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**Audit Report**

**Global Standard for Food Safety Issue 7: July 2015**

1. Audit Summary			
Company name	Vion Food Group	BRC 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	2017-11-14		
Re-audit due date	2018-12-17		

Voluntary modules included		
Modules	Result	Details
Choose a module	Choose an item	
Choose a module	Choose an item	
Choose a module	Choose an item	

2. Audit Results			
Audit result	<b>Certificated</b>	Audit grade	<b>A</b>
Audit type	<b>Announced</b>		
Previous audit grade	<b>B</b>	Previous audit date	<b>2016-11-23</b>
Number of non-conformities	Fundamental	<b>0</b>	
	Critical	<b>0</b>	
	Major	<b>0</b>	
	Minor	<b>8</b>	



### 3 Company Details

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

### 4 Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	51-500	No. of HACCP plans	1-3
Subcontracted processes	No				
Other certificates held	ISO9001, CoC/CBL, Organic, BeterLeven 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 Furthermore the sales activity is moved from VION HQ to Encebe BV so the company has its own responsibility (back) in sales and NPD activities.	Management of the organisation has changed: new general manager, new QA manger, new production leader all in MT. Further new QA officer. Since last audit an investment plan is made and improvement activities are carried out. Over 2017 and 2018 appr €1,4 million will be invested in new floors, ceilings, walls and new smoking/cooking equipment including software application. Floors in the tumbling department an ceiling in the salting department are already improved.				



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 in a one shift operation (excepting smoking department: 2 shifts). Only a small part of them (+/- ) is working at a temporary base. 1 HACCP study is available and site is appr. 8.000 m2 (part of facility VION Boxtel).

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 'Beter Leven Kenmerk', CoC of CBL and ISO 9001 as part of a multi site ISO system.

Main selling market is the industrial market and a minor part at the 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. Since the previous audit no major changes in processing, equipment, routing and assortment have been occurred but several improvements on floors, ceilings and walls are observed.

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	03 - Raw prepared products (meat and vegetarian) 08 - Cooked meat/fish products 09 - Raw cured or fermented meat and fish Category 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 heat treatment and another preserving method; eg acetate, diacetate.				



Allergens handled on site	<b>Soya</b> <b>Milk</b> <b>Celery</b> <b>Mustard</b> <b>Cereals containing gluten</b> <b>Sulphur dioxide and Sulphites</b> 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	<b>Organic, BLK, CoC</b>
Product recalls in last 12 Months	<b>Yes</b>
Products in production at the time of the audit	<b>Slice: ontbijtspek. Smoke: rookworst. Salting: belly. Worstmakerij: Berliner and Leverkaas</b>

6. Audit Duration Details			
On-site duration	<b>16 man hours</b>	Duration of production facility inspection	<b>7 man hours</b>
Reasons for deviation from typical or expected audit duration	<b>18 hours is to be expected but due to good results in the past and a mature system including HQ support, it was reduced to 16 hours</b>		
Next audit type selected	<b>Announced</b>		

Audit Duration per day			
Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
<b>1 (start date)</b>	<b>2017-11-13</b>	<b>09.00</b>	<b>17.30</b>
<b>2</b>	<b>2017-11-14</b>	<b>08.30</b>	<b>17.00</b>

Auditor (s) number(s)	Names and roles of others
Auditor Number	
Second Auditor Number <b>N/A</b>	



Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.9)				
Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
/ General Manager	X		X	X
/ QA Manager	X	X	X	X
Assistant /Quality Assurance	X		X	X
Manager /Production	X	X		X
/HR Manager	X		X	X
/Foreman E2 (High Care)		X		
/Employee smoking department E2		X		
/Employee storage dispatch E2		X		
Assistant Foreman Industrial E2		X		
/Assistant Foreman Slicing E2		X		
/Employee Slicing E2		X		
/Assistant Foreman Storage dispatch E2		X		
/ Sourcing Manager Ingredients			X	
/ Department Manager E1		X		
Assistant Foreman incoming goods		X		
/ Assistant Forewoman Cutting dep.		X		
/Assistant Foreman Casing dep.		X		
/Assistant Foreman Salting dep.		X		
/Maintenance worker		X		
/Employee planning			X	
NPD/Specs /Employee			X	



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Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements			
No.	Clause	Details of non-conformity	Critical or Major?

Critical		Anticipated re-audit date	
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



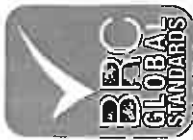
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No.	Clause	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Date reviewed	Reviewed by
1	2.7.3	Control measure to prevent pathogen growth is time in climate cell 103 which is verified on F-NCB_NL-10066. The circumstances in the cell are monitored but not verified so correct drying conditions are not demonstrated. <b>FULLY CLOSED</b>	The temperature and relative humidity are verified and registered twice a day.	Verification activities are already in place.	Seen Attachment 1, dagelijkse controle klima's	2017-12-08	
2	4.3.1	The map to show the designated areas where product is at different level of risk from contamination is made (P-NCB-NL-10002) but some enclosed product areas are designated as high care area (eg storage of ingredients in carton boxes) and some areas were product is sliced (ready to eat and heated above 72°C for eg cooked ham "Achterham") are not defined as high risk. Prerequisite program fits to the chosen area (high care) but not to the level of risk from contamination. <b>CLOSED TO BE VERIFIED</b>	We are already working on a masterplan to reduce the high care area to only that area's that high care is needed. Plans are under construction and needs to be approved on by the board of Vion central. Therefor we cannot give timings yet. First presentation of the masterplan by (general manager Encebe) to Vion Pork (our division) is on 7-12.	RCA: current way of working was always approved in previous audits. PAP: the masterplan is under construction, expected to be finalized Q1 2018. Then it will be presented to the board of Vion central for final approval. Considering the amount of the investment it might take several years to implement the whole masterplan.	Seen Attachment 2, concept drawing of new zones.	2017-12-08	



3	<p>4.11.2</p> <p>The cleaning procedure includes all equipment but the method and materials of cleaning done by own employees instead of external cleaners is not specified. Some equipment is cleaned by VION but method, frequency and materials and monitoring is not demonstrated. (Eg of the clipper in the production department is no planned cleaning program available)</p> <p><b>CLOSED TO BE VERIFIED</b></p>	<p>Internal cleaning is performed and already daily monitored using pre-sop checks. A new cleaning schedule will be made, inventory/concept is now ready and need to be discussed with the production staff and further need to be complimented.</p>	<p>RCA: In the past, materials and methods of internal cleaning were excluded from procedures as these were susceptible to change. Also most of the information is spread over several documents. PAP: Including materials and methods to new cleaning schedule and implement this within the production plant. Implementation, in use: 2-1-2018.</p>	<p>Seen: Attachment 3.1: 2 pre-sop forms, one with remark and one without. Attachment 3.2: concept opzet eigen schoonmaakplan</p>	2017-12-08	
4	<p>4.11.2</p> <p>The cratwasher does not function correctly as the cans for "leverkaas" were dirty after washing. The cleaning machine has no monitoring on temperature and no control on stopping if temperature is too low.</p> <p><b>FULLY CLOSED</b></p>	<p>An alarm on the temperature is installed by our own TD and a new alarm on the dosing of the cleaning agent will be installed in week 50/51.</p>	<p>RCA: if cleaning was insufficient, this was not reported but fixed by cleaning the cans again. Therefore, no root cause was determined before. PAP: currently, the Vion Operating System (continuous improvement) is being implemented, to change the mindset that problems should not be quick-fixed but submitted for root cause analysis. A "A3 verbeterplan" was used and several actions were taken (inspection, cleaning, alarm).</p>	<p>Seen: Attachment 4.1: A3 verbeterplan krattenwasser. Attachment 4.2: pictures TD Attachment 4.3: Mail CID-lines alarm</p>	2017-12-08	
5	<p>4.11.2</p> <p>Lorries to transport meat in are cleaned but after cleaning residual</p>	<p>We have altered the temperate to 62°C, now there is already</p>	<p>RCA: our maintenance department had done work on</p>	<p>Seen: Attachment 5.1: picture</p>	2017-12-08	





6	<p>water stays in. It is not demonstrated that this water is no risk to the product.</p> <p><b>CLOSED TO BE VERIFIED</b></p>	<p>less water in de lorries but on temperature we are bound by the machine and the cleaning agent.</p>	<p>the washing machine to reduce the water, this was not sufficient.</p> <p>PAP: Because we can't do more on the temperature in week 52/01 the builder of the washing machine will be here to see what actions they can take regarding the machine. Plan/idea is to tip de lorries more over in the machine.</p>	<p>whiteboard Attachment 5.2: mail TD confirmation appointment</p>	
4.15.1	<p>In P-NCB-NL-10230 temperature settings per cell are displayed but the critical limits are for the freezing cell set to -10 and -11. It is not demonstrated what delay times are chosen. Correct monitoring not demonstrated.</p> <p><b>FULLY CLOSED</b></p>	<p>The critical limits have been adjusted.</p>	<p>RCA: The settings where so agreed on by former quality personal.</p> <p>PAP: The limits are implemented and the alarms are set.</p>	<p>Seen: Attachment 6.1: "Wijzigingsformulieren" change of settings Attachment 6.2: Pictures of the settings on the display of the TBS-system</p>	2017-12-12
7	<p>For allergen management a table is made with risk factors. The chosen risk factors are set and cleaning is to be executed in between. The cleaning is the rinsing with warm water after production of Berliner at cutter 1 in the production. Not demonstrable is whether this cleaning step is sufficient to prevent cross contamination of the allergen lactose.</p>	<p>As planned, the cleaning procedures are being validated using allergen swabs.</p> <p>Sulfite is only present in premixes (EG potatostarch). In finished product the concentration is too low to declare. At this moment, we do not produce products with soy or celery, these recipes are</p>	<p>RCA: it was estimated that intermediate cleaning would be sufficient.</p> <p>PAP: Validation of intermediate cleaning using allergen swabs.</p>	<p>Seen: Attachment 7.1: invoice swabs  Attachment 7.2: Action plan and first three results of the swabs after rinsing of production with lactose.</p>	2017-12-12



8	5.3.4	<p>Ingredients containing allergens were temporary stored in an area where storage of allergens not is allowed in storage cell 10.</p> <p><b>FULLY CLOSED</b></p>	<p>currently on hold, are not produced. if we would produce them it would not be in the cutting department but in the salting department.</p> <p>Pallet has been moved to the correct location</p>	<p>RCA: the employee thought that this was allowed because bags were closed and it was only temporary when he was reorganizing the shelf.</p> <p>PAP: The employee has been direct addressed and later on trained extra on this subject</p>	<p>Seen: Attachment 8: trainingsformulier dd 6-12-2017.</p>	2017-12-08	
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Comments on non-conformities



Voluntary Modules Non-Conformity Summary Sheet

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

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



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FSMA Module Non-Conformity Summary Sheet

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

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



## Detailed Audit Report

### 1. Senior management commitment

#### 1.1 Senior management commitment and continual improvement

The signed Management Review (Q3/2016 - Q2/2017) 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; IFS certification; new planning method Encebe 1; increase discipline and awareness on hygiene; realisation of OEE and several others.

The management team of Encebe comprises 6 persons of which 4 are in position less than a year. The team managed to realise several investment budgets on improvements (on floors, ceilings and smoking and cooking cabinets) and the team has a task in reviving the company to increase added value in the meat chain.

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.

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 Q2 2017 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 Overlegstructure P-NCP-NL-10006) is conducted by:

- White board communication (Hurdle Tier boards); concerning quality issues (VOS version 2)
- MT-meeting once per week;
- PPD-meeting & HACCP team meetings once per 4 weeks;
- Employees meeting once per year;

The General Manager attended the opening and closing meeting of the audit and intensions were discussed during the opening meeting with the General Manager |

Root causes of the 1 major and 6 minor non-conformities of the latest BRC audit have been identified. The NC's did not reoccur. Also, the recall in the Q1-2017 is discussed as is was reported to LRQA and a report available on closure (dd 10-7-2017).

#### 1.2 Organisational structure, responsibilities and management authority

The organisational structure is part of P-NCB-NL-10001 v21 dd 30-10-2017. The production departments directly report to the production-manager. The production manager is member of the MT. The QA manager (also MT member) informs the general 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.



**Details of non-applicable clauses with justification**

Clause reference	Justification
na	

**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 (P-NCB-NL-10027 v32 dd 30-10-2017) was developed by a multi-disciplinary HACCP team, namely General Manager, QA Manager, Quality Assurance Assistant, Production Manager and team leader. All team members show enough and the right experience and knowledge.

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.

Flow diagrams are prepared and available in \_\_\_\_\_ all process steps were present. Verification is done yearly in Q2-2017 as part of the management review. A good detailed lay out (P-NCB-NL-10002 v4) 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 (P-NCB-NL-10027) v32 dd 30-10-2017
- Summary Allergens and CCP's (P-NCB-NL-10223 v4 dd 22-9-2017)

CCP' s which are determined, including critical limits, according to P-NCB-NL-10027 dd 13-01-2015:

- 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 and 84 hours)
- CCP 7. Temperature control of heat treated meat products pasteurization (P70>3 minutes)
- CCP 9. Temperature control of chicken meat at reception (≤4°C)  
(CCP 8 does not exist anymore)

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. During the assessment last year (a major on CCP determination and after the recall in Q1 a reassessment was done and resulted in the determination of the above 8 CCP's. 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.

Minor 1: Control measure to prevent pathogen growth is time in climate cell 103 which is verified on F-NCB\_NL-10066. The circumstances in the cell are monitored but not verified so correct drying conditions are not demonstrated.

**Details of non-applicable clauses with justification**

Clause reference	Justification
na	

**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 F7, 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 ' ' is in place and available to departmental managers.

**3.2 Documentation 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. 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. All documents are kept for at least BBD + 12 months. Longest shelf-life is 15 months (sterilized products). All electronic data (eg cooking and cooling times and temperatures, temperatures in cells) are secured by daily back-ups.

### 3.4 Internal audit

There are detailed schedules of internal audit against documented procedures, carried out by trained independent staff (from the VION company). All departments are included in the plan. The audit is done twice a year. One unannounced and one 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. Corrective action have been taken in a timely manner. Assessed: Announced audit report .

In addition, hygiene audits and site / building inspections are performed at weekly intervals to respond to the KPI of increasing discipline and awareness on hygiene. This interval is more frequent (it was monthly) and because of positive result will be continued.

### 3.5 Supplier and raw material approval and performance monitoring

#### 3.5.1 Management of suppliers of raw materials and packaging

Purchasing and supplier approval is 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 includes 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. Suppliers performances are 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 and microbiological performance (meat 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 P-100197 Process Purchase Non Food, P-Food-10026 and S-MMI-10548 v4 including questionnaires and specifications. Also, F-Food-10001 V6 16-4-14 is complete. Seen for supplier supplying garlic mash specification dd 28-9-2017. In P-Food-10048 v1 30-6-2016 includes retrieval times of relevant information as questionnaires and specifications. Seen for several ingredients/products in the trace test the acceptance document in F-NLFOOD-10037 Article Entrance: 25HK505500 Flavour bouillon WM-872-505-9 dd 1-4-2015; 25HK991050 nietrietzout 0,9% dd 12-2-2015; 25HK991040 fijn keukenzout dd 12-2-2015; 25HK854010 : 13-11-2015; 25HK623000 Wijncervelaat 13614dd 22-9-2016; 25HK901030 100 23-1-2015.

Risk assessment on Food fraud is done by Vion Central and implemented in the risk assessment of ENCEBE.





### 3.5.2 Raw material and packaging acceptance and monitoring 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 outsourced processing and packing

Na

### 3.6 Specifications

Specifications for raw materials, packaging materials, cleaning agents and finished products are available through Navision 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 taken at this visit demonstrate control, eg:

- End product "Wijncervelaat gerookt ind. 012400 dd 6-7-2017
- Ingredients and additives: see 3.5.1.
- "Vliessnippers" ham 23 dd nov 2016
- Food safety declaration dd 02-05-2013

### 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.

### 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.

### 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 annually but due to the recall which started on 17-3-2017 the test was replaced by a real example. Performed on 17-3-2017 and as concluded during the IFS audit (the



evaluation was missing) ended with an evaluation dd 19-10-2017.  
 Trace test during the audit was on raw material 48163 "Vliessnippers Ham" (delivered at 18-8-2017 1002kg, including packaging) was possible within the records. Information was available within time. Mass balance, for raw material to final product was correct. End specification available (dd 6-3-2017)  
 Raw material specifications , PRE SSOP's and SSOP's, training records on CCP were all available in time.

### 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 setting as there should be a decline with 10% with previous year.

Overview of complaints 2017 ytd: 124 complaints from customers with majority on packaging open/leakage (19). Regarding to food safety, foreign body (plastic and metal) is the major part of the complaints and several complaints on mould and weight.

The Management focuses on reducing all customer complaints and seen is a shift from customer to internal complaints. Actions are taken such as the usage of the huddle system to improve daily communication with employees about quality and safety issues and furthermore projects as the A3 improvement project, reducing the use of blue plastic in production. 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 (P-FOOD-10014) 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 used past year as a fermented product with listeria was found due to shortened fermenting/ripening time caused by commercial pressure. Authorities, CB and customers were informed correctly and an evaluation was written on 19-10-2017 to close out the recall.

### 3.12 Customer focus and communication

Most articles are Private Label articles. This means that products are developed on the basis of customer specifications and products are developed in close consultation with the customer. After testing the customer gets an advice for e.g. BB period and important quality and food safety issues. PD and QA are involved in these processes. Further personnel are instructed were necessary. Were applicable suppliers are contacted.

### Details of non-applicable clauses with justification

Clause reference	Justification
3.5.4	No primary product processes are outsourced.




#### 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; f.e. 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 Security

The site is part of the VION plant and together they use approval EG61 NL. The company is registered by the Food and Consumer Product Safety Authority (official). 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.

##### 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 all zones are "low risk" or "high care". Transfer points have been considered as part of the HACCP study and do not represent a potential threat to product safety. Premises allow sufficient working space and capacity to work in a proper way. There were no temporary constructions.

Minor 2: The map to show the designated areas where product is at different level of risk from contamination is made (P-NCB-NL-10002) but some enclosed product areas are designated as high care area (eg storage of ingredients in carton boxes) and some areas where product is sliced (ready to eat and heated above 72°C for eg cooked ham "Achterham") are not defined as high risk. Prerequisite program fits to the chosen area (high care) but not to the level of risk from contamination.

##### 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 'high-care' area does contain several departments of which only two departments are equipped with a positive air pressure ventilation system. Recently an investment plan was made and several ceilings and floors were improved e.g. in tumbling area.

##### 4.5 Utilities – water, ice, air and other gases

Utilities constructed, maintained and monitored to a good degree.  
The water used for cleaning and process is mains water ( ) . Quality of water is monitored in



an adequate way and is included in the microbiological monitoring program. Also the ice is included in this program (P-NCB-NL-10080) as in an internal audit was found that it was not included.

The air is controlled by regular filter inspections (airbags in place). and All gases used on site in contact with food or packaging are bought from approved suppliers and certified as being food safe.

Compressed air is used for equipment and to clean, filter changes done by service supplier Seen  
proof of latest filter change 4-11-2017. Oil used in the system is food approved (seen specification 2-5-2013).

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 and specified.

#### 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 "Smeerschema P12-2017". Specifications:

#### 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. Staff facilities are suitable for the operation both changing on high care as on low risk. 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.

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. The changing complies with the requirements. Well-designed canteen separated smoking area. Well controlled facilities. No external catering.

#### 4.9 Chemical and physical product contamination control

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

In production areas regular foreign body checks are done on products and semi-finished products ("conformiteits controles" seen various records of such checks during the audit).

##### 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.



<b>4.9.2 Metal control</b>
<p>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.</p> <p>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.</p>
<b>4.9.3 Glass, brittle plastic, ceramics and similar materials</b>
<p>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). The frequency of the weekly HON (Hygiene Orde Netheid) rounds are intensified and done by QA together with production as previously they were done only by production.</p>
<b>4.9.4 Products packed into glass or other brittle containers</b>
<p>No products packed into glass or other brittle containers</p>
<b>4.9.5 Wood</b>
<p>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. (But these pallets should not be in high care areas, see minor in 4.3.</p>
<b>4.10 Foreign-body detection and removal equipment</b>
<b>4.10.1 Foreign-body detection and removal equipment</b>
<p>Metal detection in processes.</p>
<b>4.10.2 Filters and sieves</b>
<p>Not applied.</p>
<b>4.10.3 Metal detectors and X-ray equipment</b>
<p>Metal detection in processes.</p>
<b>4.10.4 Magnets</b>
<p>Not applied.</p>
<b>4.10.5 Optical sorting equipment</b>
<p>Not applied.</p>
<b>4.10.6 Container cleanliness – glass jars, cans and other rigid containers</b>
<p>Cans are checked at receipt and before usage.</p>



#### 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. Socks controlled by maintenance department. The effectiveness of the cleaning and disinfection process is followed by hygiene audits (pre-SSOP). Swabs for pathogenic bacteria like Listeria are taken.

Minor 3: The cleaning procedure includes all equipment but the method and materials of cleaning done by own employees instead of external cleaners is not specified. Some equipment is cleaned by Encebe but method, frequency and materials and monitoring is not demonstrated. (Eg of the clipper in the production department is no planned cleaning program available)

Minor 4: The cratewasher does not function correctly as the cans for "leverkaas" were dirty after washing. The cleaning machine has no monitoring on temperature and no control on stopping if temperature is too low.

Minor 5: Lorries to transport meat in are cleaned but after cleaning residual water stays in. It is not demonstrated that this water is no risk to the product.

#### 4.11.7 Cleaning in place (CIP)

Na

#### 4.12 Waste / waste disposal

A set of types of waste are defined. Correct collection and identification was 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 material is described in 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 Control

Contracted (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). All documentation is present in the contract map of (digital). Up to date site plans (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 and on 21-04-2017 EIV tubes are placed. On total location Non Tox is used.

#### 4.15 Storage facilities

Internal storage in separated cooling departments, temperating 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.

Minor 6: In P-NCB-NL-10230 temperature settings per cell are displayed but the critical limits are for the freezing cell set to -10 and -11. It is not demonstrated what delay times are chosen. Correct monitoring not demonstrated.

#### 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 (eg Distrifresh).

#### Details of non-applicable clauses with justification

Clause reference	Justification
4.3.5, 4.8.4	No High Risk area
4.3.7, 4.8.5	No ambient High Care area
4.5.3	No unpotable water used
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. Product control

##### 5.1 Product design/development

Product- or process development is part of the QMS and recently a new gateway procedure is put in place partly copied from the former documented product design and development procedure (P-NCB-NL-



Lloyd's Register  
LRQA

10122). A development / validation protocol is included. Claims made on organic status / non GMO / BLK 1\* / Good Farming Star. Procedures and working instructions are available and in practice correct implemented to comply with the claim(s) standard. No remarks. Seen PPD for 0391 on 334700 which is included in the PPD-actionlist.xlsx.

The Gateway procedure guarantees that all relevant departments as QA, production etc. are involved where required in R&D projects.

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

Seen the checklist "Aankopen nieuwe materialen" as the new curtains, floors and ceilings are also validated.

#### 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, celery, gluten, milk and soya. 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.

Minor 7: For allergen management, a table is made with risk factors. The chosen risk factors are set and cleaning is to be executed in between. The cleaning is the rinsing with warm water after production of Berliner at cutter 1 in the production. Not demonstrable is whether this cleaning step is sufficient to prevent cross contamination of the allergen lactose.

Minor 8: Ingredients containing allergens were temporary stored in an area where storage of allergens not is allowed in storage cell 10.

#### 5.4 Product authenticity, claims and chain of custody

Logo's and claims applicable about organic status / nonGMO / BLK-Good Farming Star. 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 labeling. 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.

#### 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 liners are applied depending on the content. Casings to produce sausage is also seen as primary packaging.





**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. The frequency of monitoring depends on the risk and the product group.

- 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.

Monitoring program (P-Food-10008) is available and used as plan.

Results of TPC and pathogens are analysed and reported on a monthly basis (periodical report). Trend graphs are applied. Raw materials are checked visually and on temperature at receipt. Seen "Trend analyse Microbiologie 2017".

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

**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.

**Details of non-applicable clauses with justification**

Clause reference	Justification

**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 start up checks are applied. All CCP check's were demonstrated during the audit. Essential equipment for CCP control and the weighing devices were calibrated.

#### 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.

#### 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 100gr and 175 gr on 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 2017 including results of thermometers CCP 1/2, metal detectors, scales, pressor meters (for sterilisation), smoking equipment.

#### 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 available a procedure on training education P-NCB-NL-10127 v3 dd 12-10-2017. There is evidence of induction training for new starters, temporary workers and contractors. (Vragenlijst voedselveiligheid en hygiene including exam. Competency training (on food safety and quality) has taken



place for the staff sampled. Training effectiveness is monitored (exam). Checked for several employees if they are trained for their job, working with a CCP and personal hygiene.

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 trainings. On individual training is registered on F-NCB-NL-10238. Seen the CCP training on 2-6-2017 for 7 persons (by QA).

Assessed: Files Temporary worker , OK done on 10-11-2016

**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 (1x) and own employees (3x). Smoking is only allowed at a separate room at the canteen. Hand cleaning is provided at the entrance of the production and special for packing employees at the entrance of the clean room. Medicine use is set at the hygiene rules.

**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 red trousers, jackets and rubber boots / shoes in low risk. Balaclava hairnets with surgical masks are applied in high care, and all hair is enclosed. White clothes and white shoes in high care. 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.

**Details of non-applicable clauses with justification**

Clause reference	Justification



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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	



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





Module 15 FSMA Preventive Controls Preparedness Module				
Item no.	Clause	Module item	Conforms (Y/N)	Comments
1	117.20	Handwashing areas, dressing and locker rooms, and bathrooms must have adequate lighting.		
2	117.37	The water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
3	117.40	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.		
4	117.80	Ice used in contact with food must be manufactured in accordance with the good manufacturing practice (GMP) requirements of 21 CFR § 117.		
5	117.110	Where defect action levels (DALs) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
6	117.130 (a)	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: <ul style="list-style-type: none"> <li>• economic adulterants which affect food safety</li> <li>• 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</li> <li>• radiological hazards</li> <li>• unintentional adulterants that affect food safety.</li> </ul>		
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"> <li>• notifying consignees of how to return or dispose of recalled product</li> <li>• conducting effectiveness checks to verify recall is carried out</li> <li>• appropriate disposal of recalled product (i.e., destroy, divert, repurpose).</li> </ul>		
10	117.145	Establish monitoring activities and a written procedure for each preventive control in a manner consistent with the requirements of BRC section 2.10.		
11	117.150	Establish corrective action procedures when preventive controls are not implemented in a manner consistent with the requirements of BRC sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).		
12	117.160	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring revalidation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.		
13	117.165 (a)	The PCQI (or authorized designee) reviews the monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or their authorized designee) reviews the verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record has been		



		created.		
14	117.165 (b)	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: <ul style="list-style-type: none"> <li>• sampling procedure to include method, quantity, frequency, and number of samples</li> <li>• analytical method</li> <li>• laboratory conducting an analysis</li> <li>• corrective action procedure where a pathogen is detected.</li> </ul>		
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"> <li>• adequate number and location of sample sites</li> <li>• timing and frequency of sampling</li> <li>• analytical method</li> <li>• laboratory conducting the analysis</li> <li>• corrective action procedure where a pathogen is detected.</li> </ul>		
16	117.165	Devices used to verify preventive controls must be calibrated.		
17	117.180	Identify a PCQI responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training or qualifications via job experience.		
18	117.305	All records required by 21 CFR § 117 must include: <ul style="list-style-type: none"> <li>• the date and time of the activity being documented</li> <li>• signature/initials of individual performing the activity or conducting the record review</li> <li>• information to identify the facility (e.g., name and location)</li> <li>• the identity of the product and lot code where applicable.</li> </ul>		
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 <b>before</b> receiving and using raw materials and ingredients. Verification activities must be conducted <b>before</b> 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 <b>before</b> using raw materials and ingredients and periodically thereafter at an adequate frequency.		