United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW.
Washington, D.C. 20250

March 5, 2024

Dr. Wim Pelgrim
Chief Veterinary Officer
Ministry of Agriculture, Nature and Food Quality
Department of Food, Animal Health and Welfare and Consumer Affairs
2500 EK The Hague/2595 AJ The Hague
The Netherlands

Dear Dr. Pelgrim,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of the Netherlands' inspection system June 26–July 11, 2023. Enclosed is a copy of the final audit report. The comments received from the Government of the Netherlands are included as an attachment to the report.

Sincerely,

MARGARET BURNS RATH

Digitally signed by MARGARET BURNS RATH
Date: 2024.03.05 17:03:59 -05'00'

Margaret Burns Rath, JD, MPH
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF THE

NETHERLANDS

JUNE 26–JULY 11, 2023

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

VEAL AND PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

February 28, 2024

Food Safety and Inspection Service
U.S. Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of the Netherlands conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) June 26–July 11, 2023. The purpose of the audit was to verify whether the Netherlands' food safety inspection system governing pork and veal products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. The Netherlands currently exports thermally processed, commercially sterile pork; raw intact pork; and raw intact veal to the United States.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- The Central Competent Authority, Netherlands Food and Consumer Product Safety Authority (NVWA), allows calves identified during ante-mortem inspection as non-ambulatory disabled (NAD) for noninfectious disease-related conditions (e.g., injury during transportation) to be slaughtered and dressed on the same slaughter line and at the same time as calves that are eligible for export to the United States. However, NVWA prohibits meat derived from NAD calves to be exported to the United States.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- Two-point sampling (pre-evisceration/post-chill) was not conducted at the audited swine slaughter establishments in a manner consistent with the NVWA's written requirements.
- The audited microbiological laboratory was not analyzing the entirety of N60 samples associated with the government verification program for Shiga toxin-producing *Escherichia coli* (STEC) in raw veal products. This may affect the accuracy of test results.

During the audit exit meeting, NVWA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of NVWA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of the Netherlands' food safety inspection system June 26–July 11, 2023. The audit began with an entrance meeting June 26, 2023, in Utrecht, Netherlands, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA)—Netherlands Food and Consumer Product Safety Authority (NVWA). The audit concluded with an exit meeting conducted remotely via video conference July 11, 2023. Representatives from NVWA accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection system governing pork and veal products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Verification of NVWA's egg products inspection system was not included in the scope of this audit because the Netherlands has not exported egg products to the United States since the previous FSIS audit in 2021.The Netherlands is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Beef	Veal - All Products Eligible except Advanced Meat Recovery Product (AMR); Finely Textured Beef (FTB); Partially Defatted Chopped Beef (PDCB); Partially Defatted Beef Fatty Tissue (PDBFT); and Low Temperature Rendered Product
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product (AMR)
Raw - Intact	Raw Intact Beef	Veal - All Products Eligible
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Thermally Processed - Commercially Sterile (TPCS)	Thermally Processed, Commercially Sterile	Pork - All Products Eligible
Heat Treated - Not Fully Cooked - Not Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Meat	Pork - All Products Eligible

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

Process Category	Product Category	Eligible Products[1]
Eggs/Egg Products[2]	Egg Products	Poultry - All Products Eligible except Unpasteurized (Frozen or Liquid) and (Tanker/Large Tote) egg products (blends of whole egg, egg whites, and/or yolks, with/without added ingredients), egg whites (with/without added ingredients), whole egg (with/without added ingredients), and yolk (with/without added ingredients).

The USDA's Animal and Plant Health Inspection Service (APHIS) disease status for the Netherlands is as follows: veal imported from the Netherlands is subject to foot-and-mouth disease (FMD) requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.11 and bovine spongiform encephalopathy requirements specified in 9 CFR 94.18 or 9 CFR 94.19. Pork imported from the Netherlands is subject to African swine fever requirements specified in 9 CFR 94.8, classical swine fever requirements specified in 9 CFR 94.31, swine vesicular disease requirements specified in 9 CFR 94.13, and FMD requirements specified in 9 CFR 94.11.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed the Netherlands' Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews and reviewed records to verify whether the Netherlands' food safety inspection system governing pork and veal products is being implemented as documented in the country's SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from NVWA through the SRT.

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard

[2] Currently, the Netherlands is not exporting egg products to the United States.

Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at NVWA headquarters, and eight local inspection offices within the establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of 8 establishments was selected from a total of 12 meat establishments certified to export to the United States. This included three swine slaughter and processing establishments; one veal slaughter and processing establishment; one veal processing establishment; and three pork processing establishments. The products these establishments produce and export to the United States include thermally processed - commercially sterile (TPCS) pork, raw intact pork, and raw intact veal.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed NVWA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditors also audited one government-operated laboratory that conducts chemical residue and microbiological analyses to verify that the laboratory is capable of providing adequate technical support to the food safety inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• The Netherlands Food and Consumer Product Safety Authority (NVWA), Utrecht
Laboratory (government microbiological and residue)		1	• Wageningen Food Safety Research (WFSR), Wageningen
Veal slaughter and processing establishment		1	• Establishment No. NL 9 EG, EKRO B.V., Apeldoorn
Veal processing establishment		1	• Establishment No. NL 939 EG, T. Boer en Zonen B.V., Nieuwerkerk aan den Ijssel
Swine slaughter and processing establishments		3	• Establishment No. NL 61 EG, Vion Boxtel B.V., Boxtel • Establishment No. NL 312 EG, Vion Apeldoorn B.V., Apeldoorn • Establishment No. NL 367 EG, Vion Groenlo B.V., Groenlo
Pork processing establishments		3	• Establishment No. NL 82 EG, Vion Scherpenzeel B.V., Scherpenzeel • Establishment No. NL 129 EG, Van der Laan (Zwanenberg Food Group), Almelo • Establishment No. NL 153 EG, Lupak (Zwanenberg Food Group), Raalte

FSIS performed the audit to verify that the Netherlands' food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code (U.S.C.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1907); and
- The Meat Inspection Regulations (9 CFR parts 301 to the end).

The audit standards applied during the review of the Netherlands' inspection system for pork and veal products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From March 1, 2020 to February 28, 2023, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 53,676,070 pounds of meat from the Netherlands. This included 1,076,204 pounds of TPCS pork; 34,527,039 pounds of raw intact pork; and 18,072,827 pounds of raw intact veal exported by the Netherlands to the United States.

Of these amounts, additional types of inspection were performed on 6,217,417 pounds of meat (264,633 pounds of TPCS pork; 4,158,708 pounds of raw intact pork; and 1,794,076 pounds of raw intact veal). These additional types of inspection included physical examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens (Shiga toxin-producing *Escherichia coli* [STEC] serogroups O157, O26, O45, O103, O111, O121, and O145 in raw veal products). As a result of this additional testing, no products were rejected for issues related to public health. An additional 99,844 pounds of pork and 31,816 pounds of veal were refused for other issues not related to public health including shipping damage, labeling, or other miscellaneous issues.

The previous FSIS audit conducted in 2021 identified the following findings:

Summary of Findings from the 2021 FSIS Audit of the Netherlands
Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System
• NVWA did not document its verification of validation studies (scientific support and execution/data collection components) for two processing establishments it certified to export raw veal or NRTE pork products to the United States.
Component 6: Government Microbiological Testing Programs
• Corrective actions taken in response to the prior (2019) FSIS audit finding concerning testing for STEC in raw veal products were incomplete. While the assigned government laboratory, Wageningen Food Safety Research, has modified its procedures to ensure that all 60 pieces of the sample are tested, the laboratory's standard practice is to trim individual pieces to a final weight of 330g when the total sample weight for 60 pieces is

greater than 330g. The remaining portions of these trimmed pieces are not being tested, which may affect the accuracy of the results.

The FSIS auditors verified that the corrective actions for the previously reported findings related to Component 4 were implemented and effective in resolving the findings. However, a similar finding regarding the incomplete analysis of N60 samples for STEC was identified and documented under Component 6 of this report.

The FSIS final audit reports for the Netherlands' food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

The first equivalence component the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

NVWA is the CCA responsible for safeguarding the health of animals and plants, animal welfare, and the safety of food and consumer products. NVWA provides official oversight during imports and exports, inspection, certification, granting approvals, and tasks in the context of monitoring plants and animals. It also verifies rules concerning primary production on farms, and thus monitors the whole production chain, from raw materials and processing to end products and consumption. The FSIS auditors verified that there have been no significant changes in the organizational structure of NVWA since the last FSIS audit in 2021.

NVWA supervision in the meat sector consists of inspection oversight, annual audits of establishments certified to export to the United States, and at least a quarterly audit of inspection activities in each establishment. Within the Netherlands, all meat establishments certified to export to the United States are directly supervised by official veterinarians (OV) and veterinary assistants (VA). These individuals are NVWA employees and are responsible for conducting daily verification activities apart from post-mortem inspections. Official auxiliaries who are employed by Kwaliteitskeuring Dierlijke Sektor (KDS) carry out post-mortem inspection for red meat under the direct onsite supervision of the OVs.

The FSIS auditors verified through interviews and record reviews that OVs and VAs, as civil servants, are paid and hired by the government of the Netherlands. OVs perform ante-mortem inspection, evaluate the performance of KDS inspection personnel, and make final veterinary dispositions on retained carcasses and viscera. The FSIS auditors confirmed that all OVs must have a doctor of veterinary medicine or equivalent degree, and VAs must have specialized experience or education that allows them to perform their assigned duties.

The FSIS auditors verified through record reviews and interviews that government inspection personnel receive training on topics relevant to their assignment. Key topics include animal welfare; ante-mortem inspection; post-mortem inspection; sanitation standard operating procedures (Sanitation SOP); sanitation performance standards (SPS); HACCP; labeling verification; export certification; separation of product intended for export to the United States; control over condemned materials; official government sample collection practices; and enforcement of FSIS import requirements.

At the eight visited establishments, the FSIS auditors verified through record reviews and interviews that NVWA's staffing program is sufficient to ensure an effective level of oversight is maintained. Government inspection personnel conduct inspection activities at least once per shift for processing establishments and complete offline verification procedures, whereas KDS inspection personnel conduct post-mortem inspection of every carcass, head, and viscera during slaughter operations in establishments certified to produce pork and veal products for export to the United States.

NVWA has the legal authority and responsibility to certify and decertify establishments as eligible to export products to the United States. A slaughter establishment is certified through the following process: an establishment applies for certification, an offsite audit of the establishment's written programs is conducted, and, if the result is acceptable, an onsite audit is conducted. A second onsite audit is conducted after the establishment is permitted to operate and document their programs as implemented. If the second onsite audit is acceptable, the establishment is then considered certified as eligible to export to the United States. The certification of a processing or cold storage establishment follows a similar process but has only one onsite audit after which it may be certified as eligible if the results are satisfactory.

As a European Union (EU) Member State, the Netherlands has adopted European Commission (EC) Regulation (EC) No. 178/2002 regarding the definition of adulterated and misbranded products. This regulation includes requirements related to the responsibilities of establishments; product traceability; the withdrawal, recall, and notification for food and feed in relation to food and feed safety; and imports and exports. Establishments bear the legal responsibility to market safe and unadulterated products only and must recall any adulterated product that has entered commerce. The FSIS auditors verified that the visited establishments have a recall plan in place and can trace products forward in the event of a recall, as required by NVWA.

NVWA is responsible for managing food safety emergencies, including monitoring the corrective actions and preventive measures taken, and initiating a Rapid Alert System for Food and Feed (RASFF) notification. In the event a product is determined to be adulterated, Commission Implementing Regulation (EU) 2019/1715 stipulates the duties of the RASFF network members and defines the different types of notifications classified according to risks. It provides for a 24/7 on-duty permanence of the system and tasks the commission with verifying the RASFF notifications and informing countries outside the EU. The regulation requires member states to transmit alert notifications within 48 hours of the risk being reported to them and for the Commission to transmit them within 24 hours of receiving them.

The FSIS auditors confirmed that NVWA ensures that product eligible for export to the United States is not commingled with domestic or other products that are not eligible for export to the United States. Additionally, the FSIS auditors confirmed that, in accordance with requirement RL-159, NVWA ensures that source materials used in processing operations originate only from establishments certified to export to the United States.

During export certification, NVWA inspection personnel perform randomized inspection to verify that all FSIS import requirements are met. These requirements are described in NVWA instruction RL-159. NVWA remotely certifies an export consignment based on the information provided by the local government inspection personnel and the establishment personnel allowing product to be exported. The FSIS auditors reviewed the export certification process and documents and did not identify any concerns.

The FSIS auditors verified through record reviews and interviews that NVWA receives and reacts accordingly to results of laboratory testing and has procedures in place to notify FSIS of the shipment of adulterated products. Further, NVWA has the ability to take enforcement actions if a certified establishment does not meet its requirements. The FSIS auditors verified that certification of product for export does not occur until the results of microbiological testing, conducted in conjunction with either establishment or government testing programs, are received as acceptable. In addition, the FSIS auditors observed at the visited establishment that all product tested in conjunction with the national residue program or establishment independent testing was precluded from export to the United States.

The FSIS auditors verified through record reviews and interviews that NVWA has adequate oversight of WFSR, the government laboratory performing analyses for official sampling and testing programs for veal and pork products exported to the United States. This laboratory is accredited consistent with International Organization for Standardization (ISO)/International Electrotechnical Commission Guide (IEC) 17025 standards. The FSIS auditors reviewed the most recent accreditation report available for WFSR and confirmed that any identified findings were addressed in a timely manner.

Test results of official samples are stored in the digital system of WFSR and published on a special drive for laboratory results of NVWA. NVWA informs government inspection personnel at establishments certified to export to the United States of official testing results and initiates appropriate follow up in response to positive results. The FSIS auditors verified that official sample collection, handling, delivery, and receipt in WFSR comply with general quality assurance requirements. At sample receipt, the laboratory verifies that the seal is intact and matches the number on the laboratory submission form. Once the laboratory verifies and documents the temperature of the sample and confirms sample integrity, a unique laboratory sample number is assigned; the laboratory rejects the sample if these requirements are not met. Only the assigned laboratory sample number accompanies the sample through the analytical process to eliminate any potential bias. Laboratory personnel store the samples in accordance with the laboratory’s standard operating procedures.

The FSIS analysis and verification activities indicated that NVWA's pork and veal products inspection system has an organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second equivalence component the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of all animals; post-mortem inspection of every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The Netherlands implements a Supply Chain Inspection System, which uses a combination of pre-slaughter data and post-mortem inspection information that is relevant for meeting requirements in slaughter operations. The Supply Chain Inspection System ensures that animals arriving at the slaughter facilities can be traced back to the farms they originate from and have the appropriate health certificates. This ensures the OV is able to confirm any requirements for disease statuses outlined by APHIS.

In accordance with Regulation (EU) 2017/625, NVWA ensures that government inspection personnel perform ante-mortem inspection of all livestock prior to slaughter. The OVs perform ante-mortem inspection, make decisions concerning live animals, and supervise the arrival of animals at the slaughter establishment. NVWA requires OVs to examine animals for clinical signs of systemic disease as outlined in procedure K-RV-AM-WV04. Animals which are ineligible for slaughter according to procedure K-RV-AM-WV04 are to be declared unfit for human consumption (condemned) and euthanized separately to ensure that other animals or carcasses are not contaminated. However, the FSIS auditors identified a conflict between these written standards and FSIS requirements related to the segregation of non-ambulatory disabled (NAD) calves at slaughter establishments:

- NVWA allows calves identified during ante-mortem inspection as NAD for noninfectious disease-related conditions (e.g., injury during transportation) to be slaughtered and dressed on the same slaughter line and at the same time as calves that are eligible for export to the United States. However, NVWA prohibits products derived from NAD calves to be exported to the United States.

The Netherlands implements Council Regulation (EC) No. 1099/2009 related to the protection of animals at the time of slaughter. This regulation is consistent with FSIS animal welfare requirements and NVWA's requirement WLZVL-017. The FSIS auditors confirmed through interviews and record reviews that NVWA was verifying animal protection requirements at the time of delivery and during slaughter operations. OVs stationed at certified slaughter establishments are responsible for monitoring compliance with animal protection requirements. The FSIS auditors verified that government inspection personnel were conducting daily

inspections related to animal welfare and documenting their findings in an electronic inspection system. If OVs identify nonconformities with the humane handling requirements during ante-mortem inspection or periodically during operations from receipt of transported animals to slaughter, the OV is to notify the establishment of the nonconformity and can take enforcement actions outlined in NVWA's requirement WLZVL-017.

The FSIS auditors verified that government inspection personnel perform post-mortem inspection at the time of slaughter in accordance with the NVWA's requirements. In the swine and veal slaughter establishments, KDS inspection personnel may conduct visual inspection of every carcass, head, and viscera according to the equivalent alternative post-mortem inspection procedure for market hogs and veal calves. For both post-mortem inspection systems, the FSIS auditors verified that every carcass, head, and viscera are inspected by KDS or NVWA inspection personnel. The verification activities conducted during ante-mortem and post-mortem inspection ensure that visually inspected carcasses and organs are wholesome and not adulterated. No concerns were identified.

As per requirement RE-36, NVWA performs team leader conformity assessments (Supervision 1) of the registered establishments at least quarterly. These assessments by NVWA verify the OV and establishment conformance to EU and Dutch requirements, and FSIS import requirements. NVWA also performs an internal audit (Supervision 2) of the effectiveness of NVWA supervision and reports findings approximately every three months. The FSIS auditors verified that NVWA headquarters has the direct linkage to establishments certified to export to the United States through access to supervisory reports and results of inspection procedures which are documented in an electronic system.

Through interviews and record reviews, the FSIS auditors confirmed that government inspection personnel routinely verify the identification, removal, and disposal of specified risk materials (SRM) in veal slaughter and processing establishments. NVWA follows Regulation (EC) No. 999/2001, which defines SRMs as the tonsils, the last four meters of the small intestine, the caecum, and mesentery of animals of all ages. Additionally, NVWA's requirement K-RV-PM-WV03-TSE, classifies the intestine from the duodenum to the rectum, the mesentery, and the tonsils as SRMs in veal. As indicated previously, NVWA mandates (through RE-31) that NAD calves be excluded from exports to the United States.

NVWA implements the requirements of Regulation (EC) No. 1069/2009 regarding the classification of animal by-products into three categories not intended for human consumption. NVWA requires the establishments to segregate and store inedible products (including SRMs) in a separate area from edible products. In addition, containers used for collecting inedible products must be conspicuously marked and distinguished from other containers. The FSIS auditors verified through interviews and record reviews that after ante-mortem and post-mortem inspections, all animal by-products that are deemed unfit for human consumption (condemned animals, parts, and inedible materials) are subject to administrative seizure, and collected for disposal or use pursuant to Regulation (EC) No. 1069/2009. Government inspection personnel stationed at the certified slaughter establishments carry out daily checks of inedible and condemned materials disposition. Animal by-product disposition is also assessed and verified at least once per year during the quarterly supervisory visits.

In accordance with RE-31, NVWA requires certified establishments to develop and implement a species monitoring program for meat products intended for export to the United States. According to RL-159, to be eligible and certified for export to the United States, NVWA requires its OVs to ensure that pork and veal products meet FSIS requirements. OVs are to ensure that establishments certified to export to the United States have complied with set controls to ensure that declarations made on the export certificate have been met.

The FSIS auditors concluded that NVWA continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control using statutory authority consistent with criteria established for this component. However, the FSIS auditors identified a conflict between NVWA ante-mortem procedures and FSIS requirements related to the segregation of NAD calves at slaughter establishments.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written Sanitation SOP to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS and sanitary dressing.

The EC legislation outlines the criteria and standards for good hygiene practices. The legislation also requires the CCA in each EU member state to be responsible for enforcing the EC food regulations by maintaining a system of official controls and other verification activities appropriate to each situation. Chapter IV of Regulation (EC) No. 853/2004 describes the requirements for sanitary dressing (slaughter hygiene) of livestock throughout the slaughter operations. Chapter IV, Section I of Regulation (EC) No. 853/2004, states that the carcass must not contain visible fecal contamination and that any visible contamination must be removed immediately by trimming or alternative means. To eliminate the presence of STEC on meat surfaces, food business operators need to prevent fecal contamination. If fecal contamination occurs, the food business operator shall immediately remove the contamination appropriately.

Through interviews and record reviews, the FSIS auditors verified that government inspection personnel routinely verify that establishments implement sanitary dressing procedures throughout the slaughter process in accordance with the instructions provided by NVWA's Meat Chain Improvement Plan which provides a uniform method for controlling and verifying the hygienic slaughter and absence of fecal contamination on carcasses. In addition, NVWA's RE-36 requires slaughter establishments to have a critical control point (CCP) for fecal contamination, and nonconformities and corrective actions must be documented on a noncompliance report.

The FSIS auditors verified that NVWA requires sanitary dressing procedures of livestock at slaughter establishments. Through interviews and record reviews, the FSIS auditors verified that the audited slaughter establishments had implemented sanitary procedures to prevent potential carcass contamination throughout the process, including sanitary procedures to prevent carcass contamination during hide removal, direct contact between carcasses during dressing procedures, and carcass contamination with gastrointestinal contents during

evisceration. OVs conduct daily verification of sanitary dressing procedures. The FSIS auditors did not identify any concerns with NVWA's verification activities for sanitary dressing procedures.

NVWA follows Regulation (EC) No. 852/2004 to maintain official controls over establishment construction, facilities, and equipment. Annexes II and III of Regulation (EC) No. 852/2004 stipulate that food premises are to be kept clean and maintained in good repair and condition. The layout, design, and construction of the establishment facilities must permit adequate maintenance to prevent conditions that can lead to insanitary conditions. Equipment and utensils must be maintained in a sanitary manner. The program includes requirements pertaining to sanitary performance standards and hygienic design of equipment and facilities.

NVWA's RE-31 requires establishments to perform daily sanitation inspection and when deficiencies are identified, establishments must take corrective actions and preventative measures sufficient to prevent product contamination. NVWA also requires establishments certified to export to the United States to develop, implement, and maintain daily pre-operational and operational sanitation plans to prevent the direct contamination or adulteration of meat products designated for export to the United States. NVWA's RE-36 requires government inspection personnel to perform pre-operational and operational sanitation inspection daily in slaughter establishments and weekly in processing establishments. Government inspection personnel must monitor production during all shifts in which veal and pork products are produced for export to the United States.

The FSIS auditors confirmed through record reviews and interviews that government inspection personnel are verifying implementation of pre-operational and operational Sanitation SOP in accordance with NVWA's requirements. Inspection verification activities include document reviews, observations, and hands-on inspections. The FSIS auditors also reviewed a sample of noncompliance reports generated by government inspection personnel to verify that they had identified deficiencies during pre-operational and operational verification activities. The government inspection personnel closed noncompliance reports after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures.

The FSIS auditors assessed the adequacy of the pre-operational inspection verification by observing in-plant government inspection personnel conducting pre-operational sanitation verification inspection. The in-plant government inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the in-plant government inspection personnel's pre-operational sanitation verification inspection.

FSIS onsite audit verification activities indicate that NVWA requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs to ensure that the establishment's construction, facilities, and equipment prevent the contamination or adulteration of meat products destined for export to the United States. The FSIS auditors observed isolated noncompliances related to the inspection verification of sanitation requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

The fourth equivalence component the FSIS auditors reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

Regulations (EC) No. 852/2004 and 853/2004 and NVWA's RE-31 require establishments certified to export to the United States to develop, implement, and maintain a HACCP plan. NVWA requires establishments exporting to the United States to develop and implement a HACCP program. NVWA periodically audits the HACCP system of establishments certified to export to the United States and conducts at least two onsite audits annually of slaughter establishments and one onsite audit of cutting and processing establishments.

The FSIS auditors verified that establishments' HACCP programs include written hazard analysis, flow charts, and HACCP plans to identify, evaluate, and prevent or control food safety hazards in their production processes. The HACCP plans included activities designed to validate adequacy of controls, to conduct monitoring and verification procedures, and to document the results of monitoring and verification activities as well as implementation of corrective actions, if needed.

The FSIS auditors conducted an onsite observation and document review of CCPs in all the audited establishments, including the zero tolerance (for feces, ingesta, and milk contamination) records generated in the audited establishments. At each slaughter establishment, the FSIS auditors observed the establishment personnel conducting hands-on HACCP monitoring and verification activities for the zero tolerance CCP. The FSIS auditors also reviewed the establishment and the in-plant government inspection personnel's zero tolerance records. The FSIS auditors reviewed records and verified that the establishments took appropriate corrective actions in response to any deviations from their critical limits. Furthermore, the FSIS auditors confirmed at all audited establishments that the physical location of the zero tolerance CCP verification for both the establishment personnel and in-plant government inspection personnel is after the final post-mortem inspection station and in accordance with NVWA's requirements which are consistent with FSIS requirements.

The FSIS auditors verified that veal slaughter and processing establishments certified as eligible to export to the United States addressed contamination of carcasses with STEC within the context of their HACCP system. In addition, each establishment had controls in place to ensure that carcasses were chilled in a manner sufficient to prevent the outgrowth of microbial pathogens. Furthermore, the audited establishments have implemented microbiological testing for indicator organisms (aerobic plate count and Enterobacteriaceae) in carcass samples and STEC in beef trimmings to support their hazard analysis. The FSIS auditors' interviews and document reviews of both establishment microbiological sampling and testing programs and inspection verification procedures in relation to implementation of establishments' indicator organism and STEC microbiological testing programs did not identify any concerns.

The FSIS auditors verified that NVWA has verification activities in place for the establishments producing TPCS products. Establishments are required to have a HACCP plan for the thermal processing step addressing microbiological concerns that include time and temperature. The establishments that produce TPCS products certified by NVWA for export to the United States utilize a HACCP system, with a validated HACCP plan for the thermal process.

NVWA's requirement RE-31stipulates that establishments certified to export to the United States must have a written procedure requiring that every batch of finished product is to receive a pre-shipment review inspection which includes verifying that CCPs have been met. The pre-shipment review inspection must be signed by the plant authority. RE-31 stipulates that any lot associated with a non-negative result, or potentially in contact with a lot with a non-negative result, is ineligible for export to the United States. NVWA requires establishments certified to export to the United States, as part of their HACCP system, to hold any production lot that was sampled for STEC until an acceptable result is ascertained. Furthermore, the HACCP plan at establishments certified to export to the United States is to include and define all the corrective and preventive actions taken in the event of a positive result.

The FSIS auditors identified isolated establishment noncompliance related to the support for hazard analysis decisions and HACCP recordkeeping requirements. These findings are noted in the individual establishment checklist provided in Appendix A of this report. The FSIS onsite verification activities indicate that NVWA requires establishments to develop, implement, and maintain a HACCP system for each processing category. FSIS concludes that NVWA continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

Regulation (EU) 2017/625, Regulation (EC) No. 178/2002, and Commission Implementing Regulation (EU) 2022/1646 mandate the development, content, implementation and reporting of a national chemical residue control program, which includes random and targeted sampling for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants. These EU legislations require the Netherlands to design and submit an acceptable residue plan annually for evaluation that follows EU guidelines. NVWA is responsible for the coordination of the drafting and implementation of the National Residue Control Plan (NRCP). NVWA determines the number of samples to be taken. WFSR develops the sampling allocation for the NRCP and issues sampling requests to NVWA inspection personnel responsible for sampling meat products. To ensure compliance with maximum residue levels recognized by FSIS, NVWA currently does not permit meat from carcasses tested under the NRCP to be exported to the United States.

The FSIS auditors confirmed the NRCP includes the number of samples for each species, as well as locations for samples to be taken, including during the primary production phase (farm) and at the slaughter establishment. Results of laboratory analysis are reported to NVWA headquarters. Results are evaluated in accordance with Regulation (EU) 2017/625, which identifies banned substances (substance group A) with zero tolerance levels and substances with maximum residue levels (substance group B) permitted in foodstuffs. The follow-up of non-compliant samples is performed by the Livestock Department within NVWA. The FSIS auditors confirmed that the Netherlands' enforcement programs include: (1) procedures to document the disposition of contaminated product, (2) enforcement action against violators, and (3) measures to prevent recurrence of the same or similar violations.

The FSIS auditors verified through interviews and record reviews that government inspection personnel collect routine residue samples and OVs may choose to collect additional targeted residue samples based on dispositions made during ante-mortem or post-mortem inspections. All residue samples are transported by NVWA employees to WFSR.

The results of the onsite audit activities indicate that NVWA continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in pork and veal products destined for export to the United States. There have not been any POE violations related to this component since the last FSIS audit in 2021.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat prepared for export to the United States are safe and wholesome. This component also addresses requirements for TPCS meat products.

The FSIS auditors verified that NVWA requires all slaughter establishments certified to export product to the United States to collect and analyze carcass samples for indicator organisms in accordance with Annex I, Chapter 2, Sections 2.1.1 (cattle) and 2.1.2 (swine) of Commission Regulation (EC) No. 2073/2005. NVWA also has specific requirements for swine slaughter establishments certified to export to the United States, described in RE-31, which indicate that swine slaughter establishments must implement indicator organism testing using two-point sampling locations (at pre-evisceration and at post-chill) to monitor the effectiveness of the process control for enteric pathogens. NVWA's requirement RE-31 instructs slaughter establishments to either a) conduct two-point sampling procedures as described by FSIS (referencing 9 CFR 310.18); or b) monitor the effectiveness of process control with an alternative method providing a comparable level of public health protection. The FSIS auditors observed that while post-chill sampling was performed at a frequency consistent with 9 CFR 310.18 (1 sample/1,000 carcasses), pre-evisceration sampling was performed at a much lower frequency (approximately 20 samples/twice per year). Furthermore, the NVWA has not submitted documentation to FSIS demonstrating that the use of this alternative sampling and testing frequency provides a comparable level of public health protection.

- Two-point sampling (pre-evisceration/post-chill) was not conducted at the audited swine slaughter establishments in a manner consistent with the NVWA's written requirements.

In addition to requirements for establishment testing, NVWA performs a microbiological examination for aerobic colony count and Enterobacteriaceae of 10 randomly selected carcasses at a frequency of twice per year at all slaughter establishments certified to export products to the United States. NVWA also implements a verification testing program for *Salmonella* on carcasses in veal and swine slaughter establishments which includes equivalent performance standards, as outlined in requirements RE-29 and RE-30.

NVWA's RE-33 outlines the official verification testing program for STEC at veal slaughter and processing establishments certified to export raw veal products to the United States. This document further specifies that all veal products contaminated with STEC are ineligible for export to the United States. In accordance with the requirements outlined therein, the FSIS auditors verified that government inspection personnel conduct STEC verification sampling of veal products at a minimum frequency of at least four times per month. Samples are randomly selected and collected from all shifts the establishment operates and sent to WFSR for analysis. Establishments are required to hold and maintain control of the sampled lot for raw veal products until results are reported as negative for STEC.

The above referenced documents describe the sampling procedures and instructions for government inspection personnel regarding sampling frequency, collection sites on swine and veal carcasses, randomized selection, sampling techniques, submission of samples to the designated laboratory, laboratory testing methods, interpretation of test results, and enforcement strategies. Samples for official NVWA programs are collected by government inspection personnel and analyzed at the official laboratory.

The FSIS auditors interviewed personnel at WFSR regarding analytical methods for official NVWA sampling programs. This laboratory conducts analytical testing, including *Salmonella* and STEC, for official verification of products destined for export to the United States. These interviews included review of records for each phase of the analytical process, including sample receipt, application of equivalent testing methods, and reporting of results for these pathogens. During interviews, the FSIS auditors identified that the laboratory does not analyze the entire 60 pieces as required by the N60 testing methodology when the sample portion collected for STEC is greater than the size of the prescribed test portion in the laboratory analytical method.

- The audited microbiological laboratory was not analyzing the entirety of N60 samples associated with the government verification program for Shiga toxin-producing *Escherichia coli* (STEC) in raw veal products. This may affect the accuracy of test results.

Annex 2, Chapter XI of Regulation (EC) No. 852/2004 defines TPCS product as product subjected to heat treatment under specified time and temperature parameters and placed on the market in hermetically sealed containers. The FSIS auditors interviewed government inspection personnel regarding verification activities and reviewed related documentation addressing

process schedules for products exported to the United States; procedures to address operations (e.g., posting of processes, retort traffic control, initial temperature) in thermal processing areas; incubation records; retort heat distribution tests; and procedures to ensure proper closure of containers, including training of closure technicians. No concerns were identified.

The FSIS auditors found that NVWA's pork and veal inspection system has a microbiological testing program organized and administered by the national government, and that NVWA has implemented the necessary sampling and testing programs to verify the effectiveness of its system. While NVWA's program includes microbiological sampling requirements that are equivalent to United States standards, the FSIS auditors identified deficiencies related to microbiological testing practices that could potentially impact the accuracy of results.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held July 11, 2023, by videoconference with NVWA. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- NVWA allows calves identified during ante-mortem inspection as NAD for noninfectious disease-related conditions (e.g., injury during transportation) to be slaughtered and dressed on the same slaughter line and at the same time as calves that are eligible for export to the United States. However, NVWA prohibits products derived from NAD calves to be exported to the United States.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- Two-point sampling (pre-evisceration/post-chill) was not conducted at the audited swine slaughter establishments in a manner consistent with the NVWA's written requirements.
- The audited microbiological laboratory was not analyzing the entirety of N60 samples associated with the government verification program for Shiga toxin-producing *Escherichia coli* (STEC) in raw veal products. This may affect the accuracy of test results.

During the audit exit meeting, NVWA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of NVWA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
EKRO B.V. Apeldoorn	06/29/2023	NL9EG	Netherlands
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	X
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Veal slaughter and processing.
Prepared Products:	Raw intact beef (veal): primals/subprimals, edible offal, trimmings

60. Observation of the Establishment

The following non-compliances were not identified by the Netherlands' inspection officials during the establishment review:

12. The establishment’s written program did not specifically address the requirement to document “the disposition of product” as a part of corrective actions taken in response to operational SSOP deviations.

22. a) Establishment monitoring records for the zero tolerance CCP addressing the presence of ingesta and feces on veal carcasses did not include a description of the specific type of contamination identified when a deviation from the CCP occurred. b) Establishment records documenting ongoing verification activities did not include the time that each specific event occurred (e.g., direct observation of monitoring, or review of records).

In addition, FSIS identified the following findings related to the implementation of the Netherlands' inspection system:

48. Veal calves identified during ante-mortem inspection as non-ambulatory for certain noninfectious disease-related conditions (e.g., transportation injury) may be slaughtered on the same slaughter line and at the same time as calves that are eligible for export to the United States. However, non-ambulatory disabled calves are segregated after the slaughter process and are not eligible for export to the United States.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/29/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Vion Boxtel B.V. Boseind 10 Boxtel	07/03/2023	NL61EG	Netherlands
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork: primals and sub-primals, cuts, edible offal

60. Observation of the Establishment

The following non-compliances were not identified by the Netherlands' inspection officials during the establishment review:

16. Establishment monitoring records for the "zero tolerance" CCP (pork carcasses) did not include a description of the specific type of contamination identified (e.g., feces or ingesta) when a deviation from the CCP occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/03/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Vion Scherpenzeel B.V. . T Zwarte Land 13 Scherpenzeel Gld.	07/03/2023	NL82EG	Netherlands
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

The following non-compliances were not identified by the Netherlands' inspection officials during the establishment review:

39. Maintenance of ceilings: a) Holes and gaps around pipes were observed on the ceilings of rooms where pork products were being processed; b) The ceiling directly above the product staging area in the smoking room had collected soot and debris and needed cleaning; c) Two exhaust fans in operation right above product presented a significant build-up of dirt and grime. d) In the curing room, a defective drain allowed the collection of stagnant water and piece of meat and fat residues. The drain was immediately unblocked by establishment personnel. No product adulteration was observed at this time. The establishment committed to promptly address these issues.

41. Beaded condensation was observed on and around a condenser and the surrounding pipes in an area where smoked pork bellies were waiting to be moved after exiting from the cold shower spray chiller. No product contamination was noted at the time of observation was made. The establishment took immediate corrective action and retained the product for evaluation and proper disposition.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/30/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Van der Laan (Zwanenberg Food Group) Sluisweg 7 Almelo	06/28/2023	NL129EG	Netherlands
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT X ON-SITE AUDIT ☐ DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Pork processing.
Prepared Products:	TPCS (canned) product

60. Observation of the Establishment

The following non-compliances were not identified by the Netherlands' inspection officials during the establishment review:

20. The establishment’s written HACCP plan did not include specific instruction to ensure that all four parts of corrective actions were taken in response to a deviation from a critical limit for CCP 1 (metal detection). Specifically, the corrective actions did not specify that "the CCP will be under control after the corrective action is taken."

22. The establishment’s HACCP verification records did not include the time each specific event occurred (e.g., direct observation of monitoring, review of records).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/28/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Lupak (Zwanenberg Food Group) Raalte	06/30/2023	NL153EG	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Pork processing.
Prepared Products:	TPCS (canned) weiners

60. Observation of the Establishment

The following non-compliances were not identified by the Netherlands' inspection officials during the establishment review:

22. The establishment’s HACCP ongoing verification records did not include the time each specific event (e.g., direct observation of monitoring, review of records) occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/30/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Vion Apeldoorn B.V. Laan Van Malkenschoten 77 Apeldoorn	06/29/2023	NL312EG	Netherlands
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	X
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

The following non-compliances were not identified by the Netherlands' inspection officials during the establishment review:

41. Condensation was observed on overhead rails at the door and inside in multiple coolers where carcasses were present. No direct product contamination was noted at this time. The establishment took the immediate corrective action to remove the condensation and committed to implement further preventive measures.

52. During the verification of humane slaughter, the FSIS auditor noted a corroded steel pipe with sharp edges that could cause injury to pigs in one of the holding pens. In addition, one of the drop-down gates used to prevent pigs from moving back into the main passage was missing the rubber padding which softens the impact of the gate should it drop on the back of animals. The establishment took immediate corrective action to address these noncompliances. No injury to animals was observed at this time.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/29/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Vion Groenlo B.V. Den Sliem 8 Groenlo	06/30/2023	NL367EG	Netherlands
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

The following non-compliances were not identified by the Netherlands' inspection officials during the establishment review:

39. a) The overhead gasket and rubber flaps of several carcass chiller doors were damaged and required cleaning; b) Holes of varying sizes were observed in the ceiling directly above the offal chillers. No product adulteration was observed at the time observation was made. The establishment committed to promptly address these issues.

41. Condensation was observed above the cooler doors and on carcass rails where carcasses were present. While no product adulteration was noted at the time, the establishment took corrective action remove the condensation and retained the product for further evaluation and proper disposition.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/28/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
T. Boer en Zonen B.V. Gravenweg 350, Nieuwerkerk aan den IJssel	06/28/2023	NL939EG	Netherlands
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/03/2023

Appendix B: Foreign Country Response to the Draft Final Audit Report

Ministry of Agriculture, Nature and Food Quality

> P.O. Box 20401 2500 EK The Hague The Netherlands

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Your ref.

Encl.
4

Date 08-Feb-2024
Re Response draft final FSIS audit report

Dear Dr Catlin,

Thank you for your letter of 13 December 2023 concerning the draft final audit report, following the onsite verification audit of the Netherlands' meat inspection system from 26 June to 11 July 2023.

With this letter I would like to provide our comments regarding the information in the audit report. FSIS identified three findings within two equivalence components, of which none represented an immediate threat to public health. In addition, the auditors observed several non-compliances in the individual establishments.

Attached you will find the corrective actions taken by the Netherlands Food and Consumer Product Safety Auhtority (NVWA) and the audited establishments, along with the relevant annexes.

I look forward to receiving the final report. Thank you for your cooperation.

Sincerely,

H.I.J. Roest, DVM, PhD

Attachments:
- Table corrective actions FSIS findings
- Table corrective actions Appendix A checklists
- RE-31 translation
- Project specific annex sample testing

COMPONENT	DEFICIENCY	CORRECTIVE ACTIONS/CURRENT SITUATION
COMPONENT ONE: GOVERNMENT OVERSIGHT	NO DEFICIENCY	
COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY, FOOD SAFETY, AND OTHER CONSUMER PROTECTION REGULATIONS	NVWA allows calves identified during ante-mortem inspection as NAD for noninfectious disease-related conditions (e.g., injury during transportation) to be slaughtered and dressed on the same slaughter line and at the same time as calves that are eligible for export to the United States. However, NVWA prohibits products derived from NAD calves to be exported to the United States.	Non-ambulant calves are prohibited at veal slaughterhouses with an US-export registration. These calves are not allowed to enter the establishment. They have to be killed upon arrival and destined for destruction. This requirement is now detailed clearly to prevent any misunderstanding about the topic. See the related NVWA working manual, RE-31, *United States, requirements for companies,* v1.3.3, Chapter 4.2.2, “Slachterijen” (slaughterhouses).
COMPONENT THREE: GOVERNMENT SANITATION	No deficiency	
COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM	No deficiency	
COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS	No deficiency	

COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS	Two-point sampling (pre-evisceration/post-chill) was not conducted at the audited swine slaughter establishments in a manner consistent with the NVWA's written requirements.	Pork slaughterhouses has to conduct the two-point sampling as detailed in working manual RE-31, *United States, requirements for establishments*, v1.3.3, Chapter 4.2.2.1 "Pork slaughterhouses".
	The audited microbiological laboratory was not analyzing the entirety of N60 samples associated with the government verification program for Shiga toxin-producing Escherichia coli (STEC) in raw veal products. This may affect the accuracy of test results.	NVWA immediately amended the specific project protocol concerning the arrangements with the laboratory (WFSR). The laboratory now refuses every STEC-sample which weight exceeds the requirements. A substitute sample has to be taken; if it is not possible to take a sample from the same/ original recipient, the related batch (original sample) is not eligible for the export to the US. See the form "*Project Specifieke Bijlage monsteronderzoek*" (Project specific attachment, *PSB*); the document deals with the agreements between NVWA and the laboratory (WFSR).

All deficiencies and the corrective actions, taken by the related establishments, has to be subject of the annual NVWA-audit; extra attention will turn on these items.

Annexes:
- RE-31, United States, requirements for establishment
- Project Specific Annex sample testing to Project Protocol EXP24100 Third Party Certification (Project Specifieke Bijlage monsteronderzoek (PSB))

Project Specific Annex sample testing (PSB) to Project Protocol

EXP24100 Third Party Certification

- This document serves to record the agreements per project between NVWA and WFSR in accordance with ISO17025 and must be agreed in consultation between the parties.
- **Before this PSB is sent to SPC, it must be coordinated by the NVWA project leader with the WFSR project leader. Project leader WFSR is responsible for coordination with sub-program leader.**
- During coordination, make sure it is clear who added comments to the document.
- If this improves the overview for the laboratory and NVWA, it is possible to add file(s) and link(s) (provided that they are readable by external parties) in the sections.
- In the case of already established (general) agreements, the source must be stated.
- Enter N/A in the fields that are not applicable.
- Always complete version control.

Version	Date	Editor	Explanation
0.1	9-6-2023	SPC	Partially completed based on 2023
0.2	17-10-2023	Greetje Castelijn, Elke Tiggeloven and Menno van der Voort (WFSR)	Added: clarification of what the minimum and maximum sample size must comply with, clarification regarding reporting period, and agreements about WGS and using samples on Saturdays added
0.3	11-01-22024	Bettine Murlat, Greetje Castelijn	Sample research period adjusted; had already been discussed earlier in connection with samples on Saturdays, for example. This is necessary to comply with the agreements with the US

General information	
Project protocol *Project protocol code and name under which this PSB falls*	EXP24100 Third Party Certification
(Sub)project code and name/sample reference *Indicate which (sub)projects and codes apply, if any, without the year*	VYKS045 USA-Export veal
Laboratory + team	WFSR teams involved are: Team 32, 33 and 34
Project name Laboratory *To be completed by WFSR*	Microbiology 1294002205
Reason for sampling	
Reason (reason) for sampling *Import/regular enforcement/market exploration/BPT/etc.*	Export Country requirement USA
Research question	STEC detection, attachment genes, O serotypes
Legal framework(s) *Law/regulation/decision/regulation etc.*	N/A, third country requirement
Legal requirements) *Item (s)*	STEC verification, USA (FSIS) requirement for veal production
Sample information	
Species /type of sample *food/ feed etc.*	veal
Value type/Matrix	Meat, organs of calves – fresh and/or in consumer packaging

What type of product is supplied (e.g. meat/fish)?	
Delivery period/period of sample(s) *The programming and numbers of the samples. A copy of the numbers from the AK (Excel file) is sufficient.*	Samples are supplied throughout the year.
Minimum amount of sample material *Number/gram/ml etc. of sample supplied*	Within this project there are various sample flows for which different agreements apply regarding the minimum and maximum sample size. These are explained in more detail below. 1. Veal control samples (N60) Minimum 330 grams in total, minimum 110g per sub-sample and maximum 125 g per sub-samples. The 3 sub-samples may not weigh more than 375 g in total. Pieces: 3x 20 pieces 2. Grab samples Sample at least 30 pieces of meat, or minced meat, and a total of at least 330 g of meat. Enter this as 3 subsamples. **NO** large pieces of meat! 3. Organs 1 large organ or several small parts. Enter this as 3 subsamples. 3 sub-samples of 110 g (3x 110 g) are used. 4. Consumer products Sample a total of at least 330 grams of meat and record this as 3 sub-samples (more or less than 3 packages allowed).
What criteria must a sample meet to be examined by WFSR? *Cancellation of samples is specified in SPC MA-01. Only complete if this is necessary.*	Refusal of samples and handling thereof see SPC-MA01 Additional agreements specific to this project regarding reasons for refusal are: - For the sample flow for checking veal at the slaughterhouse, samples of which the 3 sub-samples weigh more than 375 g in total (reason for refusal: too much sample material in accordance with project protocol) - Large pieces of meat and less than 30 pieces of meat for monster flow grab samples Refusal of samples and handling see SPC-MA01. The reason for refusal is indicated on the documentation and, if relevant, recorded with a photo. The photos can be requested from WFSR if necessary.
Are emergency samples expected? *Indicate if and when applicable.*	☐YES ☐NO ☒OTHER *Explanation:* As a rule not applicable.
What are the agreements regarding emergency samples? *Agreements that are different for emergency samples; Consider lead time, for example.*	N/A
Sample registration system used by NVWA. *Registration system (s) e.g. BVT, Formdesk Sampling app etc.*	Trippelform

Sample registration system to be used by WFSR. *Registration system (s) e.g. Labvantage, SQL LIMS, Siemens. To be completed by WFSR*	Labvantage
Save / store samples	
Sample storage conditions *As supplied, unless otherwise stated.*	At the insight of the laboratory, in such a way that the composition of the sample and the components to be examined are guaranteed.
Sample retention period *Who, what, where, how long and when? If applicable, also distinguish here between urgent, partial, sub-, storage and counter-samples if applicable.*	When the monster has been completely dealt with it may be destroyed.
Are counter-samples [1]taken? *Only complete if WFSR needs to do something with this.*	☐YES ☐NO ☒OTHER *Explanation:* As a rule not applicable
How long and under what conditions should counter samples be stored by WFSR? *Only complete if WFSR needs to do something with this*	
Partial [2], sub- [3], storage [4], collective samples[5] *Check if applicable for WFSR: Indicate what applies and for whom and agreements made about this*	☐Subsample ☒Subsample ☐Storage sample ☐Collector's sample ☐N/A *Dates:* Enter 3 subsamples each time. The subsamples are analyzed separately for the requested parameters.
Research	
Research method(s) to be used	See below

In this project, each subsample is examined for the presence of the parameters below.
When STEC is isolated from the products, it is stored for possible further research. For this purpose, the isolate is included in the WFSR biobank.

Bacteria	Analysis	Work instructions	Unit
STEC	Insulation from 110-125 grams	TYP01-WV011	110-125 grams
STEC	confirmation	TYP01-WV012	isolate
Attachment genes	characterization	TYP01-WV024	isolate
O serotypes	characterization	TYP01-WV022	isolate

[1]Definition of counter sample: 1) an additional sample taken intended for microbiological or chemical counter-expertise. 2) Homogenized sample material/laboratory sample and/or raw data from the conducted research obtained on site or at another location that is made available to the auditee for audit, recovery and arbitration purposes.
This sample is taken during sampling at the request of the interested party and left sealed at the company (company sample). In a number of cases, counter samples are sent to WFSR.
[2]Subsample: A comparable sample from the batch taken during sampling or part of the collective sample that is obtained by representatively splitting that sample into several (sub)samples.
[3]Subsample: A part of a sample after division. The splitting can take place at the sampling location or in the laboratory.
[4]Storage sample: A representative sample of a fully packaged unit of a batch of (end) product.
5 Collective sample: The total of all incremental samples taken from the lot or sub-lot ; Aggregate samples are considered to be representative of the lots or sublots from which they were taken. English term = aggregate sample

For isolates for which toxin gene(s) are found positive, the presence of attachment genes *eae* , *aggR* and *aaiC* determined. *Stx* and *eae* positive *Escherichia coli* isolates _ typified for serogroups O157, O111, O104, O26, O103, O145, O45, O121 and O174.	
Method accredited	☒YES ☐NO ☐OTHER *Explanation : _*
Agreements regarding measurement uncertainty	N/A
Clustering of samples [6]by lab allowed?	☐YES ☒NO ☐OTHER ☐N/A *Explanation:*
Sample examination period: within how much time after receipt must WFSR examine the samples? *Describe in concrete terms the maximum period within which WFSR must use the analyzes after supplying the sample. This is related to the next question about batch sizes.*	NVWA strives to provide samples and information in such a way that perishable products sampled at a temperature of 3 ± 2 °C can be used within 36 hours after sampling. Samples are also used 36 hours to a maximum of 72 hours after sampling. For samples that have still been used after 48 hours, a comment is made in the LIMS and on the report. Frozen samples that have been transported frozen may be kept frozen for 5 days until the start of analysis.
Agreements regarding batch sizes. *Agreements about saving samples into full series or delivering multiple samples simultaneously. Analyzing in series entails lower costs. Describe here agreements about the delivery of samples and how long WFSR may store samples before starting an analysis.*	N/A
Does WFSR take photos of samples? *If yes, then also describe which ones should be made and how they should be included in the report.*	☐YES ☐NO ☒OTHER *Explanation:* Photo only if sample is refused
What sample (related) information must be recorded by WFSR? *Only complete if this deviates from standard agreements.*	Minimum: Sample number, product designation (if known) date of sample receipt Refuse reason (see SPC-MA01)
Research results	
Method of reporting: How should the results be reported to NVWA? *Who is this communicated with and how? Also mention any interim reports here.*	• All results are available in Labvantage and these results can be accessed by the project leader. • Every year, an overview is generated by WFSR of samples analyzed within this project with associated analysis results (typing). Overview is generated in Jan/Feb of the following year. Test report according to NEN-EN-ISO 17025
Content reporting *Indicate what information must be reported by WFSR. Also consider performance characteristics and any interim report(s).*	Standard, as laid down in the Quality and Service Protocol (KSP) 'chapter 5.4 Reporting'. • Research method(s) • NVWA seal number • Sample number WFSR • Date of sampling

[6]Clustering of samples: Merging multiple samples into 1 analysis sample. This does NOT mean saving samples for serial analyses.

	• EC number of sample location (if known) • Date of sample receipt • Date of start of analysis • Product • Designation • Reference number of analysis report • Laboratory accreditation number	
Standard/Limit *If this value is exceeded, follow-up activities must be carried out by WFSR.*	WFSR does not carry out standard testing for microbiological results Positive if: *stx* + attachment gene (*eae* or *aagR* + *aaiC*) + O serotype (see Research Methods) present	
What activities must WFSR carry out if the standard/limit is exceeded? *Only describe when this deviates from standard agreements.*		
Term reporting *Max. term within which results must be delivered after sample delivery (see method list).*	Negative result within 2 working days of digital and physical receipt at the WFSR microbiology department. This is visible on the report under "Date start of analysis".	
Other		
Relationship with other projects/organizations	VYKS2104	
Other comments	Related work instruction: RE-33 If STEC isolates are isolated from samples within this project, the standard further typing is carried out here for MLST and serotype determination (using Whole Genome Sequencing (WGS)). These isolates are also included in the kinship analysis. If no further characterization of an isolate is required, this must be explicitly reported by the inspector when reporting the sample. The further characterization using WGS will only be carried out urgently if the inspector has indicated this when reporting the sample. Work for this project also takes place on Saturdays.	
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Attachments		

Appendix A Individual establishment, as provided in checklists	**Deficiency**	**Corrective actions by establishment**
Est. NL9EG, EKRO B.V. Apeldoorn	12. The establishment's written program did not specifically address the requirement to document "the disposition of product" as a part of corrective actions taken in response to operational SSOP deviations.	12. The company has acknowledged the problem. Therefore, the company is amending all documents related to this omission. Corrective actions has to be laid down for operational SSOP deviations. These are measures taken regarding the product and the process. The options for registering the measures regarding the product are currently being developed. Given the volume of documents, this process is not yet fully completed.
	22. a) Establishment monitoring records for the zero tolerance CCP addressing the presence of ingesta and feces on veal carcasses did not include a description of the specific type of contamination identified when a deviation from the CCP occurred.	22 a) See the answer to point 12.
	b) Establishment records documenting ongoing verification activities did not include the time that each specific event occurred (e.g., direct observation of monitoring, or review of records).	b) See the answer to point 12.
	48. Veal calves identified during ante-mortem inspection as non-ambulatory for certain noninfectious disease-related conditions (e.g., transportation injury) may be slaughtered on the same slaughter line and at the same time as calves that are eligible for export to the United States. However, non-ambulatory disabled	48. Non ambulant calves will not enter the slaughter establishment. They'll be euthanized on the spot and removed for destruction. This method will be included in an unambiguous manner in the establishment's USA protocol. Note: It is also laid down in instruction RE-31, US, Requirements at establishments.

	calves are segregated after the slaughter process and are not eligible for export to the United States.	
Est. NL61EG, VION Boxtel B.V.	16. Establishment monitoring records for the "zero tolerance" CCP (pork carcasses) did not include a description of the specific type of contamination identified (e.g., feces or ingesta) when a deviation from the CCP occurred.	16. The establishment has adjusted the document for the CCP monitoring and has shared it with the NVWA.
NL 82EG, VION Scherpenzeel B.V.	39. Maintenance of ceilings: a) Holes and gaps around pipes were observed on the ceilings of rooms where pork products were being processed; b) The ceiling directly above the product staging area in the smoking room had collected soot and debris and needed cleaning; c) Two exhaust fans in operation right above product presented a significant build-up of dirt and grime. d) In the curing room, a defective drain allowed the collection of stagnant water and piece of meat and fat residues. The drain was immediately unblocked by establishment personnel. No product adulteration was observed at this time. The establishment committed to promptly address these issues.	39. a) After research by the company it has been concluded that there are no openings to the outside. However, during the upcoming scheduled ceiling maintenance, the company is planning to address the issue.. b) The ceiling was cleaned timely. The cleaning frequency for the ceiling is regularly twice a year. This cleaning frequency will be increased for the year 2024. c) The exhaust fans were cleaned once a year, the frequency is now changed to four times a year. d) The drain is controlled and will be cleaned weekly by the cleaning company.

	41. Beaded condensation was observed on and around a condenser and the surrounding pipes in an area where smoked pork bellies were waiting to be moved after exiting from the cold shower spray chiller. No product contamination was noted at the time of observation was made. The establishment took immediate corrective action and retained the product for evaluation and proper disposition.	41. The kind of production process leads very often to condensation problems. This is due to the combination of heat and curing of product. Therefore, to address the problem, there are now regularly 3 employees per shift involved in the task of controlling condensation throughout the production.
Est, NL129EG, van der Laan, Almelo	20. The establishment's written HACCP plan did not include specific instruction to ensure that all four parts of corrective actions were takenin response to a deviation from a critical limit for CCP 1 (metal detection). Specifically, the corrective actions did not specify that "the CCP will be under control after the corrective action is taken." 22. The establishment's HACCP verification records did not include the time each specific event occurred (e.g., direct observation of monitoring, review of records).	20. The establishment has amended the protocol regarding metal preservation (WI-460.03/1, chapter 3.4). 22. The CPP control form is adjusted; the time can (and has to) be noted.
Est. NL153EG, Lupak, Raalte	22. The establishment's HACCP ongoing verification records did not include the time each specific event (e.g., direct observation of monitoring, review of records) occurred.	22. The company has added columns to the CCP registration document for time registration. Accordingly the time at which the verification takes place is now recorded on al forms.

Est. NL312EG, VION Apeldoorn B.V.	41. Condensation was observed on overhead rails at the door and inside in multiple coolers where carcasses were present. No direct product contamination was noted at this time. The establishment took the immediate corrective action to remove the condensation and committed to implement further preventive measures.	41: Condensation coolers. The frequency of controls of the coolers has been increased and allows now for immediate corrective action when condensation occurs. Furthermore, all the evaporators are preventively checked, weekly, by the maintenance department on the correct working of the draining system and on any freezing of water inside the trays.
	52. During the verification of humane slaughter, the FSIS auditor noted a corroded steel pipe with sharp edges that could cause injury to pigs in one of the holding pens. In addition, one of the drop-down gates used to prevent pigs from moving back into the main passage was missing the rubber padding which softens the impact of the gate should it drop on the back of animals. The establishment took immediate corrective action to address these noncompliances. No injury to animals was observed at this time.	52. Constructive non-conformities lairage. The non-compliances which were found during the audit were immeditelely solved. The corred steel pipe is removed and changed for a new metal pipe without any sharp edges. The rubber under the HPG, which was missing, is replaced for new rubber. Preventive action: Before the start of the of the night shift, checks of the lairage, the main passages and on any non-conformaties of the construction takes place. All non-conformities which are found are mentioned in the establishment (SSOP) control document and the maintenance department is immediately informed.
Est. NL367EG, VION Groenlo B.V.	39. a) The overhead gasket and rubber flaps of several carcass chiller doors were damaged and required cleaning; b) Holes of varying sizes were observed in the ceiling directly above the offal chillers. No product adulteration was observed at the time	39. a). All the mentioned structures were cleaned. The technical department was informed of the damaged rubber flaps; these were replaced and also cleaned. Following the audit, an assignment was given with regards to periodic (monthly) cleaning. This is a continuously ongoing process. b) Part of the pre-SSOP and SSOP checks is to look closely at the status of the structures, including the ceilings. If a deviation (such as a crack/hole/missing tile) is found, it has to be documented, and the technical service will be approached to repair the deviation. Following

	observation was made.The establishment committed to promptly address these issues 41. Condensation was observed above the cooler doors and on carcass rails where carcasses were present. While no product adulteration was noted at the time, the establishment took corrective action remove the condensation and retained the product for further evaluation and proper disposition.	the audit, the detected holes have been sealed off. The employees involved, have been addressed concerning the importance of detecting, documentation and resolving of any deviations. 41) Contamination of carcasses with condensation is monitored as a checkpoint in the pre-SSOP and SSOP checks. Trained employees carry out regular checks to ensure that the production areas are condensation-free before commencement of activities, and that carcasses and products are not contaminated with condensation. If condensation occurs as a result of the warm carcasses entering the cold rooms, there are established procedures for handling the carcasses to prevent cross-contamination, such as immediately removing the condensation from the rails or conveyors and flaming of the entire carcass halves on both sides. These steps are carried out by trained employees.
Est. NL939EG, T.Boer en Zonen B.V., Nieuwekerk aan de Ijsel	There were no significant findings to report after consideration of the nature, degree, and extent of all observations.	

Regarding the points above, NVWA emphasizes at the national USA meeting[1] that all HACCP pillars are to considerer.
At Supervision 2 (head of department and team leaders) the team leaders were reminded to take the problems into account. They will, when executing supervision 1, discuss the necessary actions/ amendments to be taken with their teams at the establishments.

[1] NVWA-employees from various NVWA-levels, related to US-requirements.