



Audit Report Global Standard Food Safety Issue 8

1. Audit Summary								
Company name	VION Groenlo BV		Site Code	2074194				
Site name	VION Groenlo BV	VION Groenlo BV						
Scope of audit	The slaughtering of pigs, the deboning and cutting to specification and packing in bulk, bag in box, vacuum packaging of pork							
Exclusions from scope	The intestinal washing process							
Justification for exclusion	Process is executed by a third party in the premises of VION							
Audit Start Date	2022-04-04 Audit Finish Date 2022-04-06							
Re-audit due date	2023-04-22	2023-04-22 Head Office Yes						

Additional modules included							
Modules	Result	Scope	Exclusions from Scope				
Choose a module	Choose an item						
Choose a module	Choose an item						

2. Audit Results								
Audit result	Certificated	Audit grade	AA	Audit Programme	Announced			
Previous audit grade			Previous audit date	2021-04-22				
Certificate issue date	2022-05-19		Certificate expiry date	2023-06-03				
			Fundamental	Click or tap here	to enter text.			
Number of non-conformities		Critical	Click or tap here to enter text.					
		Major	Click or tap here to enter text.					
			Minor	5				

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3. Compar	company Details								
Address	Den Sliem 8 7141JH Groenlo								
Country	The Netherlands	Site Telephone Number	+31 544 476100						
Commercial representative Name	Click or tap here to enter text.	Email	Email						
Technical representative Name	Click or tap here to enter text.	Email	Click or tap here to enter text.						

4. Compar	4. Company Profile								
Plant size (metres square)	10-25K sq.m		No. of employees	501-1500	No. of HACCP plans	1-3			
Shift Pattern		Day s	Day shift						
Subcontracted processes No		No							
Other certificates	Other certificates held ISO9		ISO9001, IFS PIA, SKAL, BLK						
A N S C			America America nia						
Company registr number	ation	EG 367 NL							
Major changes since last BRCGS audit New QA manager. grounds (15.000 m of trucks. Reallocate		ids (15.000 m2), th	nese grounds are	used for parking a	nd manoeuvre				

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4. Company Profile	
	the renewed stables coming years. Shift and growth in own workers/agency workers from to .

VION Groenlo B.V. is part of VION Food Group. In the Netherlands they own 3 pig slaughtering houses who together slaughter more then pigs annual. The location slaughters pigs and sows (appr. per week, and subsequent deboning and cutting to specification. Sows are (partly) sold as carcasses, all pig carcasses are divided and cut to specification for B2B customers. Most of meat (%) stays in The Netherlands but can be sold all over the world.

Pigs are bought by another VION subsidiary who is in close contact with the farmers, who have contracts with VION. Pigs are also bought on the free market. All pigs come always directly from the farm. There are several quality lines in the breeding of the pigs: EKO for which a SKAL certificate is in place, FSA for which a global gap approval number is acquired, BL** and BL* and IKB. VION has on top other quality lines and separation methods on behalf of customers and on behalf of third countries legislation by an EKS procedure. EKS is the procedure on demands of Asian, American and other counties for which meat is to be certified by Dutch Authority NVWA for export approval.

The company has one HACCP study which is part of a central HQ VION study (HQ is located in Boxtel). Centrally organised processes are QA, HR, Finance, Purchase, Sales, Logistics and IT. The location has about employees working in 1 shift, of VION and some are agency workers. The production volume is ca. pigs (including sows)/week. The original building dates from 2002 and is extended several times with a new cutting department and expedition area in 2016 and the crate facility building improved in 2020. The current total site is about m2 including a pigs trailers washing house, parking for trucks, personnel parking lots.

Meat is sold hanging on hooks/brackets and dividers, is packed in cartons with pe foil or crates or big boxes (dolavs) with or without PE foil. The audit was on time announced and onsite.

5. Product Characteristics						
Product categories			01 - Raw red meat Category Category Category Category Category Category Category Category			
Finished product safety rationale			pr pa	ocessing requ	it (bulk, carcasses and cut ired, chilled (max. 7 °C fre s, max 3 °C for organs). Sh nis premises.	sh products, 6 °C vacuum
High care	No	High risk		No	Ambient high care	No
Justification for area		Pr	Product undergoes full cooking prior to consumption			

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5. Product Characteristics	
Allergens handled on site	Milk Choose an allergen
Product claims made e.g. IP, organic	Organic, FSA, BL**, BL*, IKB
Product recalls in last 12 Months	No
Products in production at the time of the audit	Pigs in slaughtering house, pork in dividing department, short ribs in packing department, FSA line in cutting department, 70/30 mm in mixing department.

6. Audit Duration Details							
Total audit duration	20 man hours Duration of production facility inspection 10 man hours						
Reasons for deviation from typical or expected audit duration	Expected is 26 hours reduced to 20 because mature system supported by HQ, good results in the past and large outside premisses. Also, process is with many personnel performing each a short simple task. Grounds in use as washing spaces for trucks and parking spaces for personnel and trucks.						
Next audit type selected	Unannounced						

Audit Duration per day						
Audit Day	Date	Start Time	Finish time			
1	2022-04-04	8.30	17.30			
2	2022-04-05	08.30	16.30			
3	2022-04-06	08.30	12.30			

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Audit Team	Auditor number	Name	Role
Lead Auditor	Click or tap here to enter text.		Lead Auditor
Second Auditor	Click or tap here to enter text.		Please select

Present at audit	Present at audit						
Note: the most senior op closing meetings (ref: cla		n site should be liste	d first and be present a	at both opening &			
Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting			
Plant Manager ai	X			X			
QA manager	X	X		X			
Group Quality Manager			X				
Production manager	X	Х	X	X			
Maintenance manager	X	Х	X	X			
Company Controller	X						
HR officer			X				
HR Officer			X				
Purchase officer HQ			X				
Procurement Non Food HQ			X				
accountmanager HQ			X				
Ass. Afdelings manager snijzaal		Х					
Afdelings manager Logistics and Facility		X					
Ass. Voorman Expeditie		X					
Voorman Veredeling		X					
Voorman facilitaire dienst		X					

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Afdelingsmanager packing	X		
Afdelingsmanager slaughtering and stables	X	X	
Porter	X		
Controlling		X	
Werkvoorbereider TD	X	X	

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

Document control					
CB Report number	RQA0732002_4669610				
Template Name	F834 Food Safety Audit Report Template v11				
Standard Issue	8		Template is	sue date	2022-02-15
Directory allocation	Food	Vers	sion	1.0	

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Non-Conformity Summary Sheet

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

Critical	Critical				
No.	Clause	Re-audit date			

Major	Major						
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

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Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	4.10.3.3	In the packing department metal detector did stop but person did not react correct. Instruction and execution not clear enough. (Product was retested after discovering).	The crate with meat was put aside and blocked during the audit. The crate was afterwards visually and manually controlled on the presence of metal and recontroled through metal detector. No metal was found. The meat was then downgraded to cat.3.	The packaging department has been re-instructed what to do in case that the conveyor belt of metal detector stops. To avoid this in the future a refreshment training will be given each quarter of a year. See: 4.10.3.3 Instructie metaaldetectie.pdf 4.10.3.3 Procedure metaaldetectie.pdf	The worker at the end of the line didn't pay attention to the reaction of metal detector and therefore he put the detected crate on the pallet. to This is not according to the procedure. He didn't understand the procedure well.	2022-04- 25	
2	4.11.1	Person with white clothes seen with broom in cutting department as instruction is only to use a broom in red clothing. Plastic to pack cleaned goods in stored improper near the cratewasher.	The employee changed to the correct clothing during audit. The plastic has been removed as waste.	The Snijzaal foremen and the involved employee have been reinstructed about wearing the right clothing when meat is picked up from the floor. See 4.11. Minor 2-1 Instructie kledingvoorschriften	The employee work normally at decontamination table or to weighing hams and bellies in Cutting room. He saw that too much skin was on the floor and thought that he must pick it up and put to cat.3 bin. He	2022-04- 25	

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Minor							
				The FD have been re-instructed where to store the plastic rolls. A foil holder has been placed (see picture foil holder) to make sure that the foil cannot come in direct contact with any other materials. See 4.11.1 Minor 2.2.Instructie beware rol folie, 4.11.1Procedure kledingvoorschriften	didn't think to change the white clothing first with red ones. He didn't follow the procedure. We missed to see the hygiene risk of improper storage of the foil. The foil roll couldn't be stored somewhere else because there was not yet a designated place.		
3	5.1.1	and are software applications which are recently installed at maintenance department. users are defined but no verification took place whether their roles and rights are correctly applied. For role of Manager Production is not	The title "Voorman" has been replaced with "Manager" after the audit.	Verification of the roles and rights has been done by the Technical department manager. This will be done each time a new user is added to See 5.1.1 Minor 3 software	The use of has just started at Vion Groenlo. The current roles and rights in have been in use just for two weeks prior BRC audit. The Technical department had already planned the verification for 1	2022-04- 25	

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Minor							
4	7.1.3	In last cutting department 2 persons working on a skimming membrane machine without correct signings on the helmet.	The signing has been put on the helmet during the audit See 7.1.3 minor 4 helm met sticker.docx, photo.	The manager has been instructed to give the information on time to HR for new signing on the helmet. See 7.1.3 minor 4 instruction afdelingsmanager.pdf All the employees that handle the machines will receive an instruction that the appropriate signings must at any time be on his/her helmet. The employee will then receive the signing from the HR department.	May 2022 together with . He was not aware that the verification could be better done before the start-up of in order to avoid wrong rights The employees didn't receive the signing because the department manager had not yet informed the HR about the completion of training.	2022-04-25	
5	7.1.6	Intake form F-GRO-NL- 10171 available in several languages/version dates. Form does not in detail specify which training is given and what instruction	The document was up dated. The row "Introduction booklet/ Hygiene Regulations" is update to "Working to Vion".	HR department has to make the modifications of documents when appropriate, update the version and date and upload it on Vion	The information about "Introduction booklet/ Hygiene Regulations was not clearly defined, although all the	2022-04- 25	

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Minor				
	(video's) were shown, which exam was conducted.	See 7.1.6. Werken bij Vion.pdf	employees have received it in their own languages "Work to Vion".	
		7.1.6 Minor introduction booklet		

Click or tap here to enter text.

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Additional Modules / Head Office Non-Conformity Summary Sheet

Critic	Critical				
No	Clause	Detail	Re-audit date		

Majo	Major						
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Min	Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by	

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Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The Quality Policy Statement is documented as P-GRO-NL-10044 and is signed by the plant manager. This policy is published on several places, central communication boards and during the pandemic, the tv screen in the canteen is used as communication mean.

The site is situated in an industrial area of Groenlo. There are no potential risks associated with the site associated with food safety or integrity. The slaughterhouse is built in 2002 and renovated several times. It is extended with a cutting department and expedition area in 2016 and the facility department including a corridor to transport crates is upgraded in 2020. The complex is secured by gates and guarded by a porter. Key processes are the slaughtering of pigs and sows, the dividing of the carcass and deboning, cutting, portioning, packing, storage and dispatch of pork meat and organs. The (inhouse) intestines department belongs to ___, an external third party operating with the same licence number. All is cooled, no freezing capacity on site. All customers are B2B and product needs further processing.

The site is ISO9001 certified in a multisite certification with all VION Food Nederland plants, expiry date July 2022A. Audit was just before this audit on this site.

The company is using lean management principles to realise continual improvement. For setting the objectives, a system called X-matrix is in use. Not all objectives for 2021 were achieved but clearly analysed and re-scheduled for 2022. There are non negotiable (NN) objectives set from HQ and objectives defined by local MT, in total 9. Eg objective on digitalising SSOP forms, length of tail project, building new satble with CO2 stunning.

KPI's are defined and are scoring figures per CCP and CP including trending. The Food Safety and Quality Culture Plan is defined on in operation and is on improving the onboarding of new employees, more insight in chains of custody by installing a internship, improving training on foreign body detection. The yearly management review reflects the period July 2020- June 2021 and is discussed in the Tier 2 meeting (site MT level) of July 2021. This review included the HACCP verification/ re-assessment. The corrective actions related to the previous visit have been evaluated and were closed effectively. Site is aware that reoccurrence will lead to upscaling of issues.

Throughout the year there's a quarterly review process on the progress of objectives (X-matrix), KPI, complaints, CCP deviations, relevant legislation and other topics related to food safety and quality. The quarterly review report of Q1 and Q2 over July-dec 2021 and Q3- over the first quarter of 2022 (not yet finished) is also seen. Presence attendance and monitoring of site management and department management seen of the MT meeting, Q meetings, Tier 1 and Tier 2. Tier 2 is also the (local) HACCP-team

Staff can report concerns relating to safety, integrity, quality and legality to HR on a confidential way as a whistleblowing policy is communicated several ways (tv-screen, notice boards). The policy on confidential reporting system is stated in booklet "The good business practice, how we do business at VION" and is part of the introduction documents and available in several languages. Part of the recall test included a test with Organic pork to also test the confidential reporting system and the whistle blowing policy.

The organisation keeps up to date with legislative changes, codes of practice and emerging issues by experts part of the Quality department of HQ.

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The audit was performed on time, onsite and announced. During the opening meeting, the site management was present, and they showed commitment to the quality management system (QMS) to be present and available during the whole audit.

BRC 8 standard is available on side (digital version). No logo usage.

1.2 Organisational structure, responsibilities and management authority

The site organisation chart is documented as P-GRO-NL-10117 dd 3-2022 and is up-to-date. The chart has site management (site manager since feb 2020), QA Manager, Planning manager, HR manager, Maintenance manager, Controller, Production manager with 5 departmental managers. Every production department (5) has its own leader: slaughtering, facility/logistics, dividing department, cutting department, packing department. Deputization is described.

The responsibilities, authorities and reporting relationships of all staff members are in job descriptions per iob.

Clear communication seen on work instructions, on publication boards and on TV screens in the canteen (supported by pictograms, so understandable in different languages/up to 10). Highly involvement of management and shift leaders on production issues and on (personnel) situations of the employees.

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

2 The Food Safety Plan - HACCP

VION has a corporate risk assessment process for food safety and quality aspects and a corporate defined PRP programme. This is documented as P-VION-10000 and is managed by the corporate QA department of the HQ in Boxtel.

The local HACCP plan of VION Groenlo BV is based at the VION corporate HACCP-analysis, based on the products produced as defined in the scope. The output of the central HACCP VION HACCP plan is processed in the local process management plan. The local HACCP plan is maintained by a multi-disciplinary team described in P-GRO-NL-10180. (Plant manager, QA manager, Production manager, Maintenance manager and Department managers). Minutes seen made weekly and include attendance, action list in place.

Product characteristics: Delivery of pigs, slaughtering of pigs and sows, cooling, dividing, deboning, cutting, trimming, packing, store and dispatch of pork and pork by-products. A set of flow diagrams is part of the HACCP documentation, the steps are: receiving pigs/sows, dirty and clean section of slaughter

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process, cooling, dividing, deboning and cutting, packing, store and dispatch. The flow diagrams of the processing process are up-to-date and yearly verified in the re-assessment of July-2021.

The HACCP system is well established, mature and has been carried out in accordance with Codex Alimentarius. Hazards are on raw material and on process. On raw material the hazards are on microbiological, chemical residues, physical, radiological parameters and are dictated by HQ. On process, the hazards are described in the local process management plan. Hazards are on likeliness of a hazard occurring = 3 x 3 matrix). A decision tree is used. Score ≥6 is CCP, <3 PRP and 3<6 CP. Some 30 CP's apply next to the CCP's. EG CP on metal detection.

Based at the actual HACCP plan, CCP's apply (P-GRO-NL-10139) with the critical limits:

CCP1: faecal contamination on carcass. Zero contamination allowed in hourly sampling of 25 carcasses, in line measurements.

CCP2: product temperatures at dispatch for organs (<3°C)

CCP3: product temperatures at dispatch for meat (<7°C)

CCP3A: product temperatures at dispatch for vacuum packed products (<6°C)

CCP4: product surface temperatures at dispatch for warm carcass s (≤7°C), sampling of every truck delivery (transport of meat is allowed if outside is <=7°C (EG2017/1981)

CCP4a: product temperatures at dispatch for warm carcass s (≤15°C). (the time of cooling to kernel temperature is in this regulation)

CCP5: Incoming/returned organs <3°C CCP6: Incoming/returned meat <7°C

Last formal HACCP verification incl. CCP's covers July 2020- June 2021 and has been used as input for the overall management review of this period.

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

3. Food safety and quality management system

3.1 Food safety and quality manual

The documented Quality management system is managed by the HQ-QA department and available via online application Key staff members have direct access.

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Instructions of employees have been worked out in multiple languages, instructions with photos, class room sessions and e-learning tools. > 70% of the employees does not native speak Dutch, but Polish, Romanian, Hungarian or other nationalities. EPL's from VOS system mostly with pictograms without text, not in a language.

The company has a Quality Manual, which states the company's commitment to quality and food safety. The quality manual is the total of all quality documents, going from the policy, system procedures, working procedures, work instructions and registration documents. Next to this each department disposes of the specific chapter with procedures, work instructions and forms. Key functions can use the original electronic version too. No restrictions for use with valid password.

3.2 Document Control

A general procedure is in place for document control. The QA manager is coordinating the authorisation steps in . A general procedure is in place for document control. The QA manager is coordinating the authorisation steps in

3.3 Record completion and maintenance

Most records are handwritten and currently a digital record making application is being validated: which is allready in use in other VION plants. Introduction of tablets is delayed but will be implemented for Pre-SSOP and SSOP records coming year. Minimum retaining period is defined for 2 – 5 years. All electronic data are secured by daily back-ups.

Records are verified of 2021-12-16, 2021-12-17 (vertical test): records of SSOP's, CCP's, pre-SSOP's, water analysis, microbiologic product and environmental analysis results, etc, were seen.

3.4 Internal audits

The internal audits within the VION company are scheduled and coordinated by HQ QA department. All internal auditors are trained by which is a HQ responsibility. Mostly QA managers of all sites are internal auditors. Scheduling and reporting of internal audits is organised via the auditor-online tool and also plotted in the MRM. System audit frequency is 2x/year, 1x announced and 1x unannounced. Beside these general audits focussed on BRC requirements and quality management in general, also specific audits are conducted focussed of glass, building and environment, foreign body control and hygiene. And furthermore numerous client audits take place.

Seen reports of internal audit of 05-05-2021. Audit reports seen were on general hygiene, Animal welfare and document audit. The NC's (only minor NC's) were reported in the action list. The follow up of minor NC's is timely and demonstrable. Audit reports also contain information about conformity aspects. All Vion internal auditors have followed the external LAQ course, are experienced and competent.

Hygiene and fabrication inspections are kept at a daily base with the pre-SSOP and SSOP checks. There's a monthly verification of the SSOP checks by the QA department. Schedule has been set up and communicated. Results of the SSOP process are verified with hygiene audits (Q-based) with focus on hygiene and engineering aspects.

In addition to the internal audits, daily hygiene /fabrication inspections take place for all departments (SSOP/ Pre-SSOP) seen Pre-SSOP and SSOP forms in the vertical test (Pre SSOP: 10192 Facilitaire dienst, 10154 Expedition, 10186 Slijperij, 10168 Cutting department, 10028, dviding department, 10175 packing department, 10026 slaughtering. SSOP 10044 Expeditie, 10042 Dividing/[packing, 10050 Azie). Strict complete system observed. There's a monthly verification of the records by QA department. Schedule has been set up and communicated and verified.

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3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

The purchase and delivery of pigs/sows is managed by VION Farming, located at the HQ in Boxtel. The intake of the pigs, including of the verification of relevant documents is a local responsibility. This includes verification of data from VION Farming. Intake is checked for the delivery of pigs, delivered at 2021-12-16 (vertical test). The suppliers of that day were all demonstrable recognised and approved for and No other raw material than pigs and sows. The results of the inspection (am and pm), are communicated to farmers and HQ. This includes delivered dead, urgent slaughterings, slaughtering defects.

Suppliers are divided in 3 groups as described in central procedure P-Food-10002: - pigs/sows; - Agencies; - non food (ingredients, services, packing material).

All suppliers also of packaging materials and services have to be approved by HQ. Intensive communication including reporting of defects and complaints is demonstrable. Site is responsible for reporting defects, HQ does negotiations. Past year a new approval tool is invented and currently the first suppliers are evaluated. Corporate contracts on all including logistics, maintenance and cleaning. At the HQ there is a central purchase department for non-food, food (ingredients but not relevant for this site) and services. The approval and evaluation process of non-food suppliers and services is with input of the several sites of VION and described in P-FOOD-10032 v9 18-11-2021. Also, P-FOOD-10025 on supplier assessment and P-FOOD-10026 on Product and service requirements. Purchasing is done by the purchase department and makes use of the centrally agreed contracts. HQ procurement officer was audited on the procedure and seen was the supplier of foil . Seen all evaluation results overview in Supplier Evaluation.xlsx. On 5 subsidiaries are to give their evaluation which is combined with HQ evaluation. Risk assessment is in place, including scope and grade checking in F-Food-10000. Non Food Suppliers are monitored and evaluated on quality, reliability, price and HACCP. The risk assessment depends on the kind of material and is based on enquiries, trial delivery, specification and (eventually certificated) QMS of the supplier.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Intake of all packing materials is managed by the facility department. Supplier approval and evaluation file shows no poor performing suppliers as some are not delivering anymore and placed on the blocked list. Seen evaluation on packing material supplier with valid BRC GS P6 certificate. Form used to record reception of crates/empty goods F-GRO-NL-10096 is seen in place v2 dd 25-09-2015 Form to trace packing materials on is F-GRO-NL-10178.

3.5.3 Management of suppliers of services

Approval and assessment of suppliers of services is the responsibility of the central purchasing department of VION. The several plants are requested for input for the assessment process. Input Groenlo excel file 2021, reported by the QA manager, was seen.

3.5.4 Management of Out sourced processing

No outsourced processing and packing.

3.6 Specifications

End product specifications including labelling information is generated by application MDM (Master Data Management) a central led tool for specification management. Data on product: chemical, nutritional, microbiological, logistical, allergens, storage instructions are available. There is also available a label catalogue and a packaging catalogue.

The following specifications are sampled during the audit and in the vertical test:

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Buik A zb zw kn 23/54

- PE foil DOC dd 20-05-2021 (also available but after tracetest date is DoC dd 03-03-2022)

- Grease

cleaning detergentcleaning detergent.

All sampled specifications were available and in an actual version, last review of specifications is depending on request of change of the customers or specifications, provided by suppliers in relation to the company VION, but the specifications are reviewed at least every 3 years. During the audit no specifications seen older than 3 years.

Specifications of finished products are created in MDM by sales managers. There is close cooperation between the department managers of cutting departments and sales managers during the development of new specifications of final products.

3.7 Corrective and preventive actions

Correct control seen for handling corrective actions related to CCP, pre-SSOP and SSOP checks. Several action lists in place. The principles of lean management are in use for the management of corrective and preventive actions. This is translated in VOS 2.0/ (VOS = VION Operating System). Corrective actions are initiated via the team huddle communication structure. If not closed within the time frames actions are escalated towards the tier 1 level. A4 papers are in use when root cause analysis is to be done and defining corrective actions. For complex items an A3 approach is in use for the indepth root cause analysis. VOS report/evaluation during Q meetings. Currently no A3 change projects in place.

3.8 Control of non-conforming product

The procedure for non-conforming product is documented as P-GRO-NL-10168 and during the audit records of incidents of non-conformity are seen and verified. For fallen meat a special procedure for cleaning is in place and at every department. Seen several examples of correct correction of fallen meat seen during the audit. Blocked batches are reviewed during the huddles and tier 1 meetings. Clear visual identification seen on blocked product and on blocked and to be cleaned crates seen including reports/checks by QA. On the issue on the metal detector (see minor in 4.10) correct blocking took place. Non-conforming packing (e.g. leak after vacuum packing) are handled promptly and are re-packed.

3.9 Traceability

No consumer packed end products are applicable Traceability system is well defined by traceability of slaughtering and production day. It is linked to the product integrity aspect of the pigs, the chain of custody. For primary packing materials the traceability is batch based.

During the audit a vertical test was on product Buik A, packed in E2 crates, with PE foil, produced at , pigs slaughtered at . Forward and backward information is readily available within the system. All relevant documents were available within 4 hours.

All involved records were also checked pre-SSOP, SSOP's (of all departments could be shown, fully filled out), CCP and CP's records, cleaning records, training records etc.) incl. supplier approval. The trace test was done within 4 hrs. The product was chosen by the auditor.

Trace test (incl. recall test) done by as internal test by plant by Vion Groenlo at 2022-02-22 which also included forward and backward test. This test was on BIO MM 70/30 and was initiated by HQ also to test the whistle blowing procedure.

3.10 Complaint-handling

Complaints are sent by sales to the complaint inbox email address of VION Groenlo. All complaints are discussed in Tier 1 meetings. Appr 30 complaints per month are categories in several categories according thet complaints procedure. Corrective actions related to complaints are organised and coordinated by the responsible department managers. Complaints including analysing reports and trend are part of the monthly quality reports and the quarterly management review report. The complaint

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handling of customer on foreign bodies was seen. Correct communication seen between customer and the organisation.

3.11 Management of incidents, product withdrawal and product recall

VION Food Group has 3 pork slaughtering plants in the Netherlands and 5 in Germany and in total 23 producing plants. In case of emergency situations the production will be transferred to another VION plant as was done during the slaughtering stop in June 2020 by closure of two weeks of this site. Slaughtering was transferred to the other sites.

The recall process is documented as P-VION-10015 Crisis manual and P-GRO-NL-10181 for the specific Groenlo situation.

A recall test was done on 2022-02-22, report seen. Track and trace test are performed several times per year also for other audits (eg IFS PIA, SKAL). One test is outside normal working hours. Past years no actual recall or withdrawal took place.

The certification body will be informed within 3 working days in case of a product recall.

Details of non-applicable clauses with justification		
Clause/Section Ref	Justification	
3.5.4	No processing or primary packing is outsourced.	
3.9.4	No rework takes place	

4. Site standards

4.1 External standards

The site has been designed and constructed for its processes. It is located at an industrial area and at the other site of the main road VION Retail BV is located. The plant is rebuilt in 2002, after a fire. In 2016 the cutting facilities and cooling areas are enlarged. The storage of primary packaging materials and the washing facilities for crates, pallets and dolavs are located in a separated building, upgraded and a corridor created towards production in 2020. Maintenance is also a separate part of the building with no direct entrance into the production location, workshop is reallocated this month also with maintenance offices. Still no direct access to production departments but more central orientated.

4.2 Site security and food defence

The site is fully fenced with 3 gates. One persons entrance for employees who park outside fenced area, entrance with tagging system. One gate entrance for lorries and one gate for exiting cleaned lorries for trucks who transport pigs. This exit has a disinfection bath. During opening hours, permanent supervision by a security guard with mandatory check in for each visitor / lorry driver. Revisiting personnel as contractors can enter without check-in. Currently the new fanec is being placed an new routes are installed as two new lorrie weighing bridges are bult but not yet operational.

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Site is EU approved (EG 367 NL). Site is camera secured and on non-opening hours external outsourced supervision.

The documented food defence procedure is in P-GRO-NL-10231 and verified in the management review of July 2021. This is a relatively new document created with risks related to areas and evaluations and has an analogy with the HACCP methodology.

The re- assessment is part of the annually assessment plan, as permanent supervision was introduced last year and is fully outsourced. This outsourced process is assessed during the yearly supplier assessment and is part of input of the management review (July 2020-June 2021).

4.3 Layout, product flow and segregation

The production and storage zones have been defined and based upon a risk assessment all zones are "Low risk areas" (all fresh meat is sold to B-to-B industries/butchers and do need a (heat) treatment before consumption. No high risk or high care operations. In the slaughtering department, it is not allowed to go from dirty to clean departments. At the end of the dirty slaughtering department the latest step is cleaning by heat/fire to prevent contamination.

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

The fabric and internal condition of the site is suitable and satisfactory for the processes. Space is limited.

Daily check at fabrication aspects is part of the Pre-SSOP and SSOP checks. 4x/year hygiene inspections take place to verify the process of SSOP checks. Depending on outside conditions sometimes condensation is challenging, and facility workers are trained to mop ceilings if it occurs. With pandemic conditions, extra ventilation is installed with UV lamps on several areas.

A separate building is in use for storage of packing materials as foils, bags and crates. There is also an area for cleaning of dolavs, transporting vehicles, hooks and spreaders. These are all sealed in after cleaning to prevent contamination during outside transport. A disinfection tray is placed at entrance for disinfection wheels. Also, a full 25 meter crate washing machine installed including label remover, drying department and buffering lines to transport crates to and from the cutting department.

4.5 Utilities – water, ice, air and other gases

The company is using water from public main supply for process and cleaning water. There's steam boiler equipment for the production of hot water. Water samples are analysed 4x/year at microbiological aspects and 2x/year at Legionella. A tap-plan is available and correct sampling observed. Seen "Water bemonstering 2021" with 27 sampling points and dates.

Also compressed air system installed with 6 compressors partly renewed. No compressed air in contact with meat, mostly for equipment control.

4.6 Equipment

Equipment used is fit for purpose. All made of SS and fit to endure. It is cleanable and is bought from known producers of specialised equipment for the meat industry. Also, various belt-systems in place for direct and indirect meat contact as for crate supply. All to be in contact with food declaration. Specifications of equipment is available during the audit. Documents are available and correct for the situation at VION Groenlo.

4.7 Maintenance

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The company is using the software tool for the planning and registration of maintenance, as well preventive maintenance as corrective maintenance is registered. Past year, new application is introduced, implementation still in progress (see minor on this topic in 5.1).

There are working a manager, 6 maintenance workers and 2 calculators in the maintenance department. For preventive maintenance contractors are hired. With long time contracts and relations. Daily meetings are held with maintenance workers to plan corrective jobs. Hygiene clearance after maintenance work during operating hours is the responsibility of the management of the several departments and is recorded on SSOP record.

The engineering workshop is inspected during the site audit. Still being relocated so not as tidy as past year. A new workshop with a impervious floor. Stock of lubricants is stored secured and only technicians have keys. Food grade lubricants in use for equipment which have a direct contact with meat. Segregate storage, clearly labelling and list of chemicals (food and non-food approved) is available and seen.

4.8 Staff facilities

There are several separated staff facilities and due to pandemic extra rooms and canteens are installed in former storage/other areas. There are separate facilities for the employees of the slaughter department, intestine department and for cutting and expedition departments. All split in gender. All employees have 2 lockers: 1 for work clothes and 1 for private clothes.

The staff facilities were seen in good order, sober clean and in correct state of maintenance. Handwashing facilities (with soap tap operation and air driers or single used paper towels) are provided in toilets and at entry points to and into production areas. Before entering the production areas a sole washer and hand disinfecting equipment are installed.

Catering is provided to personnel. In canteen no work coats are worn (only trousers). The production and storage zones have been defined and based upon a risk assessment all zones are graded as "Low risk areas". Smoking is only allowed in a designated areas (separate area), also one for blue and one for white and other coated employees.

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

4.9.1 Chemical control

Control of chemicals on site was demonstrated. Approval is the responsibility of HQ Procurement department. Separate (locked) storage facilities for e.g. cleaning chemicals (sea container) and lubricating oil. Checked (washing anti-cutting gloves). All chemical used are intended to use in relation to food production. This is also checked 6x/y in safety audits.

Seen check on residue on the crates with indicating paper after cleaning in the facility department: Kalium jodide check strips: no colouring: the crates were rinsed well with clean water just as checks on equipment after cleaning. Also 1x week acid cleaning including control with test strips check on residue with and/or

. All documented on Pre-SSOP records. Regular checks are performed on checks on chemical concentration, clean sieves, temperature of the washing water and clean rinsing water to prevent problems like chemical contamination and biofilm.

4.9.2 Metal control

Knifes are provided, changed every break at the same time when used SS gloves are collected for new once in change, new knives can only be provided when the old one is handed in. This accounts also for

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agency workers, checks at start and end of the day are daily recorded in the SSOP registration forms of the departments. This is verified for the SSOP checks at 2021-12-17 (vertical test).

4.9.3 Glass, brittle plastic, ceramics and similar materials

No application of glass or brittle packaging materials. A (glass) breakage procedure is defined. A glass / brittle plastic register is in place and records the location and condition of the item. Daily inspection, start-up checks on Pre-SSOP include glass / brittle materials. Records are checked as part of the vertical audit.

4.9.4 Products packed into glass or other brittle containers

na

4 9 5 Wood

The use of wood and wooden pallets is only allowed in non production areas. Packaging materials can come in on wood but are all replaced into production on dedicated transport without wood.

4.9.6 Other physical contaminants

Control on foreign bodies is recorded on SSOP like metal, dirt (lane lubricant), pieces of plastic of eg gloves/aprons, bags checks on metal pieces of equipment, glass control, fraying on table tops and belts are checked, all recorded on the SSOP on daily basis. Plasters are covered with gloves.

Pens used in production area are standard blue metal detectable pens, without small parts.

4.10 Foreign-body detection and removal equipment

4.10.1 Selection and operation of foreign-body detection and removal equipment

At this site the semi-bulk products are produced. No consumer packed product is involved. A documented assessment in association with the HACCP study is performed and based upon the HACCP study no foreign body detecting equipment is to be determined a CCP but a CP on defined production lines. 3 Metal detectors are installed (see 4.10.3) on customer request. Also the eagle is capable of foreign body detection (but not optimised yet). Foreign body alertness has the attention of all employees working in production.

4.10.2 Filters and sieves

na

4.10.3 Metal detectors and X-ray equipment

The company has 3 metal detectors in cutting department and in packing department which are identified as CP. Test pieces (certified) in use are:

- 5.0 mm Fe
- 6.0 mm non Fe
- 8.0 mm SS

Records of the use of the metal detector at 2021-12-17 are verified (vertical test) and demonstrable. Metal catches are recorded at F-GRO-NL-10098. During the site audit the control of the metal detectors is demonstrated by operators. The used method was in conformity with the instructions in P-GRO-NL-10190 v6 dd 17-1-2018.

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Minor 1: In the packing department metal detector did stop but person did not react correct. Instruction and execution not clear enough. (Product was retested after discovering).

4.10.4 Magnets

na

4.10.5 Optical sorting equipment

Na (although the is an optical sorting machine it is in use for measuring fat content in mixing of batches of meat, not for foreign body detection and removal).

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

na

4.11 Housekeeping and hygiene

Cleaning is partly outsourced and partly executed by own facility department. Facility personnel is identifiable by red clothing. Plan is documented in F-GRO-NL-10021 v13 dd 14-12-2021.

The cleaning of the plant is outsourced to a contracted specialised cleaning company with agreement validation dd 2019-11-05, inventory plan dd 15-12-2020. Daily cleaning and disinfection of the production departments <3 m. Plan in place with all items, frequencies, means and detergents. Communications via online applications and whatsapp.

Periodic cleaning (ceilings, walls >3 m) is taken place at request and is coordinated by the QA manager.

Cooling areas are cleaned by the facility department.

Daily visual check at cleaning with pre-SSOP systematic. Weekly check at the disinfection process with agar samples and residue checks. Trends in agar results show results on some places on basic level and on other places good. Corrective actions are demonstrable and are VS, PS or CS. Vertical test documents checked of week 50-2021. Residue tests show no deviations.

Daily cleaning of the staff facilities and outside terrain is responsibility of facility department.

CIP is applied in the blood tanks but these tanks are outside audit scope and owned and handled by the customer of the blood. VION does however checks if the system including the CIP is working well.

Dosage of detergents is verified externally 4x/year with titration tests by external party in close cooperation with detergent supplier.

Swabs are taken, and a trend analysis showed good results. Actual trends in are verified: show stable results. Listeria is analysed during environment check see also 4.11.8.

Minor 2: Person with white clothes seen with broom in cutting department as instruction is only to use a broom in red clothing. Plastic to pack cleaned goods in stored improper in near the crate washer.

4.11.7 Cleaning in place (CIP)

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na

4.11.8 Environmental monitoring

An environmental monitoring programme is in place, part of the micro analyses plan (both for environment as well as the products), risk based and includes the sampling protocol on agar including Listeria in different departments of the factory on identified locations including gutters and coolers. Listeria is analysed during environment checks as a CP and monitored every quarter. Goal is max 6% of the swaps positive. Correct RCA seen, corrective actions demonstrably implemented as sometimes belt are replaced or other actions as changed cleaning protocol. These corrective actions were demonstrably effective.

4.12 Waste

Waste management is at an appropriate level. Waste disposal is handled by licensed contractor (paper, cardboard, plastic, grey waste).

4.13 Management of surplus food and products for animal feed

are the licensed recipients of Category 2 (eg blood) and Category 3 material. In case product is rejected, all packaging including labels will be removed before collection of products for Cat 2 . No remarks.

4.14 Pest management

Pest control is subcontracted to company since April 2016 (HQ contract). Online application "Pest scan" verified. Monitoring includes rodents, flying and crawling insects. Scheduled surveillances take place 8x/year. In case of infestation extra visits are in place and reported. Besides surveillance also an indepth QA inspection takes place 1x/y and a PRI is executed to assess and verify plan and execution.

The competence of the pest control inspectors is available in the online application. Also in the application are the plans, the means and the chemicals used. No usage of tox inside, tox is used at the life stock truck washing place currently. This area is about to be reconstructed. In-depth surveys are scheduled yearly, based on risk assessment. The report of the last in-depth inspection was seen during the audit and was dated 13-04-2021. All related action points are completed. In 2021 some 25 actions were brought up by the pest manager and currently 5 partly from 2022, still open.

Trend analyses of 2021 shows an increasing trend for flies in summer, but also decrease from October 2021 (same as last years). Rats outside are sometimes detected, namely around the washing place for the life pigs lorries. This part will be renewed coming year. No nuisance of rats inside the building.

Bird control by good housekeeping and preventive protection on roof edges, birds (gulls) are challenging the pest managers currently as the gulls observe the bone truck on the highway and know its feeding time. During the audit a falconer was present to handle the gull-presence.

4.15 Storage facilities

Packaging materials and crates/pallets are stored in a separated building. Cooled storage facilities are sufficient. All chilled storage areas are linked to a recording system, linked to an alarm reporting system.

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The system is verified for the temperature course in the week of 50-2021 (vertical test), no issues with the temperature control in this week. Stock rotation is based at FIFO principle.

4.16 Dispatch and transport

During the dispatch process a pre-shipment control is taken place to verify the temperature CCP controls. This process is verified for 2021-12-17 (vertical test).

Transport is outsourced to contracted and specialised transport companies. Intercompany transport is organised via Distrifresh, this company is part of the VION food company (IFS log. certified). Supplier approval and contract management is managed by HQ Procurement. On the opposite site of the road is situated VION Retail to which 30% of the quantity is shipped to, to be processed for B2C/retail. Local verification of the transport process by transport audits (agar check cleanliness, verification logger /temperature) and check of cleanliness before loading of each truck.

Details of non-applicable clauses with justification		
Clause/Section Ref	Justification	
4.5.3	No air or gasses used for direct contact. Compressed air is filtered.	
4.9.2.2	No staples, purchased of ingredients and packaging which uses staples in use on site.	
4.9.4/ 4.10.6	No products packed into glass or other brittle containers	
4.9.5.1	No wood is used in open product areas	
4.10.2	No filters and sieves applied	
4.10.4	No magnets applied.	
4.10.5	No optical sorting equipment applied.	
4.11.7	No CIP cleaning in use	
4.14.3	Pest control is outsourced	
4.15.4	No controlled atmosphere storage in use	
4.15.5	No outside storage	

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5. Product control

5.1 Product design/development

Process improvements are done based upon investment projects. In 2021 the digitalisation of SSOP's is validated by HQ. In the procedure is foreseen that HACCP review will take place.

Product design aspects are changes in cutting or packing instructions, recorded in de MDM application.

Shelf life trials are coordinated by the central QA department and is a continuous programme within VION. Seen shelf life report of Product Buik A (Vertical test 2021-12-17) Shelf life: production + 7 days, results TPC: < log 7 and Entero's < log 5, all ok.

Minor 3: and are software applications which are recently installed at maintenance department. users are defined but no verification took place whether their roles and rights are correctly applied. For role of Manager Production is not correct currently as it is "Voorman"

5.2 Product labelling

VION Groenlo is producing single meat products. Labelling aspects are production date, shelf life and land of origin according to European Law. For certain Azian good supplied to eg China the labelling process has extra controls on application. If new labels are created, an agreed and signed example is available. This control processes is verified during the audit for the packaging process and is well organised.

5.3 Management of allergens

In HACCP analysis (the actual plan is described in P-GRO-NL-10139) is mentioned and judged that no allergenic material is to be declared. Milk in sows as acknowledged and swab sampling on lactose is in place 2x/y on belt and surface. No risk on contamination with allergens as concluded in HACCP analyses. No herbs and spices are used on site.

5.4 Product authenticity, claims and chain of custody

VION Groenlo is producing EKO/Bio, FS+, FS, IKB (and Standard) pork meat. Chain of custody audits are done (IFS PIA) by an external certification body. The company has a SKAL recognition for production of Organic pork meat. Measures to ensure identity of products are in place (on pig and farm level traceability is arranged). Several software applications in place and well arranged.

Mass balance checks are kept at a daily base on 5 chains and past year there was a project to improve and automate these checks.

The assessment covers purchase and delivery of pigs/sows which is managed by VION Farming. This is highly in control, as currently animal welfare is becoming more and more important in the public's eye. Video surveillance and recording in place of acceptance. Detailed checks of authority, external certification body and reception procedure under supervision of SKV including of the verification of relevant documents (VKI) is a local responsibility.

The vulnerability assessment is part of the risk assessment P-GRO-NL-10157, and under annual review as seen in the MRM of July 2021. Assessment is renewed to another format past year.

5.5 Product packaging

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Packaging materials are stored separately from production materials and part used packaging is covered prior to returning to the storage area. Product contact liners applied have colour coding and colours mean chains. As green for organic, amber for depending on the IP of the product. In all cases the labelling is prevalent to colour as products can be degraded.

All packaging materials are checked and purchased via HQ. Only packaging material suitable for food contact is in use. Proof seen during vertical test.

Vertical test result check packaging material DUM 188 lot 4500014168.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Sub contracted analyses (microbiological/chemical and allergen) are carried out by a several laboratories all operating in accordance with ISO 17025. Eg for microbiology.

Trend analyses in Quality Trends of swabs from carcasses do show good results within the limits (regarding to EU 2073/2005). Seen Jan-Dec 2021 TPC log<4 kve/g, Entero log <1,7 (within specification/ far below legislation). Salmonella: several samples of positive results are found, VION KPI max 5%, legislation max 6.5%). All within own limits.

Daily sampling on trimmings, N=5 TPC and Entero's, 1x week Salmonella and Listeria. KPI max log 3.7. Entero's KPI max log 1,7), Salmonella max. 5%, Listeria max. 5%.

The sampling program and schedule for 2022 is seen, for 2021 is met. Results of analysis of 2021 and longer ago seen. Sampling plan according national law and HQ instructions in P-NLFOOD-10016.

5.6.2 Laboratory testing

All microbiological analyses are carried out by contracted external laboratories. All laboratory is accredited for ISO17025.

Carcasses: Seen Jan-Dec 2021 TPC log<4 kve/g, Entero log <1,7 (within specification/ far below legislation). Salmonella: several samples of positive results are found, VION KPI max 5%, legislation max 6.5%).

Trimmings, N=5 TPC and Entero's, 1x week Salmonella and Listeria. KPI max log 3.7. Entero's KPI max log 1,7), Salmonella max. 5%, Listeria max. 5%.

5.7 Product release

Product release is based upon product temperature measurements (CCP) before dispatch. This is the preshipment process. 5 samples are taken from every batch. Records checked during vertical audit and site tour. Seen recording during the dispatch during the audit on F-GRO-NL-10001 and 100120 and there is a verification by 2 persons on measurement in F-GRO-NL-10044. Thermometers in use are calibrated by quality department every 2 months and also calibrated correctly.

5.8 Pet Food

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na

Details of non-applicable clauses with justification		
Clause/Section Ref	Justification	
5.2.3	No claims in use to satisfy a consumer group	
5.3.7	No claims applied regarding the suitability of a food for allergy or food sensitivity suffering	
5.6.2.2	No testing laboratory on site	
5.8	No product rendered to pet food	

6. Process control

6.1 Control of operations

The site clearly demonstrated a good control of the operational process. Processes are documented in Process Control Plans (Eg P-GRO-NL-100140 and -10157. Process control is based upon the HACCP study, legal and customer requirements. Process conditions and methods are well set at and revalidated. Systematic monitoring is demonstrated. Documented start up checks are applied and demonstrated during this visit (pre-SSOP and SSOP).

During production, correct application of CCP's and CP's was monitored and verified on a day-to-day basis. Assessed for CCP temperature control at dispatch. During production, each department has its own SSOP (checks on personal hygiene and hygiene of production performance, glass control, knife control, lane fat and condense, maintenance requests for repair. Records were checked during vertical audit and site audit. Records of 2021-12-17 (vertical test) are verified in depth, also CCP checks were verified. The fat measurement of mixed meat is done by fat measurement equipment in line. The temperature of the chilling areas is verified; these are well within conformity with the standards. All cooled areas are linked to a failure alarm. Metal detectors are controlled 1x/ 2 hours.

A product conformity check is performed at hourly base in the cutting department.

6.2 Labelling and pack contro

Labelling and pack control is on identification per id. This can be a carcass, a hook, a dolav, a crate, a box, etc. Labels are generated by application where production employees only can enter ID. Amounts by weighing/counting as system creates label ID's. The labelling and pack control process of the production for art 25275 is verified. Weighing operation only to be executed by trained and competent personnel. First and last labels of a production batch are pasted at a registration form F-GRO-NL-10184 for products

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and on -10172 for products. The label is compared with the label of the last batch. With this system the company also has a reference in case of questions are complaints related to labelling. Temperature specification of loading is defined in the CCP 2-6.

Temperature and label control seen during onsite audit of loading for customer DGS.

6.3 Quantity, weight, volume and number control

On entrance pigs/sows are counted and count of carcasses to be paid to supplier/farmer. Only sales of variable weight products. A calibration programme for measuring equipment is in place, seen calibration program of external contractor . Daily check of scales via pre-SSOP F-GRO-NL-10160, yearly external calibration of scales.

6.4 Calibration and control of measuring and monitoring devices

Calibration procedure P-GRO-NL-10029 v4 dd 07-03-2018 ensure relevant equipment is identified and regularly calibrated. All taken up in application and also . (Thermometers, pH-meter, PT100, Weighing devices, Foam/disinfect units.)

Temperature devices (CCP related) and scales (legal issue) were sampled. Hand thermometers are calibrated at least two monthly (with melting ice) and the reference yearly externally.

Seen calibration report of on the Metal detector dd 09-02-2022 and on fat analysis. Internal weighing with own weights in recorded on F-GRO-NL-160 v11 dd 26-11-2021

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

7. Personnel

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

There's a yearly training programme for all employees. Training programme 2021 is seen which was a again complicated because of pandemic. There is evidence of introduction training for new starters and refreshment training of employees. The induction program is partly e-learning and also usage of translators is in place. Almost all agency workers are not native Dutch. There is a training plan for all types of training including obligated training on truck driving, Health and first aid courses.

Competency training had taken place for the staff sampled (food safety, quality and safety). Seen the competence matrix of the slaughtering department on which personnel is planned. Level 1, 2,3 per person. Per position/task is assigned how many competent workers are needed.

Records were sampled for the new QA manager and employees including the assistant foreman in the dispatch area on CCP training. Hygiene rules and regulations are defined and available (employees, temporary employees, visitors). CCP training is available and in place.

For all own employees the refresher training is 1x/2y, latest June 2020 online. There are >10 certified animal welfare officers trained yearly.

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Minor 4: In last cutting department 2 persons working on a skimming membrane machine without correct signings on the helmet.

Minor 5: Intake form F-GRO-NL-10171 available in several languages/version dates. Form does not in detail specify which training is given and what instruction (video's) were shown, which exam was conducted.

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

Visitors have an intake at the porter and have to fill in a questionnaire on their health, contact with livestock and covid issues.

On all entrances hand wash and boot wash facilities are applied.

All personnel are instructed on the documented hygiene standard of VION to be applied, prior to commencing work, this includes temporary personnel, visitors and contractors.

The standards for personal hygiene, dress code, medicines, make up and perfume, jewellery and medical screening have been defined and communicated to all personnel prior to commencing work. These hygiene rules are effectively enforced.

The guidelines for personal hygiene are documented in the brochure which every employee receives at start of working for VION (good business practice (how we do business at VION)). Also the standard hygiene rules are published on the board in hygiene. Visitors get the brochure on entrance (auditor also). Metal detectible plasters are checked and controlled by the facility department. Records were demonstrable. All batches are checked and date of check and approval is written on each batch supplied to the different departments.

7.3 Medical screening

Visitors, contractors and temporary workers have to complete a health questionnaire (or employees visit a doctor) prior to entry to any production areas, seen the health certificate in the file of dd 18-02-2022 signed by a German Physician.

Procedures are established for personnel to notify management of infectious conditions they may be suffering from or been in contact with. Several Covid measures still in place. New employees have to complete a health questionnaire.

7.4 Protective clothing: employees or visitors to production areas

All employees are wearing suitable work clothes. White, Green, Red, dark or light Blue, depending on department. Helmets and hairnets have colour coding to indicate department and hierarchy. All employees and visitors are wearing protective clothing and shoes or boots partly provided for by VION. Change of work clothes is at least daily. The wearing of a disposable hair cap is mandatory. Wearing of jewellery is not allowed (zero tolerance policy). Laundering of protective clothing is done by a contracted professional laundry company. The subcontracted laundry is audited as part of the supplier audit programme. Agar micro results of the work clothes are good. There is a check for work wear during the hygiene inspection. (SSOP item). There are also facilities for temporary workers, visitor facility is given up to create more space for workers. Gloves are worn (policy seen), disposable gloves are changed each break. Safety gloves are washed each break on site. Aprons in use, correct cleaning seen. Jackets of Maintenance workers are not washed but replaced if too dirty/yearly.

Details of non-applicable clauses with justification

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Clause/Section Ref	Justification

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

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

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9 - Traded Products
9.1 Approval and performance monitoring of manufacturers/packers of traded food products
Not applicable
9.2 Specifications
Not applicable
9.3 Product inspection and laboratory testing
Not applicable
9.4 Product legality
Not applicable
9.5 Traceability
Not applicable

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Scope Click or tap here to enter text.

11.1 Traceability

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11.2 Approval of meat supply chain

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11.3 Raw material receipt and inspection

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11.4 Management of cross-contamination between species				
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11.5 Product testing				
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11.6 Training				
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Module 13 FSMA Preventive Controls Preparedness Module

Version 2 July 2018

	Version 2 July 2010				
Clause	Module item	Conforms Y/N	Comments		
13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.				
13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.				
13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.				
13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.				

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13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with		
	another lot.		
13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility:		
	 Economic adulterants which affect food safety 		
	Environmental pathogens where readyto-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step		
	 Radiological hazards 		
	 Unintentional adulterants which affect food safety 		
13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a		

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	preventive control" (i.e., significant hazards).		
13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: Notifying consignees of how to return or dispose of recalled product Conducting effectiveness checks to verify recall is carried out Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		

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13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRCGS section 2.10.			
13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRCGS sections 2.11 and 3.7. Corrective action			
	procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).			
13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production.			
	Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.			
13.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate			

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	timeframe exceeding 7 days is used, the PCQI must document justification.		
	The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following:		
	Sampling procedure to include method, quantity, frequency, and number of samples		
	Analytical method		
	 Laboratory conducting analysis 		
	 Corrective action procedure where pathogen is detected 		
13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a		

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	scientifically valid and written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is		
	detected		
13.1.16	Devices used to verify preventive controls must be calibrated.		
13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
13.1.18	All records required by 21 CFR § 117 must include: Date and time of activity being documented Signature/initials of individual		

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	performing activity or conducting record review Information to identify the facility (e.g., name and location) Identity of the		
	product and lot code where applicable		
13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.		
13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		
13.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities.		

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	Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials		
	and ingredients on a temporary basis from unapproved suppliers.		
13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.		
13.2.1	Human food by- products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: - During holding, human food by- products for use as		

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	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 byproducts for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies,		
	and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be		

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	identified on the site's organizational chart.		
13.3.2	One or more Ql's shall be responsible for implementing mitigation strategies at actionable process steps. The site shall have a		
13.3.2	written food defense plan, which includes the following:		
	 A vulnerability assessment identifying significant vulnerabilities and actionable process steps 		
	 Mitigation strategies appropriate to reduce the vulnerability 		
	 Procedures for food defense monitoring, corrective action and verification 		
13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum):		
	 Scale and severity of threat if a contaminant is added to product 		
	 Degree of physical 		

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	access to the product		-	
	Ability of an attacker to successfully contaminate product—including consideration of an inside attacker			
	A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.			
13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.			
13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food			

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	defense mitigation strategies.			
	Procedures shall include recordkeeping requirements for all monitoring activities.			
13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria:			
	 Method for identifying and correcting a lack of implementation 			
	 Method for reducing the likelihood of recurrence 			
	 Recordkeeping requirements for corrective actions 			
13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation procedures.			
	Verification procedures shall include: • A review of			
	monitoring and corrective action records within an			

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	appropriate timeframe (e.g., 7 days) Other verification activities as appropriate (e.g., internal audit) Method for verifying that reanalysis of the food defense plan was conducted		
	 Frequency for verification activities Recordkeeping 		
	requirements of all verification activities		
13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever		
	A change in facility operations which creates a new significant vulnerability		
	Knowledge about a new threat applicable to the food or facility becomes known		
	 Mitigation strategies are not implemented as intended 		
	FDA requires reanalysis		1-
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	based on new threats or scientific evidence		
13.3.9	All records required by 21 CFR § 121 must include: Date and time of activity being documented Signature/ initials of individual performing activity or conducting record review Information to identify the facility (e.g., name and location) Identity of the product and lot code where applicable		
13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.		
13.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food		

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	defense plan, which must remain onsite.		
13.4.1	Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used. A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall		
13.4.2	be recorded. 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		

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	conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.		
13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier.		
	Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.		
13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.		
13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall		

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	conduct an assessment		
	to determine whether		
	the food was subject to		
	temperature abuse.		
13.4.6	Contracts with carriers		
10.1.0	shall specify that the		
	carrier is responsible		
	for the following		
	sanitary activities		
	where agreed to in		
	writing with shipper.		
	Sanitary		
	condition of		
	vehicles and		
	transportation		
	equipment		
	 Following 		
	shipper's		
	sanitary		
	specifications		
	(including pre-		
	cooling		
	requirements		
	where		
	applicable)		
	 Recording 		
	compliance		
	with operating		
	temperature		
	where critical to		
	food safety		
	,		
	 Procedures for 		
	the use of bulk		
	vehicles, which		
	includes		
	recording the		
	previous cargo		
	and most		
	recent cleaning		
	for the shipper		
13.4.7	Contracts with carriers		
	shall specify that the		
	carrier implements a		
	training program for all		
	personnel engaged in		
	transportation activities,		
	which covers		
	 Awareness of 		
	potential food		
	safety		
		I.	

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	problems that may occur during food transportation Basic sanitary transportation practices to address those potential problems Responsibilities of the carrier		
13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.		
13.4.9	The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.		
13.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following: Principles of food hygiene and food safety		

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	Produce safety standards applicable to an individual's job		
13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following:		
	 Recognizing produce contaminated with known or reasonably foreseeable hazards 		
	Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards		
	 Correcting problems with harvest containers or equipment 		
13.5.3	One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.		
13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with		

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	Produce Safety regulation. This individual shall be identified on the site's organizational chart.		
13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.		
13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the		
	water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.		
13.5.7	Agricultural water treatment must be delivered and monitored at a		

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	frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.		
13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.		
13.5.9	Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria.		
	Where water treatment is not performed, reinspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.		
13.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's		

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	panel .		
	water source is secured.		
	Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA-821-R-09-007)," December, 2009 or equivalent method.		
13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water.		
	Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris).		
	Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.		

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13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.			
13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.			
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.			
13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.			
13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created.			
	Where records are stored offsite, they must be retrievable within 24 hours.			
	Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and			

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	evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts.		
	Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes.		
	The environmental monitoring plan shall include the following criteria:		
	 Target test (i.e., Listeria spp. or L. mono) 		
	 Sample frequency (no less monthly) 		
	Sample timing (i.e., when in the process are samples collected)		
	Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces)		
	The plan shall describe aseptic methods for		

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	sample collection and testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent).		
13.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts.		
	The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono.		
	If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process:		
	 Resample positive surfaces and the surrounding area to determine the extent of contamination 		
	 Clean and sanitize the affected and surrounding areas 		
	Resample and re-test to confirm the elimination of Listeria spp. or L. mono		

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•	Conduct finished product testing as appropriate	
•	Take additional action to prevent recurrence and to prevent adulterated food from entering commerce	

14.1 Additional Specifier requirements

14.1 Traceability

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14.2 Environmental Monitoring

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14.3 Product inspection and laboratory testing

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14.4 Protective clothing: Employees or visitors to production areas

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