschede and involved departments are audited announced and once a year unannounced. There is a schedule for the internal audits according to procedure 'interne audits' (P-VION-10011) carried out by trained auditors of other VION companies. The audit frequency is based on risk of activity to the business, the operation and the customers.

A hard copy of internal audit reports is maintained. Conformities and non-conformities are listed with corrective actions. Announced and unannounced internal audits are performed by several VION auditors being QA mangers from other VION sites. Both conformity and non conformity is reported resulting in demonstrable follow up of actions.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials and packaging

Purchasing and supplier approval is at VION Food Nederland on all goods except carcasses (packaging, services, pest contractor, cleaning, transport, etc.). All (other) suppliers are approved by the central VION office and entered into MMI's before they can be used. Carcass suppliers are audited regularly by VION ( ), and corrective actions are recorded. Seen audit reports and BRC certificate of . Of all carcasses it is known were they are born, bread and slaughtered. In past year the amount of carcass suppliers is decreased due to a shift in strategy. Carcases are bought by VION Intercompany (74%) by contract (24%), and sometimes on the free market from preferred suppliers.
No raw material is bought from agents / brokers.

3.5.2 Raw material and packaging acceptance and monitoring procedures

At the warehouse department incoming raw materials, packaging materials and their specifications are checked visual and (if relevant) on temperature (CCP). Records are created seen on checklist F-ENS-NL-10018 v3 23-10-2015. Microbiological parameters are analysed by external lab ( ). Also supplier audits are done, generally audits are arranged VION central.
Meat supplies are monitored onsite as every hook with beef is visual checked at delivery and recorded, temperature is measured. Seen registrations on F-ENS-NL-10003 v3 2-11-2017, at receipt of carcasses during the audit.

3.5.3 Management of suppliers of services

All service suppliers are managed by VION Food NL in Boxtel (HQ). Suppliers are monitored onsite by eg; (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 (delivery of
'

3.5.4 Management of outsourced processing and packing

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

3.6 Specifications

Specifications for raw materials, packaging materials, cleaning agents and finished product are defined and managed by the involved QA and maintenance department. Maintenance for cleaning agents, equipment to be in contact with food, lubricants and other technical aids. QA for packaging, additives, and raw materials. Several specifications seen in vertical audit. (seen minor on specification of equipment to be in contact with food.) Specifications of finished goods are kept by the sales department and available in dedicated parts of IT, also visible to production (seen list PLUlijst Enschede.xlsx on all artikels tobe sold to including pricing and labelling.

3.7 Corrective and preventive actions

VOS 2.0 (Vion Operating System is used to manage corrective and preventive actions. Also results of controls and audits are scheduled and can by incorporated in the mmm's, huddles, TIER meetings. A major nc in any audit can lead to an "A3-verbeterplan" meaning a controlled method of managing non conformities. Details of corrective actions and closing out are kept including root cause analysis as seen for several complaints.

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 on the floor, special educated operators can tide up this meat on a special table as documented in P-ENS-NL-10004 v2 dd 19-11-2004. All fallen meat has to be reported on the SSOP-checklist. Non-conforming products are categorised to CAT 1 or CAT 3. Blocked products are accompanied by form F-ENS-NL-10021.
Returned products are handled according P-ENS-NL-10008.

3.9 Traceability

A traceability procedure is in place to operate the trace system:
All raw- and packaging materials, intermediate and finished products receive a unique lot code. At all stages of production, the materials and products are traceable via IT system. All individual product packs are identified with a production code (line - week - day - hour) and shelf date.
Trace test was based on delivery on 4-9-2017 from , 436 quarters. All relevant information was retrieved. Specifications and calculation documentation and all clients supplied to were demonstrable. Mass balance was correct and CCP records available.
Records presented were: invoices of raw material; records of incoming goods control and process control (including CCP temperature checks and CP metal detection); stock lists; productions schedules and efficiencies. Also other records concerning training and prerequisite programs (including pre SSOP and SSOP forms). The yearly test is done 18-10-2017 as pre described by the trace test and recall procedure P-ENS-NL-10017 and was evaluated.

3.10 Complaint handling

Complaints are received from local sales offices and from headquarters and managed in a IT system called . (No direct contact with the client.) All complaints which are considered to be attributable to the process/ product are communicated and investigated by the quality manager (categories: safety; labelling; processing/cut). Complaints are investigated with regard to root cause analysis. Actions towards suppliers and internal processes could be demonstrated.

All complaints are trended and reviewed centrally per VION plant). Complaints and retours together are expressed in €/1.000 ton or €/amount of orders and discussed quarterly as a KPI's in MT.
In the first 6 months of 2017, there were 10 complaints about foreign material reported. There were no other complaints about food safety. There were no complaints from authorities. Most complaints are on weight loss which is considered a complaints. The target on food safety complaints is 35 per quarter and on integrity complaints 10/quarter. Also, a target on complaint follow up (no open complaints of more then 14 days set to 3/quarter.)

3.11 Management of incidents, product withdrawal and product recall

There is a general recall procedure at VION concern (P-FOOD-10015 Crisis management) which covers the process and which is applicable for all operations. Also local Procedure Recall and Crisis management P-ENS-NL-10017 applies. A combined traceability/ recall test is reported on 2017-10-27. There were no withdrawals or recalls during the past year.

3.12 Customer focus and communication

VION Enschede has no direct contact with customers, all via sales departments of VION HQ or VION country sales. Communication on specification is weekly on prices to be printed on products.

Details of non-applicable clauses with justification

Clause reference	Justification

4. Site standards

4.1 External standards

There are no potential risks associated with the site that may affect product safety or integrity. It is located at an industrial area. It is in good repair and well maintained.

4.2 Security

Site boundaries well defined and security ( ) 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 assessment of the security included in F-ENS-NL10040 Risico management beheersplan Product en procesintegriteit.

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 or high care or ambient high care production.
All produced products do need a heating step before consumption (except beef for a client who produces filet americain; this beef is on a positive release procedure.)

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

The fabric and internal condition of the site was suitable and satisfactory for the processes. Walls, ceilings and floors were generally suitable. Storage of packaging materials and maintenance material is separated from production.
Previous audit there were condensation drops on the ceiling and pipes in the expedition area, not noticed this audit.

4.5 Utilities – water, ice, air and other gases

All utilities for water, ice and heating devices (cutting department) are within the maintenance system. Water quality of the mains is monitored by ') half yearly water analysis. A water distribution plan is available; this is in computer software which also regulates the temperature. Machinery appears to be in a good state of maintenance. No steam or ice (except frozen CO_2). The company monitors on presence of Legionella and other. Compressed air is maintained by an external partner ( ). Which is on hours of working and not at planned intervals and specification compressor oil "

4.6 Equipment

In general all equipment was observed suitably designed and in good shape as to minimize potential product contamination. Relevant documents were available at the technical department, checked for the new x ray detector (see minor in 5.1 o validation) of company

4.7 Maintenance

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

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 cantine 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" 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.

4.9 Chemical and physical product contamination control

Raw material handling, preparation, processing, packing and storage areas

Control of chemicals on site was demonstrated. Pre SSOP and SSOP instructions are in place to control contamination.

4.9.1 Chemical control

Control of chemicals on site is organized by separate (locked) storage facilities for e.g. cleaning chemicals, nitrate and nitrite and lubricating oil.

4.9.2 Metal control
Knifes are provided in sets. In the SSOP there is signed that no knifes are missing. Visual checks on knives and needle breakage is done at start up. (Pre SSOP) In tracevtest seen SSOP and Pre SSOP registrations 2017-08-24.
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 2017-09-04 of several departments.
4.9.4 Products packed into glass or other brittle containers
NA, no such containers
4.9.5 Wood
No wood is allowed at the production departments, were open product is present. Only at the end of the packing equipment wooden pallets are allowed in the packing department as well as carton layers and boxes.
4.10 Foreign-body detection and removal equipment
4.10.1 Foreign-body detection and removal equipment
On detection of foreign bodies 4 metal detectors are in place and recently an x ray is bought which is in peration but not yet validated completely so no limits and rejection scheme is yet available.
4.10.2 Filters and sieves
NA, No sieves / filters used.
4.10.3 Metal detectors and X-ray equipment
Metal is controlled as a CP and recorded on F-ENS-NL-10023. Based upon risk analysis one metal detector device is placed in the cutting department, one in the sorting and labelling department. After these departments meat can be injected and / or sliced and packed, and there are also two metal detector devices in the packing department. The x ray device is behind the detector in the cutting department. Metal detection is arranged as a system with an alarm and a belt stop at the production lines. Tests are done with 3 types testing rods in the cutting department: Fe 10,0 mm; Non FE 7,1 mm; RVS 316 8,7 mm, and in the packing department: Fe 4,0 mm; Non FE 4,0 mm; RVS 316 4,0 mm. Testing is every 3 hours and also at start and the end of the production day. Regular testing is demonstrated as well as recoding results.
4.10.4 Magnets
NA, No magnets applied.
4.10.5 Optical sorting equipment
NA, No optical sorting equipment applied.
4.10.6 Container cleanliness – glass jars, cans and other rigid containers
NA, no such containers are applied
4.11 Housekeeping and hygiene
A cleaning program 11-5-2017 has been agreed with a third party ( ) and covers equipment, plant, buildings and services (with daily / weekly / monthly cleaning frequencies). Low frequent cleaning

schedule (ceilings, walls above 2,5m, evaporators) assessed also. These detail the chemicals to use, precautions to take and method of cleaning. Used detergents:
. Rotating cleaning program is in place twice a week to avoid and prevent lime scale (this program was not correctly in the program, see minor). 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 (F-ENS-NL-10036).
Daily start up checks (pre SSOP's) demonstrate visual and agar measurements. An internal facility team supports handling of waste and staff facilities (detergent, gloves, paper towels). The 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.
The dolavs 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.

Minor 3: The documented cleaning program does not show the current method of cleaning as there is a change in chemicals in practice not documented correctly. It is not demonstrable what is cleaned with what chemicals past weeks and it is not clear when the changeover has taken place.

4.11.7 Cleaning in place (CIP)

NA, no CIP

4.12 Waste / waste disposal

Different types of waste are defined. Correct collection and identification was demonstrated. Legal handling of categorised meat (Cat. 1 and Cat. 3) is collected by a licensed company. Other waste is collected on call separately by '

4.13 Management of surplus food and products for animal feed

Containers, crates etc. for Cat. 1 and Cat. 3 materials are well labelled.

4.14 Pest Control

Pest control is subcontracted to company (contract 2016-03-24). Visit frequency is 8 times per year. Flying insect traps (EIV's) are checked 4 times a year. Seen site maps with trap allocated dd 27-11-2016 and 6-12-2016. Quality in depth inspections are executed twice per year, seen QA inspection and PRI ("pest risiko inventarisatie") dd 2017-03-13. Some advises were given. Some infestations were reported over last year (mostly outside). Corrective actions from the inspections and visits are very well kept and managed in a timely manner. Specs are present on the website. No toxic traps inside the premises. Once a year the EIV light bulbs are renewed.

4.15 Storage facilities

At the production facility several cooling areas have been defined. Control of temperatures is established (only cooled) including temperature alarm settings and controlled by an external service supplier
Alarms are monthly tested (every month another area), appr. 20 monitoring devices PT1000 are in use. Also meat can need some days for ripening, this is done at the location Enschede itself. A separate area of the building (the newest part of the building, former production area) is applied for the storage of

packaging and supporting materials. No outside storage.

4.16 Dispatch and transport

Dispatch and release of products is based upon temperature measurements at CCP level (meat temperature). There's a list of approved transport companies as prescribed by headquarters. All GFSI approved.
Trucks are inspected at hygiene and temperature before loading. Results of this inspection are recorded at the CP control forms.

Details of non-applicable clauses with justification

Clause reference	Justification
4.3.5, 4.3.6, 4.3.7, 4.4.13, 4.8.4, 4.8.5	Only low risk areas
4.3.9	No temporary constructions.
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
4.10.5	No optical sorting equipment applied
4.10.6	No rigid containers are applied
4.11.7	No CIP applied
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 1760/2000 on "country of birth, breed and slaughter" applies.
Validation of the new x ray is recorded on P-ENS-NL-10042 v2 dd 17-10-2017 and is signed off by 4 persons on 19-10-2017. (General Manager, QA manager, Maintenance Officer and HR Manager).
There is not much proof of correct validation, no data no information and no supplementing material to conclude to a positive result.

Minor 4: Compliance report on Food contact materials of (ref 003/17/DL Iss 3 date Mar 2017 updated jan 2017) states that the lead free curtains do not pass the requirements for food contact material. It is not demonstrated that this issue is seen by the validation team and it is not demonstrated that this curtain has no impact on food safety. Also the criteria of validation of the machine are not demonstrable and production did not sign the validation form 10042 dd 19-10-2017.

5.2 Product labelling

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

5.3 Management of allergens

No allergens onsite.

5.4 Product authenticity, claims and chain of custody

A vulnerability study is made by headquarters P-NLFood-10211 and transposed to the site. Carcasses bought from slaughtering houses are scaled as low risk suppliers. For Enschede one supplier delivers sliced meat. This supplier is rated as middle risk. So several audit have been performed
Segregation and correct identification is established for organic beef (Skal nummer 028065).
GMO's are not on site (raw material specifications).

5.5 Product packaging

Packaging materials are stored separately from production materials and partly used packaging should be covered prior to returning to the storage area. Product contact liners applied are coloured. In use are plastic bags in several sizes and colour and for vacuuming and normal packing. Foils for and labels with and without glue layers.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Product testing is with an x-ray on fat content. Also pH, brine, and weight is inspected.
Sub contracted analyses (microbiological, chemical) are carried out by a laboratory operating in accordance with ISO 17025 ( ). There is no lab on site. The scheduled program of testing microbiology conform P-Food-10008 is demonstrated. This procedure complies with VO 2703.
Trend analyses is made over 10-2016 to 9-2017.

5.6.2 Laboratory testing

Seen COA's micro biological results for pooled product on salmonella and Listeria. In the vertical audit were raw materials on which TC, Entero's also is tested. Testing on for fresh product and product on expiry date. Results for Aerobic mesophilic count, Enterobacteriaceae, Salmonella, Listeria, Salmonella (5 samples) were within limits. Analysis by external laboratory

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).

Details of non-applicable clauses with justification

Clause reference	Justification
5.6.2.2	No lab onsite

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 and during the audit organic beef was produced. Excell sheets are used to communicate and account for production values and identification of batches.
In the retail department curing, tumbling and slicing takes lace and good process control was seen.

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, cured or processed meat. Also labelling applies on boxes, creates and other secondary packaging

6.3 Quantity, weight, volume and number control

Quantity control is done via scales at the packing department and at expedition for bulk. Planned daily checks take place as well as regular external measurements. All products are weighed and mass balances are used to check correct appliance.
E-weighing is done at the packing department and is described in F-ENS-NL-10001 v3 dd 25-10-2017.

Licence is in use since 27-04-2011 of NMI.
Injection quantity is recorded on F-ENS-NL-10025 and 10026 to record machine adjustments and monitor weight increase. Injection was in operation during the audit and weight and temperature were measured and within limits.

6.4 Calibration and control of measuring and monitoring devices

Calibration procedures ensure relevant equipment is identified and regularly calibrated on calibration form F-ENS-NL-10020.
There is a monitoring and registration system for the temperature in cooling / freezing cells and production areas. Calibration of the temperature equipment is outsourced.
Temperature devices (hand thermometers CCP and CP related) and scales (legal issue) were sampled and found calibrated. Seen: hand thermometer used at dispatch 15104366 valid until 1-1-2018.
Daily all weighing equipment is checked with a weight (F-ENS-NL-10009). Yearly the balances are external calibrated by
Metal detectors are calibrated by Seen report Metal detector packing 13-04-2017.

Details of non-applicable clauses with justification

Clause reference	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 2017 ytd)
There is evidence of introduction training for new starters and refreshment training of employees. Competency training had taken place for the staff sampled (food safety and quality). Records were sampled and available. A good overview of given training per person is in place. All employees do have to pass a test on the hygiene rules before starting the contract. This HACCP training (HACCP toets) is every two year repeated and is about to become an elearning module. Seen personal training records for several key personnel on Metal detection, HACCP toets, Instruction "Werken bij Vion voor Flex", CCP temperature, Training SSOP, Internal auditor/"Interne audit training" by 2015-07-09, HACCP update course.
There are two xlsx -files to demonstrate education and training on competenties and on training: "Invoeren opleidngsoverzicht" and "Personeelsmatrix".
The inductionfilm and training is available in 6 languages (Dutch, Polish, Slovakian, Hungarian, German and Rumanian).

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

Hygiene regulations: available in 4 languages (Dutch, German, English and Polish).
All personnel are instructed on the documented hygiene standard, prior to commencing work, this includes temporary personnel, visitors and contractors. The wearing of any jewellery isn't allowed. Instructions on changing before and after lunch breaks are clear.
Effectiveness of the hygiene procedures for personnel is part of the SSOP system.

7.3 Medical screening

Employees, visitors and contractors have to complete a health questionnaire prior to entry to any production areas. Procedures are established for personnel to notify management of infectious conditions they may be suffering from or been in contact with.
The site makes all visitors, new starters and contractors aware of the need to report infectious disease during the intake by the porter before entering the site. The health and safety service physician signs declarations for each personnel under contract of VION Enschede. Persons who are suffering from relevant infectious diseases are not allowed to enter the production facilities.
Personnel should report the use of medicine to their direct leader according the house rules in the contract.

7.4 Protective clothing: employees or visitors to production areas

Housekeeping policy defines acceptable clothing and their individual cleaning.
Visitors and contractors are supplied with protective clothing as required. For employees: white clothing (coats, overalls, tops and trousers) is provided to all production staff. Disposable hair nets and bear snoods are in use. Safety shoes also provided. For Visitor's coats, shoes and hairnets are provided.
The laundering of protective clothing is outsourced to a contracted and specialised laundry '
The wearing of sleeves, aprons and work coats isn't allowed during eating and smoking.

Details of non-applicable clauses with justification

Clause reference	Justification
7.4.4	No High-Risk or High-Care applicable.

Module 8 - Traded Goods
Scope
8.1 Approval and performance monitoring of manufacturers/packers of traded food products
8.2 Specifications
8.3 Product inspection and laboratory testing
8.4 Product legality
8.5 Traceability

Module 9: Management of Food Materials for Animal Feed	
Scope	
9.1 Management Commitment	
9.2 HACCP	
9.3 Outsourced Production	
9.4 Specifications	
9.5 Traceability	
9.6 Chemical and Physical Product Contamination Control	
9.7 Labelling	
9.8 Training	

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

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

Module 15 FSMA Preventive Controls Preparedness Module

Item no.	Clause	Module item	Conforms (Y/N)	Comments
1	117.20	Handwashing areas, dressing and locker rooms, and bathrooms must have adequate lighting.		
2	117.37	The water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
3	117.40	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
4	117.80	Ice used in contact with food must be manufactured in accordance with the good manufacturing practice (GMP) requirements of 21 CFR § 117.		
5	117.110	Where defect action levels (DALs) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
6	117.130 (a)	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 that affect food safety.		
7	117.130 (b)	All identified, known, or reasonably foreseeable hazards must be evaluated to determine 'hazards that require a preventive control' (i.e., significant hazards).		
8	117.135	Establish one or more preventive control(s) for each identified 'hazard that require a preventive control' (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
9	117.139	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 of recalled product (i.e., destroy, divert, repurpose).		
10	117.145	Establish monitoring activities and a written procedure for each preventive control in a manner consistent with the requirements of BRC section 2.10.		
11	117.150	Establish corrective action procedures when preventive controls are not implemented in a manner consistent with the requirements of BRC sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).		
12	117.160	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring revalidation 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	117.165 (a)	The PCQI (or authorized designee) reviews the 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 their authorized designee) reviews the verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record has been created.		
14	117.165 (b)	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 an analysis • corrective action procedure where a pathogen is detected.		
15	117.165 (c)	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 the analysis • corrective action procedure where a pathogen is detected.		
16	117.165	Devices used to verify preventive controls must be calibrated.		
17	117.180	Identify a PCQI responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training or qualifications via job experience.		

18	117.305	All records required by 21 CFR § 117 must include: • the date and time of the activity being documented • signature/initials of individual performing the activity or conducting the record review • information to identify the facility (e.g., name and location) • the identity of the product and lot code where applicable.		
19	117.310	The owner, operator or agent in charge of the facility must sign and date the written food safety plan initially and again upon any changes following reanalysis.		
20	117.315	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours, with the exception of the food safety plan, which must remain onsite.		
21	117.405	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified **and** the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
22	117.420	Supplier approval must be documented **before** receiving and using raw materials and ingredients. Verification activities must be conducted **before** receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		
23	117.430	One or more supplier verification activities (as defined in 21 CFR § 117.410(b)) must be conducted for each supplier **before** using raw materials and ingredients **and** periodically thereafter at an adequate frequency.		