Audit Report

Global Standard for Food Safety Issue 8: August 2018

1. Audit Summary

Company name	Encebe Vleeswaren B.V.	Site Code	9714502
Site name	Encebe Vleeswaren B.V.		
Scope of audit	Producing (cutting, slicing, mincing, blending, fermenting, pasteurising, sterilising, marinating) and packing (modified atmosphere, chilled, frozen, canned) of meat products of beef, pork and poultry in consumer and bulk packaging.		
Exclusions from scope	none		
Justification for exclusion	Justification for exclusion		
Audit Finish Date	2019-10-10		
Re-audit due date	2020-10-08		

Additional modules included

Modules	Result	Scope	Exclusions from scope
Choose a module	Choose an item		
Choose a module	Choose an item		

Head Office	Yes

2. Audit Results

Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	AA	Previous audit date	2018-10-08		
Certificate issue date	2018-12-04	Certificate expiry date	2019-11-19		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0

	Minor	8

3 Company Details

Address	Boseind 10, 5281 RM Boxtel		
Country	The Netherlands	Site Telephone Number	+31 411 658736
Commercial representative Name		Email	
Technical representative Name		Email	

4 Company Profile

Plant size (metres square)	10-25K sq.m	No. of employees	51-500	No. of HACCP plans	1-3

Shift Pattern	2 shift system
Subcontracted processes	No
Other certificates held	IFS 6.1 Food, ISO9001, CoC/CBL, Organic, Beter Leven Keurmerk
Regions exported to	Europe Choose a region Choose a region Choose a region Choose a region Choose a region
Company registration number	EG 61 NL
Major changes since last BRC audit	No major changes since last audit.

4 Company Profile

Company Description

Encebe Vleeswaren BV is a middle-sized producer of meats preparations and meat products and is part of the Vion Food Group. The company is located in Boxtel at the same location as the slaughterhouse of Vion Boxtel. Encebe Vleeswaren BV has employees (of which 56 at a temporary base) in a one shift operation (excepting smoking department: 2 shifts). 1 HACCP study is available, and site is 10.000 m2 (part of facility VION Boxtel). There are no seasonal workers.
The company is producing and selling ca. 300 different final products divided into several product groups of meats and sausages: meat preparations, (smoked) cooked sausages, sterilised products and fermented sausages. Most of the products are produced by the own production process. Additionally, purchased product (poultry) is sliced and packed in a special department.
The company is also producing an assortment of products based on organic raw materials (SKAL certified). The company is certificated for IFS 6.1, 'Beter Leven Kenmerk', CoC of CBL and ISO 9001 as part of a multi-site ISO system.
Main selling market is the industrial market but also wholesale and retail (supermarkets).
The strategy is focused at growth in the industrial market, for which an assortment tailor-made product is produced, and growth in the retail market of sliced ready to eat meat products.
Official approval EG-61-NL of the Food and Consumer Product Safety Authority which is also the number of the slaughtering house.

5 Product Characteristics

Product categories	08 - Cooked meat/fish products 09 - Raw cured or fermented meat and fish Category Category
Finished product safety rationale	Finished product safety rationale: Short shelf life, presence of preservatives, packed at modified atmosphere or vacuum, cooked, chilled, frozen, hermetically closed casing or vacuum packaging or canned.

High care	Yes	High risk	No	Ambient high care	No

Justification for area	Preservation of products is based on the combination of a heath treatment and another preserving methods; eg acetate, diacetate. (= "No" for step 5 in production zone decision tree 1 – chilled and frozen products).

5 Product Characteristics

Allergens handled on site	Soya Milk Cereals containing gluten Mustard Sulphur dioxide and Sulphites 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, CoC
Product recalls in last 12 Months	No
Products in production at the time of the audit	Italian roasted pork, Pork bellies, BLK "Rookworst" (sausage), "Leverkaas Carree", "Snijworst", "FS Schouderham", "Ambachtelijke rookworst grof", "Salami gerookt", "Vorder Schinken", "Oven gebakken spek","Boterhamworst BLK2".

6 Audit Duration Details

On-site duration	32 man hours	Duration of production facility inspection	10 man hours
Reasons for deviation from typical or expected audit duration	This was a combined audit (total 4 day's On-site) with the IFS 6.1 renewal visit. Calculated audit time for BRC is 20 hours.		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-10-07	9:15	17:00
2	2019-10-08	8:30	17:15
3	2019-10-09	8:50	17:15
4	2019-10-10	8:40	16:45

Auditor (s) number	Name	Role
Auditor Number		Lead Auditor
Second Auditor Number N/A		Please select

Present at audit

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
/ Supply Chain Operations Manager	x		x	x
' QA manager	x	x	x	x
Production leader	x	x		x
ı / HR-manager	x		x	x

Present at audit				
/ Supply chain manager	x			x
..... / Commercial manager				x
... / Afdelingsmanager Encebe 1	x	x		x
/ Afdelingsmanager Encebe 2		x		x
/ Assistent chef TD		x	x	
/ Maintenance officer			x	
/ QC officer			x	x
/ QA officer			x	x
/ QA officer (A.I.)			x	x
ı / Central purchase			x	
/ Specification control			x	
/ Product development			x	
/ Employee bedrijfsbureau			x	
/ Assisting foreman zouterij		x		
/ Production employee zouterij		x		
... Assisting foreman packaging		x		
/ Operator packaging		x		
/ Assisting foreman expedition		x		
ı / Foreman industrial		x		
/ production employee smoking		x		
/ Employee Expedition Bulk packaging		x		
/ Assisting foreman meat receipt		x		
Expedition employee		x		
/ Foreman expedition		x		
/ Production employee Cutterij (cutting department)		x		
Operator Stopperij (sausage filling)		x		

Present at audit				
.o / Production employee Cutterij (cutting department)		x		
/ Employee Warehouse/hal 150		x		
` / Foreman Warehouse		x		

Non-Conformity Summary Sheet

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

Critical			
No.	Requirement ref.	Details of non-conformity	Anticipated re-audit date

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

Minor							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	3.4.1	BRC Minor NC 3.4.1 The Food fraud plan is not demonstrable assessed in past year (seen internal audit reports from 14 May 2018 till 2019 ytd.) The audit frequencies are not demonstrable evaluated towards previous audit performances.	Correction: Two (extra) internal audits for CCPs and high care. And printscreen adapted procedure for annual frequency review.	Root cause: Within Vion, food fraud is part of the COC internal and external audit and IFS PIA will be added in the near future. The name is integrity instead of the food fraud we were looking for.	Evidence: Yearly planning 2019 (M1) (Printscreen) P-VION-10011 Internal audits (M1)	2019-10-31	

				Corrective action: Adjusted in the proceeding (P-VION-100011). Based on the site's certifications, the site's QA manager ensures that relevant risk-based audits are carried out annually and the findings are followed up. Every year, two audits are conducted by QA manager from another location, one announced and one unannounced. Based on the risk assessment, there are two additional internal audits (e.g. High Care and CCPs) are added. During the Q reports (management review of quarterly reports) it is checked whether the audit frequency is still sufficient, otherwise it will be adjusted.			

				Verification: Annual planning has been made. Review of the frequency in the internal audit procedure. By completed 29-10-2019 **Status/verification by assessor: Minor NC Closed to be verified at next audit.**			
2	4.4.8	BRC Minor NC 4.4.8 From the top site of the door portal (between lactaat department and meat storage) water is leaking down. The doorpost is corroded at the top.	Correction: New sealant is being applied on 26-10-2019.	Root cause: Condens ended up in a gap between the wall and the folded sheet metal and giving soiling on the metal. This will be done on 26-10-2019. Corrective action: During the pre-ssop check, every morning we check for condensation/water. To prevent this from	Pre- and post-photo sealant work gap between folded sheet metal and the wall. (M2)	2019-10-31	

				happening more often. Verification: Before and after photo of the gap between the folded sheet metal and the wall. 26-10-2019, directly organized. **Status/verification by assessor: Minor NC Fully Closed.**			
3	4.11.1	BRC Minor NC 4.11.1 In the High care packaging department there are two blue transport belts for packed products (line 1 and line 2) with cracks in the top surface.	Correction: The belts are being replaced on both line 1 and line 2.	Root cause: In the current assessment, the damage was examined, which means that the small cracks were not detected. Corrective actions: Check daily round pre-ssop belts. In addition, the belts are also included in the current construction round. Verification:	Blue belts offer and workorder. (M3)	2019-10-31	

				There is an offer for the belts. Status/verification by assessor: Offer is requested on 23-10-2019. Verification: Has been order under number 29-10-2019, in progress. **Status/verification by assessor: Minor NC Closed to be verified at next audit.**			
4	4.11.3	BRC Minor NC 4.11.3 Around the fulling mouth (bottom site) of the ice machine (lactaat department) there is lime scale.	Correction: Extra cleaning ice machine	Root cause: Cleaning has not been fully effective in the case of the ice machine (built in 2010), as a result of which less attention has been paid to the inside of the machine, so limescale is visible. Corrective action:	*There is a* picture of the ice machine before and after cleaning. Swabs listeria and ice *analyzed (M4)*	2019-10-31	

				Ice is checked annually on 05-03-2019, the general bacterial count and enteros were in agreement. A listeria swab was taken from the ice machine with limescale. The result was no listeria present (24-10-2019). The external cleaning company have cleaned the ice machine thoroughly, after which the frequency is determined depending on the degree of contamination. The ice machine is now included in the environmental monitoring study on listeria. Verification: There is a picture of the ice machine			

				before and after cleaning. 29-10-2019, directly *organized*, **Status/verification by assessor: Minor NC Closed to be verified at next audit.**			
5	4.15.2	BRC Minor NC 4.15.2 In the warehouse ("ruimte 10") there is a role primary packaging material ("onder folie ") which is not completely covered. The material for use in the high care packaging department.	Correction: Immediately solved, new foil was wrapped around it.	Root cause: The top film was covered with plastic, but here was a tear in the packaging material plastic around the primary film. Corrective action: Immediately solved, new foil was wrapped around it. Room 10, the warehouse, will be reviewed on low and high care packaging material and segregation to primary and secondary packaging material.	Agenda and minutes about work meetings about room 10. (M5)	2019-10-31	

				Verification: Discussed in work meeting. Cover - 29-10-2019, directly organized, Room 10 – End of November 2019, **Status/verification by assessor: Minor NC Closed to be verified at next audit.**			
6	8.1.3	BRC Minor NC 8.1.3 At the High care department water drops are falling down from the top doorpost between cooling departments "cel 149" and "cel 134".	Correction: Has been discussed in the work meeting with the team leaders.	Root cause: Hot product is passed under the door frame, causing condensation to form. Corrective action: The high care environment is checked for condensation every morning at the pre-ssop check. The relevant employees are alerted to this again.	Agenda and minutes about work meetings about room 10. (M6)	2019-10-31	

				Smart mops are used to remove the droplets/condensation on a daily basis. Verification: *Has been discussed* in the work meeting with the team leaders. October 2019, directly organized. **Status/verification by assessor: Minor NC Closed to be verified at next audit.**			
7	8.2.2	BRC Minor NC 8.2.2 The risk of contamination by air in the high care area is not demonstrable assessed in the risk assessment (30 Sep. 2019). (Motivation for Minor NC Air is filtered and microbiological air monitoring plan show acceptable levels (<100 cfu/m3).	Correction: Action 1: Reassessment risk assessment plan Expected to be ready: March 2020 Action 2: Validation of air quality high care.	Root cause: The risk assessment plan is drawn up centrally and then focused on the relevant location, such as Encebe. However, the high care departments bring with them specific hazards, whereby the inclusion of air quality in the *risk assessment plan* is not addressed.	Action 1: Reassessment risk assessment plan (central quality department). Expected to be ready: March 2020 (M7) Action 2:	2019-10-31	

			October 2019	However, the control measures have been implemented. Corrective action: Two actions have been set out. A reassessment of the risk assessment plan with regard to the hazards, critical limit values, monitoring and verification, preventive and corrective measures with responsible parties and references to the documentation. A validation is written about the air quality in the high care areas to validate the current control measures. Verification: Validation is complete, yet to be discussed in the haccp team meeting. Adjusting the risk assessment plan has	Validation of air quality high care. October 2019 (M7)		

				been set in motion on QA central. October 2019, directly organized. **Status/verification by assessor: Minor NC Closed to be verified at next audit.**			
8	8.7.1	*BRC Minor NC 8.7.1* There is a maintenance jacket after the high care entrance without "high care" label. Maintenance trousers with a "high care" label are worn in and outside high care areas by maintenance personal. According to procedure "High Care" (3 Oct. 2019). Only "high care" labelled clothing are allowed in high care areas (and not outside those areas). Clean maintenance "high care" labelled maintenance clothing is stored unpacked and open (without any protection) in the maintenance shop.	Correction: Order black clothes in plastic and different shoes color.	Root cause: *The clothing of the* employees high care department is in a different place, than the clothing of the maintenance department. As a result, it was not noticed that the clothing of the maintenance department was not wrapped in plastic Corrective action: From now on, the maintenance *department clothing* for high care will be packaged in plastic, which will be black overalls from now on.	Maintenance departement procedure. *Before photo* clothing storage, after photo. Emails about new clothing. M8	2019-10-31	

				A different color of shoes for high care will be used for the maintenance department. For low care, the green shirt or sweater and trousers are used. When entering low care, a jacket is put over the green sweater or shirt. Clothing is replaced daily. The green clothing (low and high) is sorted and emblems for high care will be removed. From now on, the green clothing will only be used for low care. The stock storage of the maintenance department clothing has changed, it will be placed in a rack at the top of the maintenance department from now on. Sorted to size, low and high care (in plastic) separately.			

				Verification: Discussed with maintenance department coordinator. end of November 2019, directly organized. **Status/verification by assessor: Minor *NC Closed to be* verified at next audit.**			

Comments on non-conformities

Additional Modules / Head Office Non-Conformity Summary Sheet

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

Major							
No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

Minor							
No.	Requirement ref.	Details of non-conformity	Corrective action taken	Root cause analysis and proposed action plan	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

There is a quality policy (Signed by Supply chain / Operations manager, dated and reviewed 03-10-2019). The signed Management Review 03-07-2019 (reflecting Q3/2018 - Q2/2019) displays an overview of all relevant KPI's and subjects as prescribed by the X-matrix reporting system of all VION plants. The Quality Management System is evolved and matured and KPI's are: registration of failures in production; customer complaints; increase discipline and awareness on hygiene; swabbing scores, no failures on CCP's, realisation of OEE and several others.

The management team of Encebe comprises 7 persons of which 5 are in position less than 3 years. The team managed to realise several investments last year; A vacuum filling machine with metal detector, new smoking cabinets and a new cutter. End 2017 and 2018 an enormous lot off investments were done. The management team showed commitment to the QMS which is also present in the systematic for continuous improvement, e.g. PDCA cycle of the multi-site ISO 9001 approval.

Plans and actions towards Food safety culture plan are identified in year plans (X-matrix, seen 2019). First step was an inventarisation (by questionaire) what personal feels as important issues.
This was finished in September (results seen). Based on this a further actionplan will be set up.
A planning to implement a Food safety culture plan for coming years has been set up and will be a part of the Review and Verification processes (3 times a year and total by management review is 1x a year).

A whistle blowing procedure is implemented. This is managed by central HR.
The procedure is regulary brought to the attention, in e.g. performance interviews and employee publications.

Internal communication is conducted by daily white board (Huddle/Tier) meetings with all employees. Several samples of this type of communication seen and discussed with the responsible department manager. A system of presenting issues like (product) quality, improvement actions and complaints is seen.
The company demonstrated a system which is maintained and compliant with the process controls and is effective in meeting customer, process and product measures. There was evidence that resources had improved the working of the QMS.
The MR contains the relevant review subjects (objectives, complaints, verification and validation of the management system, CCP control, PRP control). The reassessment of the system is done in Q3 2019 and as prescribed on a quarterly base instead of once a year.
There is an organisation with short communication lines (effective) and a direct control of the production by the management. Communication (Procedure Overlegstructuren P-NCP-NL-10006) is conducted by:
- White board communication (Hurdle Tier boards); concerning quality issues (VOS)
- MT-meeting once per week (seen minutes 02-10-2019)
- PPD-meeting & HACCP team meetings once per 4 weeks;
- Employee meetings 4 times per year;

The company is aware of applicable legislation. Encebe is supported by HQ towards legislation.

No visits from NVWA authorities last year.

No recall and no withdrawal actions over last year.

The Supply chain / Operations Manager attended the opening and closing meeting of the audit and intensions were discussed during the opening meeting.

Root causes of the minor non-conformities of the latest BRC audit have been identified.
The NC's did not reoccur. All non-conformities are fully closed.

The audit was combined with IFS audit, and executed within audit due time frames.

No BRC logo use identified.

The BRC issue 8 version is available on site.

1.2 Organisational structure, responsibilities and management authority

The organisational structure is documented ("Organogram" 03-10-2019). The production departments directly report to the production-manager. The production leader is member of the MT. The QA manager (also MT member) informs the Supply chain / Operations manager concerning food safety issues, complaints and results of internal auditing. The responsibilities, authorities and reporting relationships of all staff members are described in the job description. Replacement is arranged in P-NCB-NL-10008.

2 The Food Safety Plan – HACCP

Based on the principles of the Codex Alimentations, in a manual a complete system has been documented and implemented in practice. At VION Food NL level a thorough HACCP analysis (P-VION-10000) is made and available for the sites. The local HACCP system ("Procesbeheersplan" 04-10-2019) was developed by a multi-disciplinary HACCP team, namely, Supply chain / Operations manager, QA Manager, QA/QC Officer, Production leader and TD coordinator. All team member's shows enough and the right experience and knowledge. The team has monthly meetings (seen last report 11-09-2019).

The HACCP system has full management commitment and is an integral part of the company's Quality Management System (QMS). The HACCP system was found to be well documented and effectively implemented. Full product description including microbiological limits and shelf life is in place. The intended use (B to B/Consumer Products) of the product by the customer has been clearly defined. No specific user groups are identified.

Flow diagrams are actual (seen latest version 30-09-2019) and available in all process steps were present (including rework). Verification is done yearly in Q3-2019 as part of the management review. A good detailed lay out was shown in the manual as well as process flows. Zoning, Employee, Raw materials, Product and Waste flow are determined on the lay out.

Each identified hazard was reviewed and given a risk rating to define the severity (1 – 3) and likeliness (1 – 3) of a hazard occurring. The risks (R >=3) have been defined from the hazards with adoption of a decision tree: Risk < 3 = PRP, Risk 3 or 4 = CP, Risk 6 or 9 = CCP. Assessed:
- Procedure Procesbeheersplan Encebe Vleeswaren (30-10-2017)

Summary CCP's and CP's (30-09-2019)

CCP' s which are determined, including critical limits, according to P-NCB-NL-10027 dd 04-10-2019:
- CCP 1. Temperature control of (returned) fresh pork meat / beef at reception (≤7°C)
- CCP 2. Temperature control of (returned) animal by-products/organs at reception (≤3°C)
- CCP 3. Temperature control of separated meat at reception (≤2°C)
- CCP 4. NO2 in brine (absence or presence by indicator paper)
- CCP 5. Temperature control of heat-treated meat products sterilization (2,45 hours at 106°C)
- CCP 6. pH after fermentation process (pH≤5,3 within 45 hours)
- CCP 7. Temperature control of heat-treated meat products pasteurization (P70>3 minutes)
- CCP 8a. Temperature control of minced meat at dispatch (≤2°C) (former CP)
- CCP 8b. Temperature control of meat preparations at dispatch (≤4°C) (former CP)
- CCP 9. Temperature control of chicken meat at reception (≤4°C)

In the HACCP analyse there are several product groups determined. For each group there is a risk analyse available and out of this risk assessment CCP's and CP's are installed.
All CCP's are assessed during the audit and found to be working correctly. Critical limits have been defined for each CCP and are related (if applicable) to the legal temperature requirements for meat and meat products. CCP monitoring has been established and documented.

Corrective actions are clearly defined according to the CCP overview. The CCP's were demonstrated, including a well recording during the audit, including corrective actions. Verification during the year is demonstrable. Several reports seen (quarterly review) and HACCP verification is part of the annual Management Review (seen 03-07-2019, reflecting Q3/2018 - Q2/2019).

OPRP's (CP's) identified for specific risks: e.g. contaminations by moisture, allergen-management, procurement and verification.

A PRP programme is implemented for; Pest control, control breakable items, hygiene, cleaning, maintenance etc.

With daily checks and monthly QA inspections.

Validation reports including defined critical limits were assessed (e.g. validation report for use of new ingredient to reduce the grow of Listeria in "Boterhamworst BLK1" 19-08-2019 & validation report "Growth of Listeria in sliced products from Encebe Oct. 2019").

3. Food safety and quality management system

3.1 Food safety and quality manual

The company has a quality manual, complying with ISO 9001 and BRC 8 Food, which states the company's commitment to quality and food safety. The quality manual is the total of all quality documents, going from the policy, over system procedures (P), working procedures (P), work instructions (P), registration documents (F). An electronic quality manual named in 'Quality on-line' is in place and available to departmental managers. The system is fully implemented in the organization's processes.

3.2 Document Control

A document control procedure (P-NCB-NL-10007) controls the issue of documents to ensure they are at the correct issue status at points of use or reference. Documents are authorized by local QA (and/or HQ QA) dated and available to relevant employees on paper or digital. It also includes how obsolete documentation is handled.

3.3 Record completion and maintenance

The procedure for quality records (P-NCB-10011) defines how long records are maintained, how they are reviewed and where they are stored / archived. Most records are hand written.
Records are made by operators written on the relevant forms in production.
All documents are kept for at least BBD + 12 months. Longest shelf-life is 15 months (sterilized products).
Also, records are automatically registered in the computer systems. All electronic data (e.g. cooking and cooling times and temperatures, temperatures in cells) are secured by daily back-ups.
Records are checked as part of the vertical audit.

3.4 Internal audits

There are detailed schedules of internal audit against documented procedures, carried out by trained independent staff (from the VION company and local QA). The audits are planned throughout the year. All departments are included in the plan.

Audits by HQ are done twice a year and scheduled throughout the year, 1 unannounced and 1 announced audit by VION QA Managers trained and experienced. The audits have been carried out to schedule and are on food safety, product integrity, IOS9001 reported in several annexes.
Further 2 local internal audits: 1 on management system and 1 on traceability system.

Corrective actions have been taken in a timely manner. Actions are managed in a central action list.

Audits reports seen: e.g. 16-05-2018, 19-12-2018 unannounced & 14-05-2019 (all including CCP control), executed by QA manager of Vion Retail Groenlo or HQ auditor.

In addition, hygiene audits (HON) and site / building inspections are performed at monthly intervals to respond to the KPI of increasing discipline and awareness on hygiene.

However, 1 Minor NC on internal audit evaluation and frequencies.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

There is a procedure for selection and supply of raw materials and packaging "Procedure Supplier Audit" 21 Oct. 2019. Purchasing and supplier approval is a corporate quality department responsibility (at VION central office – VION Food NL).
Approval is on base of a questionnaire and a GFSI certificate and/or an audit. Suppliers are divided in two divisions: Meat and Ingredients. Ingredients include all that is not pork or beef, so chicken meat, packaging, additives, casings, is bought by Sourcing manager Ingredients. The decision is made on quality and commercial parameters. Towards brokers, access to suppliers is arranged for every broker.

The risk assessment depends on the kind of material and is based on enquiries, specification / food grade declaration, trial delivery and GFSI certificated QMS of the supplier and microbiological performance (meat suppliers).

Supplier performance evaluation (based on quality, expertise, delivery performance, service, complaint management, etc.) carried out annually. The evaluation is coordinated by central purchase (including

service suppliers) and executed by site QA. Traders of supplying material are identified and information from producers is demonstrable (seen evaluation over 2018 for Encebe suppliers).

Close communication was demonstrated. All suppliers of packaging have to be approved by the central VION office and entered into the system before they can be used.

Seen Approval and Evaluation documents for supplier's e.g.;
Raw materials; Vion Tilburg – Meat, · Chicken meat, – Spice blends, –
Additives, – Ingredients.
Packaging; – Primary packaging
Service suppliers; – transport, – Pest control, – Cleaning.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

On receiving of raw material meat temperature is recorded of all deliveries (as it is a CCP). During the trace test the acceptance of packaging and additives is assessed. Good practice seen.

3.5.3 Management of suppliers of services

All suppliers of services have to be approved. Purchasing and supplier approval is a corporate quality department responsibility (at VION central office – VION Food NL). Suppliers performances are well monitored and followed up. The risk assessment depends on the kind of material and is based on enquiries, specification / food grade declaration, trial delivery and GFSI certificated QMS of the supplier. Close communication was demonstrated.

3.5.4 Management of Out-sourced processing

NA

3.6 Specifications

Specifications for raw materials, packaging materials, cleaning agents and finished products are available through and managed by the involved departments. Specifications are reviewed internally to ensure they are correct and up to date. Food specifications (meat-containing raw materials + finished products) managed by PPD reviewed once in 2 year. Other specifications checked 1 x / 3 years. Specifications contain relevant aspects and requirements. Samples of specifications for raw materials, ingredients, additives, packaging materials, final product have been checked during the BRC/IFS audit (as part of the vertical audit) seen:
Finished product "blk1 Schouderham gerookt" art nr. 301120 dd 24-06-2019
"FS Pees eind blauw" (pork) 13-02-2018.
starch) " 02-05-2019.
"Pekelmix" (brine mix) 12-04-2018.
"Packaging material: Foil bag (incl. migration) 09-10-2018.
Map gasses CO2 21-02-2018 & N2 14-08-2019

Information seen in specifications was suitable and enough detailed towards relevant requirements.

3.7 Corrective and preventive actions

Corrective action system is based upon the information from internal audits, SSOP, pre SSOP, hygiene audits, pest control, non-conforming product, complaints etc. Action plans (overviews) are in place.
For daily actions the huddle white boards system is used. There is an on-going Excell action list to manage corrective actions (out of audits). Corrective actions are also evaluated in quarterly MT meetings (seen report Q2 2019).

3.8 Control of non-conforming product

Non-conforming products / product on hold are physically identified as such with a red coloured label. There is a clear documented procedure for the identification and disposal of non-conforming product. (P-NCB-NL-10013). Direct action towards non-conforming products was clearly demonstrated during the audit. A file per issue with details was seen.

3.9 Traceability

Traceability system is well developed. It covers raw materials through work in progress to finished product including additives and packaging materials and distribution. This system is fully based on written documents, batch codes (input → output per process step), bar codes and an ERP-system according to 'procedure identification – traceability'. A suitable system has been explained during the audit. The way of coding was shown during the audit.
Test for recall and traceability at least tested annually. Last test 27-09-2019 was about a fictional compliant about glass in pork belly.

A product was chosen by the auditor for an onsite traceability test: "blk1 Schouderham gerookt" 175 g **e** art nr. 301120, production date 15-08-2019, Best before 12-09-2019. . for customer
It was completed within 4 hours. Full traceability and mass balance was achieved including relevant documents.

This trace test of the auditor onsite was combined with a vertical audit trail for the same product. Detailed results were seen including delivery notes, invoice, registration of monitoring of process (including CCP), batch reports and cleaning checks, raw and packaging specifications, finished product specification, recipe, declarations, transport, rework and mass balance. All raw materials and required records were available.

3.10 Complaint handling

The procedure for complaint handling defines types of complaints and addresses requirements in terms of incident reporting as these are escalated to relevant personnel for action (corrective / preventive) and review as appropriate. Complaints can come from internal or customers and also complaints on suppliers are analysed. All complaints are trended, weekly reviewed by the site management team and monthly reported.

The reduction of complaints and complaint costs is a topical subject and part of the X-matrix/KPI.
KPI for customers complaints is 0,7% (was 0,8% till 2018) on total order rows.
Overview of customer complaints Q3 2018 to Q3 2019 shows total of 90 complaints from customers with majority on packaging. Complaint level is slightly increasing (0,8% now, mainly caused by more stringent recording).
Some complaints (18) on foreign body but no food safety issues.
Trend shows incidents but no structural complaints.
Good route cause analysis and corrective actions where demonstrable for all complaints.

No complaints from the authorities.

3.11 Management of incidents, product withdrawal and product recall

There is a company's crisis and recall management procedure "procedure Crisis management" 03-05-2019 which covers the process which is applicable for all VION sites. The procedure for non-conforming product defines 'incidents' and addresses requirements in terms of incident reporting as these are escalated to relevant personnel for review and action as appropriate. Business continuity guaranteed by

central procedures and emergency coordination protocol. The recall procedure is tested yearly (combined with a traceability test). Last test 27-09-2019 was about a fictional compliant about glass in pork belly. The recall report showed good control.

There were no recalls or withdrawals since last audit.

4. Site standards

4.1 External standards

This location has been suitable maintained and well equipped; makes in general a logical and safe way of processing possible; e.g. intake, storage, processing (raw material preparation, mixing, packing), storage and dispatch. The factory is situated in an industrial area, well maintained external areas.

No local activities that would risk product contamination could be recognized. External areas to production/ office buildings are well maintained. A paved surface is built around the building.

4.2 Site security and food defence

The company is registered by NVWA (Dutch food Authority).
The site is part of the VION Slaughter house plant and together they use approval EG61 NL.

Site boundaries well defined and 24-hour security in place with security card for employees on all potential entry points to the plant. Encebe has its own tag system. The site is fully fenced in and has camera surveillance. Visitors and contractors need to sign in and are registered.

There is a Food Defence Risk assessment dated 03-10-2019 (which is evaluated each year in the management review). Control measures are described in the Food Defence Procedure 03-10-2019.
Is assessed and well controlled.

4.3 Layout, product flow and segregation

The processing and packaging parts of the production are in general well designed to prevent contamination risk. Based upon a risk assessment there are 2 zones decided "low risk" and "high care" (BRC 8 "production zone decision tree 1 – chilled and frozen products" was used "No" for step 5 leads to high care for several departments).

Premises allow sufficient working space and capacity to work in a proper way.

Flows are decisioned to minimized product contamination.
Critical flows like waste, chemicals or allergens are separated were possible or control measures have been implemented to prevent contamination. Transfer points have been considered as part of the HACCP study and do not represent a potential threat to product safety.

Site lay outs is good, the paper versions are seen, including water and drain plan.

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 process. Walls, ceilings and floors were mostly suitable. No direct product contamination seen.
The inside of the building is from bricks (covered with coating) and/or isolated coated metal panels etc.
Floors are of coated concrete.
There are separated rooms for storage, processing and packing activities.

However, 1 Minor NC towards building condition.

4.5 Utilities - water, ice, air and other gases

The water used for cleaning and process is mains water
Utilities constructed, maintained and monitored (several times a year) to a good degree.
A map of the water distribution system is present.
Quality of water is monitored in an adequate way and is included in the microbiological monitoring program (performed by accredited
(seen COA 04-03-2019 & 19-03-2019 E Coli / Entero coccus 0 cfu/ml).

Also, the ice is included in this program (P-NCB-NL-10080).
(seen COA 05-03-2019 Entero's <100 cfu/ml

The air in high care area's is controlled by regular filter inspections, over pressure (>10 pa), washing of air socks and checks (air sampling) on micro biological quality of the air.

Gasses used on site in contact with food or packaging are bought from approved suppliers and certified as being food safe (seen specifications Map gasses CO2 21-02-2018 & N2 14-08-2019).

Compressed air is used for equipment and to clean, in 2019 new filters (spec. seen) were installed.
Oil used in the system is food approved (seen specification 24-05-2005 and DOC alllergen free 21 Dec. 2018).

Steam comes in direct contact with products. The steam is supplied by Vion. One food grade additive is used in the steam (specification oxygen binder).

4.6 Equipment

All equipment was seen as suitably designed and used to minimise potential contamination. The used equipment is suitable for its purpose. No evidence is found during the inspection on contamination of the product. Use of well-known brands of equipment for food applications. New equipment is purchased as required, specified and tested before implementation. Seen Conformity and DOC on food migration 17-05-2018 of new (filling machine).

4.7 Maintenance

Equipment is maintained and on the planned maintenance system. Maintenance is also outsourced to established companies within the food and meat business. Registrations to confirm that the preventive maintenance or preventive controls have been carried out as planned are in place. Seen "maintenance plan 2019 and additional "smeerschema" 2019. Specifications for greases and oils Fuchs ( ) NSF H1 are present.

Hygiene clearance (and over after breakdown) takes place by manual approval by operations, on work records (SSOP lists).

Engineering workshop kept clean and tidy, no contamination risks seen. Lubricants were correctly stored.

External support is hired or base upon maintenance contracts.
Contracts were shown for e.g. metal detectors and the air compressor. A visitor registration is in place.

4.8 Staff facilities
There are suitable changing rooms for staff. The rooms are sited next to production. Separation in work wear and personal clothing/items is arranged. Staff facilities are designed and operated to minimise the risk of contamination. Low care and high care entrance are separate. High-care area, personnel entered area via a specially designated changing facility with arrangements to ensure that protective clothing will not be contaminated before entry to the high care area. Suitable hand washing facilities with suitable warm water, liquid soap, single use towels, taps with hand-free operation and clear advisory sign to prompt hand-washing. Shoe brushers and hand disinfection are implemented for High care area and also low care area. For the High care area dedicated footwear is used. The changing complies with the requirements. Well-designed canteen separated smoking area. Well controlled facilities.
4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas
4.9.1 Chemical control
Control over cleaning chemicals on site was demonstrated. Separate storage facility for cleaning chemicals in place. Authorised access by cleaning company and production department. MSDS available and specifications confirm suitability for use in food processing industries.
4.9.2 Metal control
The HACCP study has determined that metal detection is not necessary as CCP but is a CP. Procedure is described in P-NCB-NL-10211. The metal detectors are checked during production by the quality employee. Procedures are in place in case the metal detector does not detect the test bullet. Metal hazard is controlled by metal checks too (machine / knife intactness) in relation to the hazard analysis. Registration and corrective actions could be demonstrated. A knife handling policy is in place. During the audit the correct working of several metal detectors was checked.
4.9.3 Glass, brittle plastic, ceramics and similar materials
A glass / hard plastic register is in place and records the location and condition of glass / hard plastic. Daily hygiene audits by production department (pre-SSOP and SSOP) include glass / hard plastic. Glass / hard plastic audits regularly carried out by department management (4 x / year). HON (Hygiene Orde Netheid) rounds are executed monthly by QA.
4.9.4 Products packed into glass or other brittle containers
NA, no products packed into glass or other brittle containers
4.9.5 Wood
Wooden pallets are not permitted in production, but clearly used at the end of the packing line; no risks to product as all products are fully packed.
4.9.6 Other physical contaminants
There are metal detectable pens in use at open product areas.

4.10 Foreign body detection and removal equipment
4.10.1 Selection and operation of foreign body detection and removal equipment
A hazard analysis has identified potential foreign body sources. Based on the hazard analysis there are instructions to minimize the risk for foreign bodies. There is extra attention to metal control (brine needles, knives etc.) and further foreign body control (glass, plastic, cardboard and paper). During daily (Pre SSOP) and monthly inspections. Metal detector is installed but as a CP (not a CCP). Limits are related to the technical possibilities for metal detection. With positive test an automatic belt stop system is in place. No historical failed test of detector. Metal detector demonstrated effectively by staff that was well aware of failure process – isolation of stock and retesting. Follow up was given to found metal during hourly foreign body checks at the packing lines, corrective actions were provable.
4.10.2 Filters and sieves
NA, not applied.
4.10.3 Metal detectors and X-ray equipment
Metal detection is a CP (not a CCP). Check on metal detection was demonstrated during the audit. Seen for: Department "Worstmakerij" (0.8 mm Fe, 1.2 mm, non-Fe, and 2.4 mm SS), Department "Industrial" (2.0 mm Fe, 2.5 mm, non-Fe, 3.0 mm SS) Department "slice" (1.2 mm Fe, 2.4 mm non-Fe, and 3.2 mm SS), Metal detection is checked according instructions by qualified operators. Check on metal detection includes reject system. Rejects are recorded and analysed. During the audit the correct working of several metal detectors was checked.
4.10.4 Magnets
NA, not applied.
4.10.5 Optical sorting equipment
NA, not applied.
4.10.6 Container cleanliness – glass jars, cans and other rigid containers
Cans are checked at receipt and before usage.
4.11 Housekeeping and hygiene
Cleaning is done by subcontractor in the evening / at night when production has stopped. Cleaning schedules of are available and cover equipment, plant, buildings and services (with daily / weekly / monthly cleaning frequencies). (Low frequent cleaning schedule (ceilings, walls above 2,5m, evaporators) executed on demand. Seen plan (last update 16-09-2019). Air socks controlled by maintenance department. Validation and verification of the procedures is done. Cleaning procedure provides information concerning responsibilities and method. The effectiveness of the cleaning and disinfection process is followed by daily hygiene audits (pre-SSOP), monthly QA inspections (HON) and swabbing program including swabs on

pathogenic bacteria like Listeria is implemented (with focus on high care). Also checks on residue of cleaning agents are executed.

Cleaning chemicals are from approved supplier and are in line with legislation. They are clearly labelled and locked away when not in use. Chemicals are suitable for food use (seen specifications and MSDS for e.g. foam cleaner 08-11-2018 and disinfectant 26-11-2018).

However, 2 Minor NC's towards the effectivity of the cleaning programme.

4.11.7 Cleaning in place (CIP)

NA, not applied.

4.11.8 Environmental monitoring

An environmental swabbing monitoring programme on Listeria is implemented (seen for 2019). Over the year Listeria swabs are taken on places decided on base of risk. High care areas are sampled each 4 weeks and low care areas 4 times a year. Swabs are analysed by accredited laboratory
In case of finding, corrective actions and resampling are required. Records show good follow up.

Also, agar monitoring on Entero's and TPC are performed every 4 weeks. If score is 3 or 4 than action is required. Some incidents in 2019, all were demonstrable followed up.

The air in the high care areas is also monitored (2 times a year). Seen results 11-12-2018 and 04-09-2019 showing < 100 cfu / m3 (within limits).

4.12 Waste

A set of types of waste are defined. Correct collection and identification were demonstrated. Legal handling of categorised meat is collected by a licensed company or pet food application. Cat 3 is correctly applied, no deviations seen during the audit. Procedure on Cat 3 materiaal is documented P-NCB-NL-10145.

4.13 Management of surplus food and products for animal feed

Cat 3 material is held separately and cooled. Legal handling of categorised meat is collected by a licensed company for pet food application.

4.14 Pest management

Contracted to ; (central) for rodents (rats and mice) and insects (cockroaches and flying insects); frequency of control is 8 x / year; maintenance of EFK is 1 x / year. And assessment on the Pest control system and a Pest risk inventory 1x / year (Frequency of the in-depth pest control survey is risk based and accepted, seen last report 21-12-2018). All documentation is present in the contract map of (digital). Up to date site plans Sept 2018 (are available to show the location of rodent baits, mouse traps, crawling and flying insect control units. Constructional action points are solved. An effective control programme could be shown (seen last service reports 13-08-2019 & 02-10-2019 show good control, no structural problems). Trends over 2019 ytd. show no signs of rodent. On total location Non Tox is used.

In summer 2019 some more, flying insects were found (but within normal expectations for summer period).

4.15 Storage facilities

Internal storage in separated cooling departments, tempering cells and cold stores. Control of temperatures is established including temperature alarm settings. Finished products are transported to a distribution centre nearby (Distrifresh). General handling procedure and temperature control is applicable during storage and loading of raw materials and products. No outside storage applicable.

However, 1 Minor NC towards storage of primary packaging.

4.16 Dispatch and transport

Dispatch and release of products is based upon general handling procedures. Checks are recorded. Temperature control is applicable during storage, loading and transport of the products. Product is loaded in covered bays. All transport and storage is subcontracted following P-NLFOOD-10038. VION Food (central office) is contract owner. The content of the contract complies with the requirements. VION reviews the performance of these transport companies (e.g. Distrifresh BRC S&D exp. 28-05-2020 & IFS Logistics exp 10-03-2020).

5. Product control

5.1 Product design/development

Product- or process development is part of the QMS (MDM). Documented product design and development procedure exists ("Procedure Product ontwikkeling" 13-05-2019).
A development / validation protocol is available. Claims made about Organic status and BLK ("Beter leven keurmerk" (Dutch animal welfare organisation). Procedures and working instructions are available and in practice correct implemented to comply with the claim(s) standard. No remarks.
The Gateway (5 steps) system guarantees that all relevant departments as QA, Production etc. are involved where required in the R&D projects. Assessed: Project "Boterhamworst BLK1 with Listeria inhibitor" art. Nr. 301520. Seen: Finished product specification (15-08-2019), Approvals in Gateway system (e.g. by QA), Best before test reports, Process instructions, Packing instructions and Final agreement by customer in SIM portal.

Allergen policy is part of the product development process and changes are discussed in the HACCP team.

5.2 Product labelling

The product labels are defined by R&D in cooperation with Vion group and private label owners where applicable. The EU 1169 has been implemented.

5.3 Management of allergens

A general production method for handling specific materials like allergens is applied. Risk assessment of allergen cross contamination has been considered for products under the scope. Identification and segregation preventive measures in place. Proper precautions of segregation are mostly taken to prevent cross contamination. Allergen containing ingredients are listed: mustard, gluten, milk, soya and sulphite. A

list has been made in which slicing sequence is normally defined. Additional cleaning required between certain slicing steps. Rework is in accordance with the rework procedure and ensures traceability.

5.4 Product authenticity, claims and chain of custody

Logo's and claims applicable about Organic status and BLK ("Beter leven keurmerk" (Dutch animal welfare organisation). Identity preservation is applicable, e.g. for organic products "SKAL" as demonstrated during the visit. Measures to ensure identity of organic products are in place, e.g. green identification labelling. Organisation adapted also the chain of custody principals and is approved for "Beter leven keurmerk".
The documented vulnerability assessment is made in conjunction with VION HQ as showed during supplier evaluation. P-NLFood-10211.

In 2018 a central Vion procedure "Product voedsel Fraude" (latest version 05-08-2019) for Food Fraud has been set up (including planning for yearly review). An assessment for Encebe according to Vion procedure has been performed "Gevaren analyse Food Fraude voor grondstoffen en groepen" 05-08-2019. Evalution parameters are e.g. RASSF, Potential for fraud (dilution, replacement etc.), Chance to find/discover, Possible appearance on Vion's purchase market. No high-risk ingredients and meat where found. Besides Organic and BLK certification (and control measures), further no special control measures are identified.

5.5 Product packaging

Primary packaging materials are appropriate for the intended use and stored under conditions to minimise the risk of contamination and deterioration. Packaging is segregated from raw materials and finished products. Return of packaging materials towards storage area does not take place. Coloured in liners are applied depending on the content. Casings to produce sausage is also seen as primary packaging. Specifications of primary packaging were assessed in vertical and show suitability for food.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

A sample scheme is set up as part of a microbiological monitoring program for product testing at production date and at end of shelf life conforms to Regulation 2073/2005/EC (Listeria, Salmonella)
The frequency of monitoring and type of micro-organisms depends on the risk and the product group.
Analyses are on Listeria, Salmonella, Stec, Entero's, Campylobacter, TPC.
Pasteurized and packed products: every 4 weeks 3 microbiological analyses;
Pasteurized and sliced products: 1 x / week 5 microbiological analyses;
Fermented products: 1 x / week 5 microbiological analyses.
All microbiological analyses are contracted to ISO 17025 accredited laboratory

Results of TPC and pathogens are analysed and reported on a monthly basis (periodical report).
Trend graphs are applied.

Seen several COA's microbiological analyses (incl. pathogens; Listeria, Salmonell, Stec) on products; "Bio Acterham" 17-01-2019, "Gordon Blue ham" 08-03-2019 & "Paling worst" 01-04-2019 & "Snijworst" 31-01-2019. All results were within limits.

Raw materials are checked visually and on temperature at receipt.
Meat is analysed if new or new supplier (seen COA beef poulet 18-01-2019 on Listeria and Salmonella, both absent). Chicken meat is regularly analysed (seen COA
chicken breast 18-01-2019 on Listeria and Salmonella, both absent)

Product (organoleptic) test is conducted after each production batch and testing on pH, Aw is in place.

There is a swabbing program on Listeria. See clause 4.11.8

5.6.2 Laboratory testing

All analyses are subcontracted to an accredited laboratory operating in accordance with ISO 17025:

5.7 Product release

Finished product is fit for delivery unless it is in blockade. Only authorised personnel are allowed to release products. Product release is done by the QA Manager or General Manager.

5.8 Pet Food

Na, no pet food

6. Process control

6.1 Control of operations

The site demonstrated a good control of operations. Process conditions and methods are well looked at and revalidated. Systematic monitoring is demonstrated. During production the correct application of CCP's is monitored and verified on a day to day basis. 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 starts up checks are applied. All CCP check's where demonstrated during the audit. Essential equipment for CCP control and the weighing devices were calibrated. A product change (2 different types of "rook worst") was assessed at the industrial department. Line clearance was followed according to instruction.

6.2 Labelling and pack control

During the production only the label involved is present on the line. Consumer label is added during slicing and clear instructions and registrations are demonstrated to comply. Procedure on rework is described in P-NCB-NL-10041. A product change (2 different types of "rook worst") was assessed at the industrial department. Line clearance was followed according to instruction.

6.3 Quantity, weight, volume and number control

Products are sold by weight and in slicing sold by e-weight. Permit available and good system shown for Check weigher line (report 14-08-2019). Metrology controls the balances for commercial purpose. The devices are tested internally on a daily basis. No issues identified. Calibration of the scales is demonstrable using standard weights. Records were available.

6.4 Calibration and control of measuring and monitoring devices

Calibration procedures ensure relevant equipment is identified and regularly calibrated. Critical measuring equipment are thermometers (CCP related) and weighing scales. Calibration with 2-monthly frequency

(thermometers CCP), 6-monthly frequency (other thermometers) or yearly frequency (balances, PT 100 probes) is adequate according to the calibration records. No adjustments are possible.
Calibration planning 2019 including results of CCP thermometers, Metal detectors, Weighing scales, / (O2 / CO2 measuring), pH meter, temperature and pressure sensors etc. Seen several calibration reports, all according to planning and results within limits.

7. Personnel

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

There is available a procedure on training education P-NCB-NL-10127 dd 03-10-2018. There is evidence of induction training for new starters, temporary workers and contractors. The training (incl exam) is arranged by special trainers of Vion Slaughterhouse (special attention is given to specific Encebe requirements and rules). All employees have to sign for hygiene rules and medical screening is required. Seen several employee files (medical attest and signed rules) as well for new as temporary personal. Seen signed rules, health statements and exam scores for several employees.

A general HACCP refresh training (incl. allergen and food defense) is given each year by QA.
Seen attendance lists 2019.

There is a skill matrix available in xlsx (with 1 to 5 level of experience) and a training/education plan.xlsx which include all personnel with their skills and training requirements.
All individual training is registered on F-NCB-NL-10238.
Seen records on e.g. CCP training on 01-05-2019, 27-09-2019, 26-09-2019 (for several CCP's and operators).

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 prior to commencing work. These hygiene rules are effectively enforced. Well detailed hygiene rules are documented and signed by employees. Checked for temporary workers as well own employees. Smoking (incl. electronical cigarettes) is only allowed at a separate room at the canteen. Hand cleaning & disinfection of hand and shoes is provided at (both) the entrance of the high-care production and as well at the entrance of the Low care. Medicine use is set at the hygiene rules. Only metal detectable plasters are allowed in production areas. Registration off issue and intake are implemented.

7.3 Medical screening

The medical screening is part of the intake of new employees and part of the instructions to visitors. The site makes all visitors, new starters and contractors aware of the need to report infectious disease via the hygiene protocol. Health questionnaire is applicable for all visitors and contractors. Persons who are suffering from a relevant infectious disease are not allowed to enter the production facilities. Medicine use is set at the hygiene rules.

7.4 Protective clothing: employees or visitors to production areas

Company issued protective clothing (inclusive work shoes) is given to all staff and visitors.
Protective clothing includes hairnets, gloves, trousers, jackets and rubber boots / shoes.
Balaclava hairnets with surgical masks and dedicated shoes are applied in high care areas.
Good adherence to the dress code observed during the site evaluation. No top coat during breaks (eating, drinking and / or smoking). Clean and dirty clothes stored separately. Sufficient amounts are available at all times. Employees can change daily.

The external laundry complies with the requirements of the Global Standard for Food Safety. Cleaning of work wear checked by means of agar.

8. High Risk, High Care and Ambient High Care Production Risk Zones

8.1 Layout product flow and segregation in high risk, high care and ambient high care zones

Based upon a risk assessment there are 2 zones decided "low risk" and "high care" (BRC 8 "production zone decision tree 1 – chilled and frozen products" was used) "No" for step 5 leads to high care for the process after cooking and fermenting till packing. So these departments have been defined as high care.

All high care departments are connected as 1 zone and segregated from low care areas.
There is 1 hygiene corridor for personnel (swing over bench), and there are 3 for materials/packaging/waste and 1 for final products.

Flows are decisioned to minimized product contamination.
Critical flows like waste and packaging are separated were possible or control measures have been implemented to prevent contamination. Transfer points have been considered as part of the HACCP study and control measures are implemented to minimize contamination risk.

The zoning is mapped well.

However, 1 Minor NC towards control of contamination

8.2 Building fabric in high risk and high care zones

Water and drain plans are present. Drains for High care and Low care areas have no direct connections.

The air in high care area's is controlled by regular filter inspections, over pressure (>10 pa), washing of air socks and checks (air sampling) on micro biological quality of the air (<100 cfu/m3).

The inside of the high care is well maintained, Walls are from bricks (covered with coating) and/or isolated coated metal panels etc. Floors are of coated concrete. Equipment is made of ss.
There are separated rooms for storage, processing and packing activities.

However, 1 Minor NC towards risk assessment on air contamination

8.3 Maintenance in high risk and high care zones

Maintenance is done after production normally. If really needed, TD has to enter the high care also via the hygiene corridor. There are dedicated tools for high care areas. Clearance procedures (after maintenance) are implemented, registrations are on SSOP checklists.

8.4 Staff facilities for high risk and high care zones

There is 1 hygiene corridor for personnel (swing over bench, taking a white jacket and trousers, shoe change, boot washer, hand washing and disinfection unit).

3.6 Housekeeping and hygiene in the high risk high care zones
Cleaning of high care areas is done by subcontractor in the evening / at night when production has stopped. Cleaning schedules of are available and cover all high care areas, equipment and tools (with daily / weekly / monthly cleaning frequencies). Washing of air socks in high care is controlled by maintenance department. A system to verify the effectiveness for cleaning and/or disinfection is designed and implemented by agar monitoring and a Listeria swabbing programme. Corrective actions to the cleaning process, are registered and verified (Pre SSOP and SSOP checklists).
3.6 Waste/Waste disposal in high risk, high care zones
Waste is collected in labelled crates.
3.7 Protective clothing in the high risk high care zones
Special dedicated high care protective clothing (with high care label) and work shoes are given to high care staff and visitors. Protective clothing includes Balaclava hairnets with surgical masks, gloves, trousers, jackets and rubber boots / shoes. Good adherence to the dress code observed during the site evaluation. No dedicated high care clothing is allowed outside the high care zone. Clean and dirty clothes are stored separately. Sufficient amounts are available at all times. Other employees do wear clothes without high care label. Work wear is cleaned external by a professional organisation, **However, 1 Minor NC towards high care maintenance clothing.**

Details of non-applicable clauses with justification	
Clause/section reference	Justification
3.5.4	No primary product processes are outsourced.
4.9.4	No products packed in glass
4.10.2	No sieves

4.10.4	No magnets in the processes
4.10.5	No optical sorting equipment
4.11.7	No CIP
5.8	No Pet food

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

Module 11: Meat supply chain assurance	
Scope	
11.1 Traceability	

11.2 Approval of meat supply chain
11.3 Raw material receipt and inspection
11.4 Management of cross-contamination between species
11.5 Product testing
11.6 Training

Module 12: AOECS Gluten-free Foods

Scope	
12.1 Senior management	
12.2 Management of suppliers of raw materials and packaging	
12.3 Outsourced production	
12.4 Specifications	
12.5 Management of gluten cross-contamination	
12.6 Management of incidents, product withdrawal and product recall	
12.7 Labelling	

12.8 Product inspection and laboratory testing

Module 18 FSMA Preventive Controls Preparedness Module Version 2 July 2018				
Item no.	Clause	Module item	Conforms (Y/N) or Not Applicable (NA)	Comments
1	13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
2	13.1.2	Water distribution system must prevent backflow from, or cross-		

		connection between, piping systems that discharge waste water or sewage.		
3	13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
4	13.1.4	*Ice used in contact with food must* be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
5	13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. *Defect levels rendering the food* adulterated may not be reduced by mixing the food with another lot.		
6	13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		

7	13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).		
8	13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
9	13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		
10	13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.		
11	13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRC sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected		

		as a part of verification activities (i.e., product testing and/or environmental monitoring).		
12	13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.		
13	13.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
14	13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
15	13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following:		

		• Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
16	13.1.16	Devices used to verify preventive controls must be calibrated.		
17	13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
18	13.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
19	13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.		
20	13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the		

		food safety plan, which must remain onsite.		
21	13.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
22	13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		
23	13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.		
24	13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.		

		* Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
25	13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.		
26	13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant vulnerabilities and actionable process steps • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
27	13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum):		

		• Scale and severity of threat if a contaminant is added to product • Degree of physical access to the product • Ability of an attacker to successfully contaminate product—including consideration of an inside attacker A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.		
28	13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.		
29	13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.		
30	13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence		

		• Recordkeeping requirements for corrective actions		
31	13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation strategies. Verification procedures shall include: • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities		
32	13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence		

33	13.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
34	13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.		
35	13.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.		
36	13.4.1	Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used. A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.		
37	13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their		

		responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.		
38	13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.		
39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.		
40	13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.		
41	13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment		

		• Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper		
42	13.4.7	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems • Responsibilities of the carrier		
43	13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.		
44	13.4.9	The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.		
45	13.5.1	Personnel (permanent and temporary) who handle produce or		

		food contact surfaces must receive additional training on the following: • Principles of food hygiene and food safety Produce safety standards applicable to an individual's job		
46	13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment		
47	13.5.3	One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.		
48	13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.		
49	13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.		
50	13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected		

		and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.		
51	13.5.7	Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.		
52	13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.		
53	13.5.9	Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria. Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.		
54	13.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis		

		for water testing is U.S. Environmental Protection Agency (EPA), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007," December, 2009 or equivalent method.		
55	13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.		
56	13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.		
57	13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.		
58	13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.		
59	13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.		

60	13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
61	13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts. Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria: • Target test (i.e., Listeria spp. or L. mono) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) The plan shall describe aseptic methods for sample collection and testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent).		
62	13.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts.		

		The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono. If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process: • Resample positive surfaces and the surrounding area to determine the extent of contamination • Clean and sanitize the affected and surrounding areas • Resample and re-test to confirm the elimination of Listeria spp. or L. mono • Conduct finished product testing as appropriate • Take additional action to prevent recurrence and to prevent adulterated food from entering commerce		