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Audit Report

Global Standard for Food Safety Issue 7: July 2015

1. Audit Summary

Company name	Vion Scheerpenzeel B.V.	BRC Site Code	8476525
Site name	Vion Scheerpenzeel B.V.		
Scope of audit	Deboning, cutting to specification, slicing, packing in bulk and consumer packaging (modified atmosphere, chilled) and freezing of pork. Production and packing in bulk packaging of cured and/or smoked bacon, meat preparations and mechanically separated meat, including Good Farming®-meat.		
Exclusions from scope	None		
Justification for exclusion	None		
Audit Finish Date	2018-10-24		
Re-audit due date	2019-10-31		

Voluntary modules included

Modules	Result	Details
Choose a module	Choose an item	

LRQA Ltd 1 Trinity Park, Blakenhill Lane, Birmingham, B3776S		
LRQA BRC 7 Food English Issue 7 August 2017	Page 1	Report: RQA9832747 Job: 1404684
		Audited:



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Choose a module	Choose an item
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2. Audit Results			
Audit result	Certificated	Audit grade	Audit type
Previous audit grade	B	Previous audit date	2017-10-25
Number of non-conformities	Fundamental		0
	Critical		0
	Major		0
	Minor		8



3. Company Details

Address	t Zwaite land 13, 3925 CK Scherpenzeel		
Country	The Netherlands	Site Telephone Number	+31 0 33 277 51 51
Commercial representative Name		Email	
Technical representative Name	A	Email	

4. Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	501-1500	No. of HACCP plans	1-3
Subcontracted processes	Yes				
Other certificates held	ISO 9001, IKB (welfare), farming star (welfare), USDA, organic (SKAL), Chain of Custody				



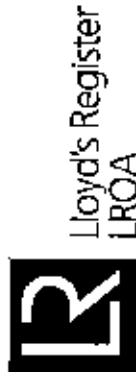
Regions exported to	Europe North America Oceania Asia Africa Choose a region
Company registration number	NL 82 EG
Major changes since last BRC audit	Expanding of the slicing and seasoning department with introduction of x-ray equipment followed by metal detector. Slow down of production speed of the deboning department to fully deploy personnel. VION Food group decided regularly on which concepts of pigs and pork will be assigned to the three slaughtering houses which affects production schedules. Currently quality lines in Scherpenzeel: FS, GB, GF, IKB, ST.
Company Description	<p>Vion Scherpenzeel BV belongs to the VION Food Group which produced pork and beef products. VION Group is one of the biggest meat processing and selling companies in Western Europe and sales is worldwide with a focus on Asia (China, Japan, Korea). This site employs approx. 1 people working basically in a 2-shift system from Monday to Friday, occasionally production on Saturdays. The main shift includes approximately administrative staff and people in production employed by Vion. About temporary workers are contracted by an in-house agency. Production capacity: approximately 235,000 tons / year.</p> <p>VION Scherpenzeel BV is specialized in the deboning, cutting to specification, slicing, seasoning, blending, packing and cooling or freezing of pork (mostly middles), production of cured and/or smoked bacon and the production of mechanical separated meat, so called desinewed minced meat (DMM). Only pork meat is processed and final products are based on welfare and good farming breed programmes of the pigs (EKO, GB, GF, QS, standard and FS (farming star). The raw materials come from own slaughterhouses, which are part of the VION Group in the Europe (Netherlands, Germany) and from some other non-Vion slaughterhouses in</p> <p>The company is under permanent veterinary control. Official veterinary approval number: NL 82 EG.</p>



Only B2B delivery; and since this summer also packing of consumer products. The storage and transport of finished products is partly outsourced (both cooled and frozen) as sister company Distrifresh is now involved in transporting from and to own VION plants. Also outsourced is the deep-freezing of some products (like DMM) and other products) to external cold stores. Furthermore there is internal cleaning of pallet boxes and partly outsourced cleaning of crates. Plant size is appr. 9500 sqm on ground floor over 2 buildings (8500 sqm + 1000 sqm).

. Dry storage of non-meat raw materials and packaging materials in a separate building away from meat processing (together with maintenance department on the opposite side of the public road).
The HACCP-study may be categorised in 3 subcategories: pork meat, meat preparations (incl. separated meat) and meat products.
The audit was calculated 20 hours and due to planning constraints, it was executed in 2x10 hours. The auditor also visited the company twice this year for CoC audits

5. Product Characteristics				
Product categories	03 - Raw prepared products (meat and vegetarian) 09 - Raw cured or fermented meat and fish Category Category Category Category			
Finished product safety rationale	Temperature < 2°C / -18°C (DMM), < 4°C (meat preparations), < 7°C or < -18°C (other products), vacuum packaging (bacon), MAP packing (< 1,5% O2 / > 98,5% CO2), dosage nitrite (> 1 gram/litre brine / > 60 ppm on ingoing product), all to be heated prior to consumption.			
High care	No	High risk	No	Ambient high care
				No



Justification for area	Appendix 2 applied. All products have to undergo full cooking step prior to consumption. Smoking process step is not considered as a sufficient heating step.	
Allergens handled on site	<p>None</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p> <p>Choose an allergen</p>	
Product claims made e.g. IP, organic	IKB: FS (farming star / "beter leven") and GB (= GF + welfare) and GF (good farming) + Qualität und Sicherheit (QS) + Organic (SKAL)	
Product recalls in last 12 Months	No	
Products in production at the time of the audit	Bacon, mechanically separated meat (type 3), DMM (desinewed minced meat), seasoned diced pork, sliced pork backs, tenderloins, trimmings 80/20 and other products from pork middles.	

6. Audit Duration Details		
On-site duration	20 man hours	Duration of production facility inspection
		10 man hours



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Reasons for deviation from typical or expected audit duration	Due to planning constraints the audit was executed in 2x10 pattern instead of 2,5 x 8. Audit was taken over last term and this option was only available	
Next audit type selected	Announced	

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2018-10-23	7.00	18.00
2	2018-10-24	7.00	17.00

Auditor Number	Auditor (s) number(s)	Names and roles of others
		Lead Auditor
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)				
	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting



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Name / Job Title				
/ Plant Manager	X		X	X
/ QA Manager	X	X	X	X
/ QA Assistant		X	X	X
/ HR Manager	X		X	X
/ Maintenance Manager	X	X	X	
/ Controller				X
/ Manager Operations		X	X	X
/ Department manager DMM		X		
/ Department manager Salting/Smoking/SDP		X		
/ Planning engineer		X	X	
Department manager Receipt and dispatch		X		
/ Receipt and dispatch of packaging material/internal services		X		
/ Employee meat reception department		X		
/ Shift leader MM department		X		
/ Department manager+VOS lean coordinator		X		

LRQA Ltd 1 Trinity Park, Bickenhill Lane, Birmingham, B377ES		
LRQA BRC 7 Food English Issue 7 August 2017	Page 8	Report: RCA9832747 Job 1404684 Auditor



Lloyd's Register
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/ shift leader SDP		X	
shift leader Slicing		X	
/ employee Salting department		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,	Date reviewed	Reviewed by

LRQA Ltd 1 Trinity Park, Bickenhill Lane, Birmingham, B377ES	
LRQA BRC 7 Food English Issue 7 August 2017 Page 9	Report: RQA9832747 Job 1404684 Auditor: /

									photograph, visit/other		

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	3.2.1	On the workflow packing instruction for art 50144 is dated 21-2-2018 and in the digital MDM/Snittenboek latest version is dated 29-8-2018. Correct replacement on documentation control not demonstrable. CLOSED TO BE VERIFIED	The latest digital version (art 50144) is directly printed by the department chief.	Root cause: The old snittenboek is not able to give an automatic reminder. Corrective/preventive action: MDM is developing a new snittenboek (finish end of 2019). The way of keeping the necessary persons, informed about new versions, is taken in consideration in the building of the software.	Seen: 50144 Sliced RF Pork CC loin 4x75g (v3).pdf	2018-11-16	
2	3.4.3	Non conformities from internal audit by on 29-5-2018 are not taken up in the action list and not clear is whether all ncs are addressed. FULLY CLOSED	These minors of HP are listed in the action list and shown and accepted by HP	Root cause: Audit is normally done by QA, this time the production manager, Corrective/preventive action: All the minors and corrective measurements will be put in the action list document on the local network and discussed with QA	Seen: Actiejist audits SPZ	2018-11-16	
3	4.9.1.1	The overview of food grade greases is not complete. : oil in cans in use is food grade but not listed	The locker in which Oil was stored is now provided with an identification	Root cause: Changing the product within the locker. Thereby forgotten to identify the cabin with his specific label.	Seen: List Chemische middelen magazijn Scherpenzeel (002)	2018-11-16	

		on the list with all food grade greases. List is not identified and verifiable and in the correct version numbered. FULLY CLOSED	label. (Green is food grade and red not food grade.)	Corrective/preventive action: Label is made and the list is provided with a date of last modified date.	foto 1 oliehok.jpg foto 2 oliehok.jpg	
4	6.1.2	Thermometers and test probes for metal detection are disinfected after usage as described in the instructions. This does not guarantee septic condition before usage. No disinfection before usage seen although test probes were handled and placed unhygienically. FULLY CLOSED	Discussed in daily Tier and Huddles.	Root cause: Production and computer cabins are daily cleaned. We understand the vision, because papers with are lying next to it are from the offices outside the production. Corrective/preventive action: The employee who did the metal detection is re-instructed, because she did not handle the probes in the way the instruction was giving. The teaching materials are replaced for 'before and after disinfection'. This part of the education is also shown on the television screens in the canteen.	Seen: CCP1 controle.ppt CCP1 verificatie.ppt	2018-11-16
5	6.2.1	Packing material (all types of foil) is stored next to the packing machine so there is too much material available. CLOSED TO BE VERIFIED	The packing material which was not used for this client removed from the slice department	Root cause: This was the foil used earlier this day and was going to be used after this particular batch. Corrective/preventive action: After discussing the subject in our BT (Weekly department meeting). There was made little space in the intern packaging storage for the slice foil. We are still looking for a better and		2018-11-16

6	6.2.3	<p>In the packing instruction (Snittenboek) is not stated which primary packaging material is to be used. There is used upper foil lower foil, 2 types of label with information. No foil codes, label codes are present in the description. Checks not possible on correct number. No procedure demonstrable on management of label pack control, although checks demonstrable on labels and to archive used labels.</p> <p>CLOSED TO BE VERIFIED</p>	<p>An adjustment for the snittenboek is requested to MDM.</p>	<p>Root cause: This very particular client foil is not yet included in the emballage catalogus. Foil and labels were traceable on daily base not on batch level. Corrective/preventive action: A foil code specific for this client foil is requested to MDM and with that the change in the Snittenboek. For the management and checking of the foil and label a pilot is now running with a form (see attachment).</p>	<p>Seen: 50144 label voorbeeld Slices RF Pork CC Loin 4 x 75 gr.pdf F-SPZ-NL-10129 v2 20-11-2018 filled in on 21-11-2018</p>	2018-11-16	
7	6.4.1	<p>There are 10 metal detectors on site. 2 detectors are not calibrated and no instruction or timescale to calibrate is present. No regularly checks on these measuring devices are demonstrable.</p> <p>CLOSED TO BE VERIFIED</p>	<p>will be replaced in 2019. Daily monitoring is ongoing.</p>	<p>Root cause: These 2 are on the investment list of 2019 to be replaced for yearly service/calibration service. Corrective/preventive action: Due to the age and new innovations these 2 detectors are reported on an investments of 2019, and will be replaced before October 2019. Trimming department (one) is capex accepted and is monitored every 3 hrs with test probes. When there not detected Technical service is directly</p>	<p>Seen: X-matrix punt 13 redesign magement.pdf Replanning of the calibration of the</p>	2018-11-16	

8	7.1.5	Duration of the training is not included in the training record. Furthermore the form has no version reference. The course content does not relate to the instruction trained. FULLY CLOSED	Is adjusted with duration, relation and format.	called. For the MSMT department the is only used for protection of the machine, because de mm's of the sieve is smaller than the detection mm's of the metal detector can detect.	Root cause: HR was not up to date about the fact that duration was necessary. The relation and version were interpreted differently by HR Corrective/preventive action: New version of the training record is made and used for new registration from November 2018	Seen new F-SPZ-NL-10128 v2.31-10-2018	2018-11-16							
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Comments on non-conformities



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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

LRQA Ltd 1 Trinity Park, Bickenhill Lane, Birmingham, B377ES		
LRQA BRC 7 Food English Issue 7 August 2017	Page 14	Report: ROA9832747 Job: 1404684
		Auditor:

FSMA Module Non-Conformity Summary Sheet

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



Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Policy documented in P-SPZ-NL-10158 and signed off by the Plant Manager. Policy deployment using the X-matrix specifying the interaction between strategic / plant objectives, responsibilities and key performance indicators. Evaluation of objectives on a weekly basis. SMART objectives (about safety & people, quality (e.g. complaint reduction), delivery / performance, cost, sales / production) and improvement projects (Vion Operating System/VOS) defined. Focus on reduction of foreign material contamination risks. Clear targets are set per department and results monitored and discussed on a weekly / periodical basis during management team meetings (Tier 2). The management team showed commitment to the quality management system (QMS) during the evaluation interviews as the plant manager was present during opening and closing meeting. The company has a management team who meets weekly but can also be assembled to discuss and plan any actions relating to food safety and legality should situations arise. Formal communication meetings (e.g. daily planning meeting per shift, weekly snapshot and periodical management team meeting) are held within this organisation. Communication is also organised through white boards, TV-screens and the Vion App. Annual management review combined with HACCP system verification. Demonstrable about period 07-2017 – 06-2018 which covers the required topics. Currently an issue is the prevention and eradication of Listeria. Microbiologic monitoring program shows incidents and trends. There was no evidence that a lack of resources had substantially affected the running of the QMS. The commitment is also evident in the systematic for continuous improvement (e.g. Multi Moment measurements, 5S, Tier 1 – 3 meetings), general introduction of asiro caps, new machinery (slice line, x-ray and metal detector). The company demonstrated an effective system. Non-conformities (1 major and 5 minors) identified at the previous audit are effectively actioned: the major and 3 minors were already fully closed during follow-up. Two minors from previous visit have been closed out and did not re-occur.

1.2 Organisational structure, responsibilities and management authority

There is a clear organisational structure (P-SPZ-NL-10092) with the necessary links in between each other. The various production departments directly report to the Manager Operations and he for his part reports to the Plant Manager. The responsibilities, authorities and reporting relationships of all staff members are described in the job descriptions. General duties described in procedures and further details in work instructions. Performance of personnel is monitored day to day with a formal review during the appraisal system.

Details of non-applicable clauses with justification

Clause reference	Justification

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2 The Food Safety Plan – HACCP

The company's food safety control system is based on the Codex Alimentarius HACCP principles. The HACCP system is implemented and maintained. The HACCP system has full management commitment and is an integral part of the company's Quality Management System (QMS). Multi-disciplinary HACCP-team (P-SPZ-NL-10144 dd 25-05-2018) consists of Plant Manager (team leader), QA Manager, Manager Operations supported by Maintenance Manager, Manager F&A and HR Manager where necessary (Tier 2). Competent team of people working for many years in the meat processing industry.

Prerequisite program assessed. Setup of PRP program centrally by HQ Vion Boxtel within 'Procedure Prerequisite requirements and additional CCP's, CP's' (P-FOOD-1000). Local process control plan set-up per site (P-SPZ-NL-10067 dd 28-02-2018). Production specification information used as input for the hazard identification / risk assessment. Due to the range of countries supplied to several protocols are available on management of requirements per country, closely guided by NVWA officers.

Full product description including microbiological limits and shelf life is in place. The intended use of the product by the customer has been clearly defined. Product suitable for delivery B2B and consumption by general consumer groups but also vulnerable consumer groups as meat product is also supplied to infant food production companies. No claims made regarding food safety aspects. Documented within central 'Procedure Hazard analysis' (P-VION-10000) and 'Procedure HACCP manual' (P-VION-10001).

Flow diagrams are prepared and available. Flow diagrams seen and annual verification of flow charts as reported in the combined HACCP-system verification / management review. Verification details of flowcharts are recorded in the document control system (). No reworking or recycling identified. Freezing (of naked product), transport and cold storage (incl. metal detection) are subcontracted and outsourced processes.

Hazard identification / risk assessment setup centrally by HQ Vion Boxtel. The HACCP plan included a review of potential physical, chemical and microbiological hazards. Each identified hazard was reviewed and given a risk rating to define the severity and likelihood of a hazard occurring. The risks have been defined from the hazards (occurrence x severity) with the adoption a decision tree. Risk calculation based on 3 x 3 matrix which has to be adapted by the production locations like Vion Scherpenzeel BV. This generic risk assessment has to be adapted to the local processes and buildings. No allergens on site (only pepper in the seasoning department). Output risk assessment will lead to CCP, CP (PRP control measure) depending on the risk score.

The company has defined 1 Critical Control Point (CCP) relating to product safety and the scope of the BRC audit: Core temperature of the incoming pork meat (including returns).

Critical limits have been defined for this CCP and are related to the legal temperature requirements for raw red meat and corporate engagements:



- Core temperature < 7°C (legal limit), < 6°C (for raw materials transferred within Vion plants), < 5°C (especially for raw materials for Japan products, e.g. seasoned diced product) linked to the growth of Salmonella.

When core temperature is between action limit and critical limit it is allowed to receive the batch but it must be quarantined (QA / management must be informed). Above the critical limit the batch must be rejected and it is not allowed to receive the batch. Due to supply chain management, trailers with meat from sister companies are parked onsite and of loading of trailers is decided by planning. Records of CCP monitoring and verification show measurements are carried out by authorised persons as planned. The procedure for CCP 1 identifies the corrective action to be taken when the limits are exceeded. Records are kept of adjustments made and any actions taken.

CP's (food safety control measures at PRP-level) identified amongst several others (34 in total):

- Product contamination (product own / foreign materials – slaughter / handling / lubricants / pest control / personal hygiene / etc.);
- Control contamination with condensed water from cooling systems;
- Temperature control during processing (trimmings: < 6°C);
- Hygiene recipients (crates, pallet boxes, etc.);
- Procurement of raw materials according to specification (incl. additives);
- Control product age (< 5 days after slaughter);
- Control printing shelf life date;
- Control MAP packing process (< 1,5% O2);
- Control dosage nitrite as preservative in brine injection (> 60-150 ppm ingoing product);
- Control vacuum packed products (visual inspection);
- Control injection brine solution (bacon);
- Control cooling down after smoking process (< 24 hours, < 7°C);
- Control temperature during transportation;
- Control metal contamination (knife integrity verification, metal detection);
- Control contamination of other foreign materials (X-ray);
- Control temperature at load-out (< 2°C DMM, < 4°C meat preparations, < -18°C frozen products).

Each department has Pre-SSOP forms and SSOP forms to record findings and actions. Good management seen.

The HACCP system is verified through daily checks, internal audits, check of all CCP's + CP's + PRP's during the yearly system verification. Report of HACCP Reassessment (07-2017 – 06-2018) assessed.

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 company has a quality manual which states the company's commitment to quality and food safety. The quality manual is the total of all quality documents: system procedures, working procedures, work instructions, registration forms. Furthermore the VOS system is applied with MMM (multimoment measuring). IT-system used for document control (HR has its own document control management system). The quality manual is available on the computer for all key functions (password protected).

3.2 Documentation control

Authorisation of documents based on system functionality. Some documents available in relevant documents as several employees of different origin are working for the company.

Minor 1: On the workfloor packing instruction for art 50144 is dated 21-2-2018 and in the digital MDM/Sniffenboek latest version is dated 29-8-2018. Correct replacement on documentation control not demonstrable.

3.3 Record completion and maintenance

Most records are hand written. All records from the weighing system to guide traceability. Records are archived for 5 years according to procedure. Maximum product shelf-life applied is 2 years. All electronic data are secured by daily back-ups.

3.4 Internal audit

Audit management by the Vion system. There is a schedule of internal audits in 2018 against documented procedures, carried out by trained auditors (Vion auditor pool of QA Managers). Twice a year the production site and involved departments are audited Both announced and unannounced internal audits carried out and relevant annexes to guide requirements on schemes (annex 3 on CoC). Procedure 'interne audits' (P-VION-10011). Reports of internal audits reviewed: AM-071-AUD-25 by dd 22-08-2018 and 4+15-04-2018. Also pre-Tesco audit as internal audit by dd 29-05-2018. Recording of findings reported on a central list.

On a daily basis so called pre-SSOP assessments are carried out in every production department. These assessments are used to identify and solve any non-conformity related to hygiene and/or state of repair of processing equipment, processing / storage areas and buildings. Reviewed examples of pre-SSOP's related to the vertical traceability test.

Minor 2: Non conformities from internal audit by on 29-5-2018 are not taken up in the action list and not clear is whether all nc's are addressed.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw materials and packaging

Risk identification / risk assessment related to raw materials setup centrally by HQ Vion Bostel resulting in product specifications specifying relevant aspects to quality and food safety (CP). Approval of suppliers based on GFSI-certification. All suppliers of packaging have to be approved by the central Vion office entered into the system before they are allowed to deliver. Supplier questionnaires used too. Some additives from the brine delivered by trading companies. List suppliers additives Vion Food NL (S-



MMI-10190 from 16-10-2017), List of 'HACCP-transporteurs 2017' (S-MMI-10013 from 17-10-2017) and 'Lijst toegelaten vrieshuizen' (S-MMI-10199 from 04-10-2017) assessed. Reviewed for j. All suppliers have to be GFSI-certified.

3.5.2 Raw material and packaging acceptance and monitoring procedures

The risk assessment depends on the kind of material according to procedure P-SPZ-NL-10030. Temperature control of incoming meat (pork middles, other pork meat) is CCP. Identification of IP-status of pork middles by means of coloured labelling (organic = green, farming star = orange, GB/GF/QS = blue). Also slaughterhouse specification by coloured labelling (determining further processing according to customer specification). Verification of slaughter date and origin at reception of meat batches. Meat guiding documents are verified by the gate keeper and must be approved before trucks are unloaded. Document must show the official approval for export countries. Overview available showing which slaughterhouse is approved to supply meat for export countries. Ingredients and packaging materials are received at the dry warehouse in a separate building and undergo visual inspection. Seen supplier of foil as primary packaging 3RC Packaging certified.

3.5.3 Management of suppliers of services

Service suppliers identified: cleaning , pest control (), laundry , maintenance (several contractors involved), transport (mainly I , controlled by Vion HQ Boxtel), cold stores (final products), laboratory services, catering, crate washing () waste.

3.5.4 Management of outsourced processing and packing

Overview available of approved external cold stores specifying their legal approval (EU-number and scope) and applicable GFSI-certificates. Cold stores involved in freezing (both naked products and packed products) but also metal detection. GFSI-certification and CoC-certification (Chain of Custody) required for cold stores. Based on the risk profile the cold stores are audited by Vion periodically. Contracts refer to relevant Vion procedures.

3.6 Specifications

Specifications of raw materials, packaging materials, cleaning agents and finished products are available and managed by the involved departments. Raw material specifications are documented and include microbiological criteria. Specifications concerning packaging and cleaning products issued by suppliers are used. Vion HQ Boxtel is responsible for formal agreement of specifications. Specifications are reviewed internally to ensure they are correct and up to date. Finished product specifications kept up to date. Review every 3 years. Samples of specifications taken at this visit demonstrate control:

- Back BSD (art. 82440)
- Brine nr. 35
- salt fine
- Potassium nitrate
- BSD Back 190-10 shtr sm 2.75 RW gf (art. 82430)
- Sodium Acetate COA dd 18-9-2016
- Film A/PF 23-04-2018
- Film VOH-PE + statement of conformity + migration test results (dd 02-11-2016)
- oil spray 1500 (- H1- declaration on allergens dd 19-01-2016)

All specifications were present in the actual version. The specifications were available for relevant staff and found unambiguous, complete and compliant with legal requirements.



3.7 Corrective and preventive actions

Corrective / preventive actions will be taken in case of a non-conformity. This can be initialized from several sources: (internal) audits, complaints, product analyses, product controls and hygienic controls. Different documents and systems are used, no central recording of PDCA-cycle concerning deviations / non-conformances. Corrective action was seen to take place in a timely manner. Deadline depends on the type of corrective action. (See minor in 3.4 on follow up of actions from internal audits.)

3.8 Control of non-conforming product

Non-conforming products / products on hold are physically identified as such with a red label / banner. There is a documented procedure for the identification and disposal of non-conforming product (P-SPZ-NL-10010). This procedure defines how non-conforming product is identified, quarantined and disposed of. Production supervisor and Manager operations are responsible for release or disposal of concerning products. Furthermore there is procedure on meat dropped down (P-SPZ-NL-10185).

3.9 Traceability

Traceability system is well developed. It covers raw materials through work in progress to finished product including packaging materials and distribution. The system is based on documents and records, bar code reading and the

Software according to procedure P-SPZ-NL-10013:
Identification of raw materials order number, date of slaughter, slaughterhouse, origin); Cutting line + salting department: batch number; Salting: tank number + brine lot number; Finished products traced as day lot or cutting / salting batch or specified code on the packing label (slicing); Scanning of batch code at weighing stations; Additives and primary packaging materials are traced on the date of delivery / breaking into new batches.

Traceability test performed on 05-10-2018 with evaluation written on 15-10-2018. Mass balance / quantity check included. During the audit traceability was checked forward and backwards on brine 35, production date 13-07-2018). Traceability was found adequate. Information was available within 4 hours. Rework operations take place at each line during processing (the same batch). When products are repacked, traceability is maintained.

Mass balance check is carried out on a daily basis to demonstrate the segregation of IP-product. These mass-balance checks are carried out at process level. Last integral mass-balance check over all processes within the plant carried out as part of the CoC-audit. More than 99% accuracy reported.

3.10 Complaint handling

Complaints are received via Sales departments in different countries of sale via mail and also complaints are gathered via software. All complaints which are considered to be attributable to the site are communicated and investigated. All complaints are trended and reviewed by the site management team and discussed frequently in tier 1 meetings. Food safety related complaints get extra focus from the organisation. They concern shelf life, too old / not fresh, too high temperature, glass / hard plastic and dirt. Food safety complaint level on foreign bodies is stable (target on fb, metal, plastic, other). Investments to reduce product contamination with foreign materials carried out are X-ray, visual final inspection (cutting line), visual inspection of raw materials (SDP), use of astro caps. The procedure for complaint handling (P-SPZ-NL-10008) defines types of complaints and addresses requirements in terms of incident reporting as these are escalated to relevant personnel for review and action (corrective / preventive) as appropriate. No complaints from the authorities. Microbiologic monitoring program shows incidents and no trend. There have been no recalls because of complaints.

3.11 Management of incidents, product withdrawal and product recall

There is a company's crisis and recall management procedure (P-VION-10015) which covers the process which is applicable for all Vion sites. The local procedure product recall (P-SPZ-NL-10009) defines the recall team and complies with this requirement. List of telephone numbers for the benefit of recall



available. Business continuity guaranteed by central procedures and emergency coordination protocol. No actual recalls in 2017 and 2018 YTD.

The recall procedure is tested 1 x / year. The report of the last recall test, carried out on 05-10-2018 is seen about a knife lost in a batch. The test was successfully conducted and evaluation is made.

3.12 Customer focus and communication

Customer focus and contract review is a part of the QMS. Sales department is responsible for contract review. They are aware of customer requirements and related product specifications. Specific customer requirements are translated into process specifications, e.g. process specification of seasoned diced pork (SDP) for the Japanese market. Settings (cutting specifications, fat content, X-ray settings, etc.) were properly implemented to comply with the product specifications. The snittenboek is being altered in MDM (Material Data Management) software.

Details of non-applicable clauses with justification

Clause reference	Justification

4. Site standards

4.1 External standards

The site has been designed and constructed for its activities at an industrial area. There are no local activities that are expected to have an adverse effect on the activities under scope. The maintenance department and storage of raw materials and packaging materials is located in a separate building across the street. Other company also are in this building. Site area is fully paved.

4.2 Security

Site fully fenced and 24 hour security in place. Site area is shared with another company. Entrance to the building using badges. Verification of issue and return of badges, especially for temporary workers. Not returned or missing badges will be blocked to prevent uncontrolled access to the production and storage facilities. Laser detection system with camera support installed around the main production building to warn production management in case of unexpected activity around the building. Bulk storage tank for salt and CO2 is fenced and locked. Raw materials and packaging materials warehouse has to be locked manually. Porter present at entrance point of trucks. Visitor reporting system implemented in the office building. Site entrance close to the office building is closed outside office hours (only entrance to the site after reporting at the porters lodge).

Meat processing company registered and officially approved by The Food and Consumer Product Safety Authority (NVWA) according to EU legislation. Official approval NL 82 EG.

4.3 Layout, product flow and segregation

The production and storage zones have been defined and based on a risk assessment: all zones are categorized as low risk areas. There are no high care or high risk areas. All products have to undergo a full cooking step prior to consumption. Site map demonstrable specifying routing of personnel, materials,



etc. (P-SPZ-NL-10159). No specific risks identified due to product flow across the building. The slicing department near the SDP processing line is properly segregated from other production areas. Bin and crate washing near expedition area but strictly segregated. Production lines are located in fully or semi-separated rooms (cutting/deboning, DMM, SDP, slicing, bacon, spare-ribs, trimmings). Separate maintenance workshop. Truck drivers have to report at the porter lodge and in the expedition area afterwards (hygiene lock is available). Visitors and contractors are instructed prior to entering production and storage facilities.

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

Walls, floors and ceilings are finished and suitable. All maintained and some aging seen. All areas are "low risk areas". Usage of process water (brine) and manual cleaning. Sufficient drain points. High level cleaning of ceilings and evaporators arranged. External doors are close-fitting. Lighting and windows are protected where they pose a risk to the product. Pre-SSOP inspections prior to production include checks on status of breakable items.

4.5 Utilities – water, ice, air and other gases

All utilities for water, cooling water and compressed air are covered by the maintenance system. Both water from the mains and well water (one source) are used. Water streams are mixed up, break tanks applied. Well water filter installed which is inspected every week as part of the maintenance program. Water used for brine is only coming from the mains (no well water applied). Well water quality is monitored as required by law (4x/y). A water distribution plan is available seen version dated 3-2-2017. Sampling tap points on a quarterly basis as indicated by procedure P-NLFOOD-10032.

Compressed air used for drying of equipment after cleaning. Food grade oil applied. Maintenance of air compressors (4) by contractor / . Monitoring of the air compressors is also part of the maintenance program (water / oil separation, drying, etc.). Filters installed in the air supply and maintained by . Daily inspection of any oil leakage in the compressed air as part of the pre-SSOP inspections (CP). Also, inspection and maintenance (incl. cleaning and anti-fungal treatment of the evaporators) is a CP.

CO2 used for MAP-packing and cooling (direct injection) is suitable for food use. Steam and ice from water are not in use.

4.6 Equipment

The used equipment is suitable for its purpose. Mainly stainless steel equipment. Use of well-known brands of equipment for food applications (e.g. slice line /). New equipment is purchased as required and specified. Conveyor belts of the cutting department supplied with confirmation of approval for food use.

4.7 Maintenance

Maintenance management system based on / stem. If possible any maintenance activities are clustered and executed every week on Saturday outside production hours. Communication to production and cleaning is done prior start-up in order to prevent contamination. Pre-SSOP checklist are used to record and confirm cleaning where necessary. Maintenance contractor instruction demonstrable, contractors sign for the external hygiene instruction. Second maintenance workshop also inside the production building. Maintenance activities causing contamination risks carried out only at the first floor. Separate storage room for lubricants. Only green labelled lubricants are food grade and suitable for food safety critical applications. Only entrance to the maintenance workshop using a badge. Only pre-organised maintenance suitcases are allowed to be used inside production and storage facilities.



4.8 Staff facilities

Central suitable staff facilities for both own employees and temporary workers. The surface of storage facilities (staff lockers) is in line with the number of employees. Based upon a risk assessment all zones are "low risk areas". Lockers available for private clothing and personal items. No storage of protective clothing in the lockers except for protective shoes. Central issue of protective clothing. Boot wash installed at the entrance to production facilities. Direct access to production facilities. Also personally issued body protection (worn underneath the clean protective clothing) may be stored in the locker. Hygiene lock at the entrance of the production facilities. Toilets are located near the changing facilities. Closed smoking room in the canteen area. Catering provided to the personnel.

4.9 Chemical and physical product contamination control

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

Within the company there is a place where the working stock for the external cleaning company stored. Foreign bodies are an integral part of the hazard analysis and this hazard is checked at several places. Different mechanisms are in place:

- metal hazard / sharp implements: there is a knife register with knife checks daily, staples etc. are prohibited.
- metal detection applied for packed finished products (bacon, SDP, sliced product). Two X-ray detectors in place at SDP department.
- glass: evidence seen of a glass breakage procedure. Also, a glass register which is checked as well as infrastructure everyday (Pre-SSOP) and quarterly.
- equipment: there is a check of the physical integrity of the equipment every day, before start-up.
- wood: the use is prohibited excepting at the smoking cabinets (beech wood chips).

4.9.1 Chemical control

Control over cleaning chemicals on site was demonstrated. MSDS available and specifications confirm suitability for use in food processing industries.

Minor 3: The overview of food grade greases is not complete. oil in cans in use is food grade but not listed on the list with all food grade greases. List is not identified and verifiable and in the correct version numbered.

4.9.2 Metal control

Knives are issued to employees by numbered sets and changed every break for cleaning. Colour codes knives in knife assembly baskets are in place and assessed was the sharpening and cleaning of the knives in a special area with two sharpeners, two whetting machines and a dish washer with calibrated chemical dosing equipment. Integrity check of knives carried out. Knives which not return every break are covered by daily (pre-)SSOP inspections. Inspections of cutting blades and needles carried out during breaks (e.g. SDP department). Breakage of injection needles in bacon processing department is considered very unlikely.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Quarterly glass audits are carried out. Missing or broken items are reported and directly linked to a maintenance task. Periodic verification of maintenance program. Daily verification of breakable items during pre-SSOP inspections. Procedure management of broken items complies with requirements.

4.9.4 Products packed into glass or other brittle containers

No glass packaging activities in place.



4.9.5 Wood

No wood is allowed in the production departments, except the wood chips for smoking bacon. These are stored and used separately.

4.10 Foreign-body detection and removal equipment

4.10.1 Foreign-body detection and removal equipment

Metal detection (products), sieves (brine injector, water) and X-ray (products) applied. Vision camera system not validated to remove foreign materials (control of quality aspects). Also during visual inspection at specific lines (for example SDP) foreign materials found are collected and evaluated. Both foreign bodies and product own materials (like bone residues due to improper cutting) are presented to supplier when necessary. Testing metal detection and X-ray detection using methods and samples compliant with commercial specification as verified during the audit.

4.10.2 Filters and sieves

Filters used to control the hygiene of the brine to prevent any obstruction of the injection needles (with the risk of insufficient injection at certain areas of the meat pieces). Cleaning as part of the cleaning program executed by . Assembling of the micro-sieve of the injection equipment by the team leader after hygiene inspection as recorded on the pre-SSOP-list as reviewed during the audit. Well water filter installed is inspected every week as part of the maintenance program.

4.10.3 Metal detectors and X-ray equipment

Metal detectors installed at:

- Packing line JK / VM12 / VM14 / trimmings / smoking process: 5,0 mm Fe + 6,0 mm non-Fe + 6,35 mm SS (check start-up, every 3 hours and end of production);
- Salting process 1 and 2: 5,0 mm Fe + 6,0 mm non-Fe + 7,94 mm SS (check start-up, every 3 hours and end of production);
- Spare-rib process line: 3,5 mm Fe + 4,5 mm non-Fe + 6,00 mm SS (check start-up, every 3 hours and end of production);
- SDP / slice lines: 3,5 mm Fe + 3,0 mm non-Fe + 4,5 mm SS (check start-up, every 3 hours and end of production);
- DMM process line: 6,00 mm SS (check start-up, every 3 hours and end of production). Metal detector used to protect processing equipment.

Also metal detection applied by contractor (frozen storage). Metal detector functioning is checked using certified sample sticks. Both belt stop systems and rejection devices used depending on the packaging size. Procedure metal detection documented (P-SPZ-NL-10052 from 19-01-2017) on registration form F-SPZ-NL-10072.

Two X-ray systems installed at the same SDP packing line (incl. rejection valve system). Verification of proper functioning of the equipment by testing samples at start-up, every 3 hours and at the end of production:

- 2,381 mm glass;
- 2,381 mm ceramic;
- 1,00 mm metal.

Verification of proper functioning of recently installed X-ray system using specified sample sizes. Test strips contain different sample sizes. Therefore the X-ray detector has to detect at least 4 objects on each strip (which is equal to the minimum samples specified below):

- 0,8 mm SS 316 ball;
- 0,4 mm SS 316 wire;
- 2,0 mm glass;
- 2,0 mm ceramic.

4.10.4 Magnets

No magnets applied.



4.10.5 Optical sorting equipment

Vision camera system installed at spare-rib packing line. System used for monitoring quality aspects (size), not for controlling foreign materials. System settings are controlled by recipes which correspond to the customer specific requirements.

4.10.6 Container cleanliness – glass jars, cans and other rigid containers

No packaging in glass jars, cans and other rigid containers.

4.11 Housekeeping and hygiene

Both equipment and facility cleaning is subcontracted to [redacted]. Cleaning program demonstrable including working instructions for specific equipment. Monitoring of hygiene status by pre-SSOP-inspection every day at every department carried out by team leaders. The effectiveness of the cleaning and disinfection process is followed by daily visual inspections, hygienograms by means of agar (TPC – 2 sets of contact points) + Listeria swabs (quarterly) and microbiological analysis of finished products. Records of checks are maintained and were sampled during the audit. Chemical residue testing using pH-strips. After a period of time again repetitive positive results of Listeria swabs found causing extra cleaning. The site organized an additional full cleaning on particular places and belts. It has the attention of HQ and site management and resources are made available to eliminate the cause. Also, microbiological monitoring of crate cleaning process performed. Calibration of chemical dosage equipment is done on a quarterly basis. Reports from [redacted] assessed. Cleaning materials are also part of the cleaning program.

4.11.7 Cleaning in place (CIP)

CIP is not applied.

4.12 Waste / waste disposal

Good control was seen over the collection and disposal of waste. Dispatch of category 2 and category 3 materials to authorized processing companies [redacted]. Other by-product (like bones) supplied to authorized processing companies for human consumption [redacted]. Other waste stored on-site and collected separately by [redacted].

4.13 Management of surplus food and products for animal feed

Category 2 + category 3 material declared unfit for human consumption, retrieved by [redacted] specialised in the destruction of this type of animal by-products. Trade documents according to Regulation 1069/2009/EC seen from 12-07-2017. A register is kept. Legal requirements are met, e.g. separate refrigerated storage and clear identification.

4.14 Pest Control

An external pest control contractor is used. The company has a corporate contract with [redacted] on pest control of rodents (rats and mice), cockroaches, crawling insects and flying insects. The frequency of control is 8x/y (e.g. 21-10-2017); maintenance of EFK is 1x/y and determination/counting 4x/y. All documentation is present in the digital web portal. The pest control file does detail the baits/pesticides used with material safety data sheets (MSDS) being available. Application of non-tox detection equipment inside and outside the production and storage facilities as well. Specification of [redacted] ([redacted] assessed. Up to date site plan is available to show the location of rodent baits, mouse traps, crawling and flying insect control units. An activity trend log is provided by [redacted].



the pest control contractor. In-dept pest control survey (1x/y) dd 14-09-2018 seen. In case of infestation an emergency call is raised to the pest control company and necessary corrective actions are taken. Emergency treatments provided in the contract and an effective pest control system is seen in place. No issues reported in 2017 and 2018 ytd. Proper follow-up of recommendations by the pest controller as demonstrable by dashboard on the website.

4.15 Storage facilities

At the production facility limited cold storage is available. Temperatures control system implemented (frozen and cooled) including temperature alarm settings (; T). System linked to contractor alarm desk forwarding alarms to Vion officers when necessary. No storage under controlled atmosphere applicable.

External contracted storage is applied for almost all goods. All transported at appropriate temperature (< 2°C for DMM and is then frozen to below -18°C by an external cold store according to legislative requirements). A separate building is applied for the storage of packaging and other raw materials. No return of partly used packaging materials to this warehouse. No outside storage, except for dirty crates. Warehouse / cold store contractors are approved.

4.16 Dispatch and transport

Dispatch and release of products is based on temperature verification (CP). Transport mainly subcontracted to a Vion transport company, which is BRC Storage & Distribution certified. Other approved logistic partners are listed. Contracts managed by the logistic / supply chain department at the corporate VION organisation covering the requirements of the BRC Food standard related to transport. Transport is organised and scheduled by the Service desk. They are only using approved transport and storage contractors. Trucks and reefer containers are inspected for hygiene and temperature before loading. Results of this inspection are recorded at the CP control forms. Trailers may be pre-loaded and parked on the Vion Scherpenzeel site area. Remote monitoring of cooling equipment by logistic contractor DistriFresh.

Details of non-applicable clauses with justification

Clause reference	Justification
4.3.5	No high-care / high-risk areas.
4.3.6	No high-care / high-risk areas.
4.3.7	No high-care / high-risk areas.
4.3.9	No temporary structures.
4.4.4	No high-care / high-risk areas.
4.4.13	No high-care / high-risk areas.
4.7.5	No high-care / high-risk areas.



4.8.4	No high-care / high-risk areas.
4.8.5	No high-care / high-risk areas.
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.
4.13.2	No customer-branded surplus food.

5. Product control

5.1 Product design/development

Product development takes place at HQ by introduction of new machines, new processes, new customers or new packaging and product cuts. The product development process is managed centrally within the Vion Food organisation according to Procedure "Product Ontwikkeling Convenience" (P-NLFOOD-10190). Any new process validation is carried out by Vion HQ Boxtel as part of the project management process. Local HACCP team is involved in case of new product introductions or new or changed processes, e.g. new slicing line, new x-ray detector. There is a trial period with extra checks on the quality of the product. Microbiological testing is done at end of shelf life. Results of shelf-life tests assessed, e.g. bacon reduced salt (art. 82430). Site of Vion Scherpenzeel BV is an allergen-free site.

5.2 Product labelling

Verification of shelf life date recorded on labelling controlled as CP. No full automatic labelling of packed product identified. Slicing is packed for of consumer products, rest is B2B. Pre-printed labels used, 6 different types (see minor in 6.2). Product labels are printed based on article numbers and have to be printed per packed unit. No functional product claims made. No allergens identified on-site. Labelling product for EU-market following EU-legislation and any additional customer requirement. Following Vion central procedure labelling for markets outside EU approved by sales (HQ Vion) after evaluation by the customer.

5.3 Management of allergens

No allergens on-site. Verification of specifications of non-meat raw materials is part of the supplier approval process.

5.4 Product authenticity, claims and chain of custody

Vulnerability assessment based on central 'procedure product and process integrity' (P-FOOD-10049) and complies with CoC certification, GGN4058186517845. Local assessment must be carried out on the basis of this procedure and is translated in Procedure 'Risicomanagement-beheersplan Product-procesintegriteit derde landen' P-SPZ-NL-10174 with high risk appraisal. Also listing of countries is

LRQA Ltd 1 Trinity Park, Bickenhill Lane, Birmingham, B377E5

LRQA BRC 7 Food English Issue 7 August 2017

Page 28

Report: RQA9832747 job 1404684

Auditor:



available in F-SPZ-NL-10095. Basically, the local vulnerability assessment is based on the evaluation of raw material characteristics, supplier evaluation and logistic services. Raw material risks are considered low as products can be easily recognised as pork meat parts. Product mainly supplied by Vion sister companies. Procurement of meat parts from external companies and external logistic services (especially when products are unpacked, e.g. freezing) are considered high risks. Chain of Custody audit program implemented for logistic service providers depending on the company risk profile. Logistic service providers have to be GFSI-certified and CoC-certified as well. Segregation and correct identification is established for several animal welfare categories (so called quality lines):

- Organic pork (SKAL certified): identification by green label, last number of article number = not in production at the time of the audit;
- Farming star ("beter leven"): identification by orange label, last number of article number =
- GB (good farming including welfare requirements for UK clients): identification by blue label, last number of article number =
- GF (IKB certified): identification by blue label, last number of article number =
- QS (Qualität und Sicherheit for German market): identification by blue label, last number of article number =

Certification of GF, GB by certification bodies and FS/CoC by LRQA. All products are produced based on EG 82 approval number, incl. regular meat (called ST "standard"). Vion Scherpenzeel BV is certified according to the CoC scheme too (Chain of Custody). Risk assessment and execution of mass balance exercises are scheme requirements. Daily verification of mass balance FS at process level (no integral check) as verified for the DMM process is accepted by the certification body (FS scheme requires full daily mass balance test). Mass balances are made on a daily basis for all quality lines. During the audit it is checked how the status of quality lines is verified and segregated at the intake department and several production departments (cutting / deboning, DMM, SDP, etc.) like the labelling of meat hooks, the identification of product lines, the production sequence (starting with high quality lines followed by lower quality lines), colour coding of recipients (coloured liners) to prevent exchange of meat categorised in different quality lines.

Procedures are implemented concerning the verification of the quality line and how to downgrade the quality lines as generally the demand of certain quality lines is lower than the availability of meat categorized in higher quality lines. Downgrading quality lines is the responsibility of trained and qualified personnel. The downgrading is allowed following the sequence: FS -> GB -> GF -> QS -> ST, BIO-> GB. At the DMM department also organic and FS categorised meat can be downgraded.

Vulnerability assessment for non-meat raw materials covered by the procedures and risk calculation based on a few factors like product characteristics, packaging materials, origin, product availability. No high-risk raw materials identified.

Also countries of destination can have their own requirements (like USA / Canada (USDA), Korea, Japan, China). Dutch authorities issue health certificates on batch level following third countries export protocols.

5.5 Product packaging

A system of coloured jumbo bin liners is in use for some clients / products (for Japan, for FS). For others mostly liners are used. Packaging materials are stored separately from production materials and partly used packaging is covered prior to returning to the storage area. Packaging materials have to comply with Regulation 1935/2004/EC (specification review / approval process) and 10/2011. Foil assessed during the trace test.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing



Product monitoring based on Regulation 2073/2005/EU and interpretation guideline ('Infoblad 85' issued by the Dutch authorities) laid down in procedure P-FOOD-10008 (from 13-02-2017). Both food safety criteria and process hygiene criteria set by legislation are translated to the monitoring program as reviewed based on sampling.

Listeria positive swabs found during monitoring of production areas (internal requirement). All products produced by Vion Scherpenzeel BV have to be fully heated prior to consumption. Serious and comprehensive action is planned by a total clean out this week.

Mechanically separated meat type 3 (according to Regulation 853/2004/EU) to be used for meat product must be heated prior to consumption. Positive release on Salmonella only required when requested by customer to be able to use the DMM for other products. Also calcium monitoring for DMM demonstrable.

A microbiological monitoring program: bacon (TPC, entero's, Salmonella, Listeria), SDP (TPC, E. Coli, Salmonella, Listeria), DMM (TPC, E. Coli, S. aureus, Salmonella, Listeria) and shelf life testing program is in place. Results are analysed and reported (). Results of 2017 and 2018 yid demonstrate compliance with the defined specifications.

Physical / chemical product monitoring as part of process control, for example meat part size and fat content for SDP.

5.6.2 Laboratory testing

No internal lab. All analyses (excepting hygienograms) are subcontracted to an accredited laboratory operating in accordance with ISO 17025 (accreditation number

5.7 Product release

Finished product is fit for delivery unless it is in blockade. Positive release on Salmonella only required when requested by customer to be able to use the DMM as raw material in meat preparations.

Details of non-applicable clauses with justification

Clause reference	Justification
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5.2.3	No claims made.
5.3	No allergens on site.
5.6.2.2	No laboratory on site.
5.6.2.4	No laboratory on site.

6. Process control

6.1 Control of operations

The site clearly demonstrated a good control of operations. Process conditions and methods are well looked at and revalidated. Systematic monitoring is demonstrated. Maintenance of the cold chain is of



prime importance including prevention of condensation. Continuous real-time temperature-recording equipment, linked to an automatic alarm system is in place. Alarms are set and the maintenance service is notified of any alarm. The system is tested regularly. All processes are validated with records maintained, to demonstrate that the process is capable of producing safe, legal and quality products. Process control is based upon the HACCP study, legal and customer requirements. Documented start up checks (pre-SSOP) are applied. Multi moment measurement (MMM) system implemented. Team leaders take a predefined number of samples during their shift and compare the processed product to reference pictures to verify compliance to customer or internal specifications. Results are reported on white boards. In case of scores exceeding predefined limits containment actions and where necessary corrective actions have to be taken. Communication structure at different levels. Daily tier 1 production meeting covering quality performance.

Minor 4: Thermometers and test probes for metal detection are disinfected after usage as described in the instructions. This does not guarantee septic condition before usage. No disinfection before usage seen although test probes were handled and placed unhygienically.

6.2 Labelling and pack control

Packing takes place in line with production planning and customer requirements. Tests of product labelling, traceability code and shelf life carried out in accordance with specifications. New to the organisation is packing consumer packaging and a system is developed with controls and instructions. Six types of products are identified and preprinted labels applied. Packs are labelled with more than one label per pack on customer request.

Minor 5: Packing material (all types of foil) is stored next to the packing machine so there is too much material available.

Minor 6: In the packing instruction (Snittenboek) is not stated which primary packaging material is to be used. There is used upper foil lower foil, 2 types of label with information. No foil codes, label codes are present in the description. Checks not possible on correct number. No procedure demonstrable on management of label pack control, although checks demonstrable on labels and to archive used labels.

6.3 Quantity, weight, volume and number control

The company has implemented a quantity control system. All products are sold by weight. controls the balances for commercial purpose. Calibration of the scales is demonstrable. The devices are tested internally by means of standard weights. Weighing equipment is calibrated 1x/y and tested daily in Pre-SSOP.

6.4 Calibration and control of measuring and monitoring devices

Calibration procedures (with use of ensure relevant equipment is identified and regularly calibrated. Critical measuring equipment are thermometers (hand held and PT 100 in refrigerators). Internal calibration with 2-monthly frequency (thermometers CCP), 6-monthly frequency (thermometers CP) and yearly frequency (PT 100) or external calibration with yearly frequency (weighing scales, reference thermometer '25') is adequate according to the calibration records. No adjustments are made by the company. Several calibration reports seen eg for the reference thermometer, the CCP related equipment and a floor weighing scale have been reviewed during the audit.

Minor 7: There are 10 metal detectors on site. 2 detectors are not calibrated and no instruction or timescale to calibrate is present. No regularly checks on these measuring devices are demonstrable.



Details of non-applicable clauses with justification

Clause reference	Justification

7. Personnel

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

There is evidence of introduction training for new starters, temporary workers (by and both in-house) and contractors. All personnel have to watch a video on rules and instructions and pass an exam. Refresher training is carried and documented within 'logboek intake'. Especially for workers from Poland, Slovakia, Romania, Hungary a translation of the hygiene and HACCP instruction is present in their own language. Seen the CCP training on oy dd 16-04-2018.

Minor 8: Duration of the training is not included in the training record. Furthermore the form has no version reference. The course content does not relate to the instruction trained.

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

The standards for personal hygiene, dress code, medicines, jewellery and medical screening have been defined and communicated to all personnel (including temporary personnel, visitors and contractors) prior to commencing work. Compliance is checked during the internal audits and daily inspections by production supervisor and QA. These hygiene rules are enforced. Hand-washing facilities are available in the staff facilities and at the transfer point from staff facilities to production. A hand disinfection station has been installed. A sole brush is installed at the entrance to production. Blue coloured, metalized plasters are in use together with gloves. The wearing of any jewellery is not allowed.

7.3 Medical screening

Visitors and contractors have to complete a health questionnaire prior to entry to any production areas. Medical screening of internal / external employees implemented. 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. In case of a disease the company is consulting a specialised company doctor. Persons who are suffering from relevant infectious diseases are not allowed to enter the production facilities.



7.4 Protective clothing: employees or visitors to production areas

Company issued protective clothing (inclusive work shoes) is given to all staff and visitors. 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 breaks, eating, smoking and using the toilets. White protective shoes are worn and washed by sole washer (before entering production) and by manual cleaning (after leaving production). Disposable hair nets, beard snoods and astro caps are in use. Cleaning facilities are provided. Knives and metal gloves are washed internally following a manual cleaning procedure incl. disinfection.

Details of non-applicable clauses with justification

Clause reference	Justification
7.4.4	No high-care / high-risk areas.



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.		
	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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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		

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LRQA BRC 7 Food English Issue 7 August 2017	Page 36	Report: RQA0832747 job 1404664	Auditor:



		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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 preventive 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: <ul style="list-style-type: none"> • 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.		

