USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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

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Dr. C.J.M. Bruschke, DVM, PhD
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. Bruschke,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote verification audit of the Netherlands' inspection system September 8–November 12, 2021. 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,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF

THE NETHERLANDS

SEPTEMBER 28–NOVEMBER 12, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

VEAL AND PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

April 25, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of the Netherlands conducted by the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) from September 28 to November 12, 2021. Due to the global COVID-19 pandemic, the audit was conducted remotely using video conferences to conduct interviews and records review. The purpose of the audit was to determine whether the Netherlands' food safety inspection system governing veal and pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The Netherlands currently exports raw veal and pork, thermally processed-commercially sterile pork, and not ready-to-eat (NRTE) pork products 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 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 HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM

- The Central Competent Authority, Netherlands Food and Consumer Product Safety Authority (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.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- Corrective actions taken in response to the prior (2019) FSIS audit finding concerning testing for Shiga toxin-producing *Escherichia coli* 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.

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 United States Department of Agriculture (USDA) conducted a remote audit of the Netherlands' food safety system from September 28 to November 12, 2021. The audit began with an entrance meeting held via videoconference on September 28, 2021 with the Central Competent Authority (CCA)—Netherlands Food and Consumer Product Safety Authority (NVWA). During that virtual entrance meeting, the FSIS auditors discussed the audit objective, scope, and methodology with representatives from NVWA.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that was conducted remotely. The audit objective was to determine whether the food safety inspection system governing veal and pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Verification of the Netherlands' egg products inspection system was not included in the scope of this remote audit because the Netherlands has not exported egg products to the United States since the previous FSIS audit in 2019. 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	Thermally Processed, Commercially Sterile (TPCS)	Pork - All Products Eligible
Heat Treated but 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.

Eggs/Egg Products	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 recognizes the Netherlands as having negligible risk for bovine spongiform encephalopathy as specified in Title 9 of the Code of Federal Regulations (9 CFR) parts 94.18, and 94.19; free from foot-and-mouth disease with special restrictions specified in 9 CFR part 94.11; free from African swine fever but subject to regionalization restrictions specified in 9 CFR 94.8; free from swine vesicular disease with special restrictions specified in 9 CFR part 94.13; and part of the APHIS-defined European classical swine fever region subject to restrictions specified in 9 CFR 94.31.

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed the Netherlands' Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether the Netherlands' food safety inspection system governing meat 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 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 Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed records related to administrative functions and oversight from NVWA headquarters, as well as government verification records from three local inspection

offices within the establishments. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to two meetings each week over a seven-week period. Through records review, the FSIS auditors evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of three establishments was selected for the remote audit from a total of 12 establishments certified to export veal or pork products to the United States. This included one veal slaughter and processing establishment, one veal processing establishment, and one pork processing establishment. The products these establishments produce and export to the United States include raw intact veal, raw intact pork, TPCS pork, and heat treated but not fully cooked - not shelf stable pork.

This remote audit focused on a review of official records associated with NVWA's verification activities conducted at the selected establishments. 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 remotely 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.

Remote Audit Scope		**#**	**Locations**
Competent Authority	Central	1	• Netherlands Food and Consumer Product Safety Authority, Utrecht
Laboratory		1	• Wageningen Food Safety Research (government microbiological and residue), Wageningen
Veal processing establishment		1	• Establishment No. NL 939 EG, T.Boer en Zonen B.V., Nieuwerkerk aan den Ijssel
Veal slaughter and processing establishment		1	• Establishment No. NL 9 EG, EKRO B.V., Apeldoorn
Pork processing establishment		1	• Establishment No. NL 82 EG, Vion Scherpenzeel B.V., Scherpenzeel

FSIS performed the audit to verify that the 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 Livestock Slaughter Act (7 U.S.C. Sections 1901-1906); 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 veal and pork products included: (1) all applicable legislation originally determined by FSIS to be

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 June 1, 2018 to May 31, 2021, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 51,527,910 pounds of meat, which included 1,265,313 pounds of TPCS pork; 36,793,749 pounds of raw intact pork; 1,282,309 pounds of NRTE otherwise processed pork; 12,186,539 pounds of raw intact veal; and 79,033 pounds of egg products exported by Netherlands to the United States.

Of these amounts, additional types of inspection were performed on 7,084,554 pounds of meat (468,214 pounds of TPCS pork; 5,144,004 pounds of raw intact pork; 294,551 pounds of NRTE otherwise processed pork; and 1,177,785 pounds of raw intact veal), and 37,698 pounds of egg products. 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) O157:H7, O26, O45, O103, O111, O121, and O145 in raw veal; and *Listeria monocytogenes* and *Salmonella* in egg products).

As a result of this additional testing, nine lots of meat were rejected for issues related to public health, including: seven lots of veal rejected for STEC-positive results; one lot of pork rejected for the presence of 2-Amino-Flubendazole (metabolites from a dewormer); and one lot of veal offal rejected for the presence of plastic contamination.

The previous FSIS audit in 2019 identified the following findings:

Summary of Findings from the 2019 FSIS Audit of Netherlands
Component 1: Government Oversight (e.g., Organization and Administration)
• NVWA inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate. • NVWA considers a chemical residue test result as violative based on European Union maximum residue limits, which do not correspond to levels permitted by FSIS.
Component 2: 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 the slaughter of non-ambulatory veal calves, which are then permitted to enter the food supply. Veal from these non-ambulatory calves is not precluded from export to the United States; however, the FSIS auditors concluded that no affected product was exported to the United States based on a review of available records.
Component 3: Government Sanitation
• The Netherlands Supervisory Authority for Eggs permitted the collection of residual egg whites drained from pipes taking empty shells away after the breaking process. This would permit egg whites to contact the outside of unwashed eggshells and enter the food supply.

Component 6: Government Microbiological Testing Programs
• NVWA microbiological 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.

The FSIS auditors verified that the corrective actions for the previously reported findings pertaining to veal and pork products inspection system were implemented and effective in resolving the findings, with the exception of those corrective actions taken concerning testing for STEC in raw veal, as described under Component Six 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/inspection/import-export/international-reports/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.

Within the Dutch government, NVWA is an independent implementing agency under the Ministry of Agriculture, Nature and Food Quality responsible for executing official tasks. The 2021 NVWA organizational chart consists of four Directorates: Strategy, Enforcement, Inspection, and Internal Organization. Since the previous FSIS audit in 2019, the Feed and Food Safety Laboratory (FFSL) is no longer part of NVWA's Enforcement Directorate. FFSL has been merged with the Institute of Food Safety of the Wageningen University & Research (WUR) into the Wageningen Food Safety Research (WFSR). WFSR continues to be part of WUR and an independent government-operated laboratory. WFSR maintains its status as a national and European reference laboratory. The official tasks carried out before the merger did not change, including analysis of official food and feed samples.

NVWA's Inspection Directorate ensures the safety of meat and meat products, animal welfare, and controls of import and export. 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.

NVWA supervision in the meat sector consists of inspection oversight, annual audits of certified establishments, 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 inspection. Official auxiliaries (OA) who are employed by Kwaliteitskeuring Dierlijke Sektor (KDS) carry out post-mortem inspection for red meat under the direct onsite supervision by NVWA official veterinarians (OV).

At the three selected establishments, the FSIS auditors verified through records review and interviews that NVWA's staffing program is sufficient to ensure an effective level of oversight is maintained. NVWA government inspection personnel conduct inspection activities at least once per shift for processing establishments and complete offline verification procedures, whereas KDS personnel conduct online inspection of every carcass and parts during slaughter operations in establishments certified to produce veal products for export to the United States.

As a European Union (EU) member, 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 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. Additionally, the FSIS auditors confirmed that, in accordance with requirement RL-159, NVWA ensures that source materials used in processing operations originate only from the Netherlands establishments certified to export to the United States.

The FSIS auditors verified through records review 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 the requirements of NVWA.

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 inspecting official or establishment personnel allowing product to be exported. The FSIS auditors reviewed the export certification process and documents and did not identify any concerns.

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 case of an adulterated product, the Commission Regulation (EU) No. 2019/1715 stipulates the duties of the RASFF network members and defines the different types of notifications. 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 and for the Commission to transmit them within 24 hours.

The FSIS auditors verified that certification of product for export does not occur until the results of microbiological testing, conducted either in conjunction with establishment or government testing programs, are received as acceptable. To address the two prior findings identified during the 2019 FSIS audit related to chemical residue testing, NVWA does not permit meat from carcasses tested under its national residue program to be exported to the United States. Per RE-31 veal slaughter establishments are required to implement their own surveillance testing programs which comply with maximum residue limits (MRL) of the United States. Carcasses or meat from carcasses sampled under these establishment surveillance programs can only be released after receiving negative results.

The FSIS auditors verified through records review and interviews that NVWA 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 SOPs); 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.

NVWA requires certified establishments to have controls in place to ensure that pork and veal products are derived from eligible sources. The FSIS auditors verified through interviews and records review that source materials used to produce meat products for export to the United States are from certified establishments in the Netherlands. NVWA has the legal authority and responsibility to certify and de-certify establishments as eligible to export products to the United States. A slaughter establishment is certified as eligible 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 a slaughter establishment is permitted to operate and document their programs as implemented. If the second onsite audit is acceptable, the slaughter establishment is then considered certified as eligible to export to the United States. A processing or cold storage facility follows a similar process, but has only one onsite audit after which it may be certified as eligible if the results are satisfactory.

The FSIS auditors verified through interviews and records review that NVWA's OVs and VAs, as civil servants, are paid and hired by the government of the Netherlands. NVWA's OVs performs ante-mortem inspection, evaluate the performance of KDS personnel, and make final veterinary dispositions on retained carcasses and viscera.

The FSIS auditors verified through records review and interviews that in addition to the NVWA yearly audit of each certified establishment, supervisory reviews occur once per month by an area Team Leader and four times per year by the head of department. The FSIS auditors verified that NVWA headquarters has the direct linkage to certified establishments through access to supervisory reports and results of inspection procedures which are documented in an electronic system.

The FSIS auditors verified through records review and interviews that NVWA has adequate oversight of WFSR, the government laboratory that performs analyses for official sampling and

testing programs for veal and pork products that are exported to the United States. This laboratory is accredited to the International Organization for Standardization (ISO)/International Electrotechnical Commission Guide 17025 standards. The FSIS auditors reviewed the most recent accreditation report available for the 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 the WFSR laboratory and published on a special drive for laboratory results of NVWA. NVWA informs inspection personnel at certified establishments 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 the WFSR laboratory 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 veal and pork 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 part; controls over condemned materials; controls over establishment construction, facilities, and equipment; inspection during all slaughter operations and at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

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 requirement WLZVL-017. Through records review and interviews, the FSIS auditors confirmed 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 NVWA 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 requirement WLZVL-017, Section 5.

The Netherlands implements Regulation (EU) 2017/625, where NVWA ensures that government inspection personnel perform ante-mortem inspection of all livestock prior to slaughter. This regulation is consistent with FSIS ante-mortem inspection requirements and NVWA requirement K-RV-AM-WV04. NVWA OVs perform ante-mortem inspection, make decisions concerning live animals, and supervise the arrival of animals at the slaughterhouse. NVWA requires OVs to examine animals for clinical signs of systemic disease or emaciation, as outlined in procedures on how to handle diseased animals in K-RV-AM-WV04. Ineligible animals are to be declared unfit for human consumption (condemned) and euthanized separately to ensure that other animals or carcasses are not contaminated.

During the 2019 FSIS audit, auditors noted that NVWA allowed the slaughter of non-ambulatory veal calves, and that those calves were not necessarily precluded from export to the United States. As part of corrective actions, NVWA revised its requirements (RE-31) for veal slaughter establishments certified to export to the United States to have written procedures and registrations concerning disposition of slaughtered animals with findings at ante-mortem inspection. Additionally, non-ambulatory calves are to be precluded from export to the United States. During this audit, the FSIS auditors verified through interviews and records review that NVWA had no non-ambulatory veal calves presented for slaughter since the previous FSIS audit in 2019.

NVWA requirements for post-mortem inspection are outlined in K-RV-PM-WV01 and in Commission Implementing Regulation (EU) 2019/627. Through interviews and document review, the FSIS auditors verified that at the veal slaughter establishment, NVWA inspection personnel were visually examining livestock carcasses and parts at the head inspection station, the viscera inspection station, and the carcass inspection station according to the equivalent alternative post-mortem inspection procedure. Determination of eligibility for visual inspection is based on food chain information, information from the Netherlands' Central Identification and Registration system which includes data about the exact age and the whereabouts of each calf from birth to slaughter. This information is collected and fixed to the specific slaughter line that the calf is processed on. The FSIS auditors also verified that OAs were conducting post-mortem inspection under the supervision of OVs. The FSIS auditors concluded that NVWA was conducting post-mortem inspection in a manner that is consistent with FSIS requirements.

Through interviews and record reviews, the FSIS auditors confirmed that government inspection personnel were verifying the adequate identification, removal, and disposal of specified risk materials (SRMs) 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. Moreover, NVWA requirement RE-31 mandates that non-ambulatory veal calves be excluded from exports to the United States. Additionally, NVWA requirement K-RV-PM-WV03-TSE, classifies the intestine from the duodenum to the rectum, the mesentery, and the tonsils as SRMs in veal.

NVWA implements the requirements of Regulation (EC) No. 1069/2009 regarding the classification of animal by-products to 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 records review 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. NVWA 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 meat 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 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.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that NVWA requires each official establishment to develop, implement, and maintain written sanitation SOPs 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. Regulation (EC) No. 853/2004, Section I, Chapter IV, 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 enterohemorrhagic *E. coli*/Shiga toxin-producing *E. coli* (EHEC/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 records review, the FSIS auditors verified that 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. NVWA requirement 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 non-compliance report. The FSIS auditors noted that NVWA requires sanitary dressing procedures of livestock at slaughter establishments. Through interviews and record reviews, the FSIS auditors verified that the audited slaughter establishment has 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. NVWA OVs conduct daily verification of sanitary dressing procedures. The FSIS auditors did not identify any concerns with NVWA's verification activities for sanitary dressing.

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 requires (RE-31) 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 certified establishments 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 requires (RE-36) inspection personnel to perform pre-operational and operational sanitation inspection daily in slaughter establishments and weekly in processing establishments. NVWA 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 records review and interviews that government inspection personnel are verifying implementation of pre-operational and operational sanitation SOPs 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' review of records generated by NVWA inspection personnel (including noncompliance and verification records) showed that NVWA inspection personnel have identified and documented sanitation findings in their daily verification or periodic supervisory review records. The FSIS auditors did not identify any concerns with NVWA's verification records of pre-operational or operational sanitation procedures.

Through discussion with NVWA inspection personnel and document review, the FSIS auditors confirmed that the inspection personnel were performing and documenting sanitation verification activities during days when products destined for the United States were produced by certified establishments. Sanitation SOP noncompliance records reviewed by the FSIS auditors indicated that, in the event of product contamination, NVWA verified the certified establishments took corrective actions to restore sanitary conditions, provide appropriate disposition of products, and prevent recurrence as required by RE-31.

FSIS analysis and remote verification activities indicate that the Netherlands' veal and pork inspection system requires all veal and pork establishments certified to export to the United States to develop, implement, and maintain sanitation SOPs to prevent the creation of insanitary conditions and contamination of products. The FSIS auditors concluded that NVWA's inspection system governing veal and pork products continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

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.

The Netherlands adopts Regulations (EC) No. 852/2004 and 853/2004 and requires certified establishments to develop, implement, and maintain a HACCP plan (NVWA requirement RE-31). The establishment's HACCP program must be approved and dated by the establishment manager; must include corrective measures in connection with exceeding of critical limits; and must be validated within 60 days after being implemented (RE-31).

The FSIS auditors verified that OVs routinely review the establishments' implementation of their HACCP systems. NVWA requirement RE-36 instructs inspection personnel of establishments certified to export to the United States to follow instructions of verification methodology, ensure that the design of HACCP systems and implementation is adequate and meet requirements, and document noncompliance. FSIS auditors reviewed a sample of noncompliance records in three audited establishments to assess whether inspection personnel are applying proper verification methodology in accordance with NVWA requirements.

NVWA requirement RE-36 requires its inspection personnel to monitor all certified establishments' compliance with their CCPs daily and document their verification activities and findings. NVWA periodically audits the HACCP system of certified establishments. It conducts at least two onsite audits annually of slaughter establishments and one onsite audit of cutting and processing establishments. The FSIS auditors identified the following finding:

- 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.

NVWA requirement RE-31 requires certified veal and pork slaughter establishments to establish a zero tolerance CCP for fecal material, milk, and ingesta. The FSIS auditors verified that government inspection personnel were performing zero tolerance verification tasks for fecal material, milk, or ingesta on carcasses at a minimum of once per slaughter shift. Zero tolerance verification activities are conducted after the post-mortem rail inspection station and before final wash, or any additional trimming, washing, or application of any intervention by the certified establishment personnel. The FSIS auditors reviewed NVWA zero tolerance verification records as well as noncompliance records issued at the veal slaughter establishment and found that government inspection personnel were verifying NVWA's sanitary dressing requirements as described in NVWA's Meat Chain Improvement Plan.

The FSIS auditors conducted interviews and reviewed documents at three establishments certified to export to the United States to verify whether the Netherlands continues to maintain equivalence with respect to HACCP system requirements. The FSIS auditors assessed the implementation and effectiveness of NVWA's requirements and verification procedures in ensuring that HACCP requirements are effectively and fully implemented in each certified establishment. The FSIS auditors reviewed CCPs and results of official veterinary verification activities to verify compliance. The audited slaughter establishment implements a CCP to address zero tolerance contamination with fecal material, ingesta, and milk, as well as additional controls to ensure that carcasses are chilled in a manner sufficient to prevent the outgrowth of microbiological pathogens.

NVWA's requirement RE-31, Section 4.1, stipulates that certified establishments must have a written procedure requiring that every batch of finished product will 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 certified establishments, as part of their HACCP system, to hold any production lot that was sampled for STEC until an acceptable result is ascertained. Furthermore, the certified establishments' HACCP plan must include and define all the corrective and preventive actions taken in the event of a positive result.

NVWA audits consist of physical inspections of CCPs, inspection of company employees, and records review. Verification procedures are outlined in Audit HACCP and USA-Requirements, which is consistent with requirements in 9 CFR 417. Establishments are required to take corrective actions and implement preventive measures when nonconformities are reported. NVWA verifies the corrective action results by performing a re-inspection.

The FSIS auditors' verification activities indicate that NVWA requires each veal or pork certified establishment to develop, implement, and maintain HACCP programs for each processing category which is consistent with criteria established for this component. However, FSIS auditors identified one finding, listed above.

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 inspection authorities or by FSIS as potential contaminants. Prior to the remote audit, FSIS' residue experts reviewed the Netherlands' 2020 National Residue Control Plan (NRCP), associated methods of analysis, and additional SRT responses outlining the structure of the Netherlands' chemical residue testing program.

Regulation (EU) 2017/625, Commission Decision 97/747/EC, and Regulation (EC) No. 178/2002 mandate the development and implementation of a chemical residue control program. These EU legislations require the Netherlands to design and submit an acceptable residue plan that follows EU guidelines. NVWA is responsible for the coordination of the drafting and implementation of the NRCP. NVWA determines the number of samples to be taken. WFSR develops the sampling allocation for the NRCP and issues sampling requests to the NVWA teams responsible for sampling meat products.

NVWA explains that the NRCP is based on EU Directive 96/22/EC and implemented by National Agriculture or Animal and Laws and Acts. The implementation for the detection of residues is delegated by the ministry of agriculture to the NVWA. Within NVWA, the Design and Services Division in the Directorate of Inspection is appointed for coordination and implementation of the NRCP. Three to four times a year, a coordinating department within NVWA organizes a meeting with representatives of both ministries of agriculture and health, WFSR, and representatives of NVWA departments participating in the NRCP, to monitor and discuss the progress of the program.

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 slaughterhouse. Regarding products for export to the United States, the NVWA samples bovine and porcine hair and urine at the farm, and bovine and porcine urine, kidney, fat, retina, liver, and muscle at slaughterhouses. Results of laboratory analysis are reported to NVWA headquarters. Results are evaluated in accordance with Regulation (EU) No. 37/2010, which identifies banned substances (category A) with zero tolerance levels and substances with maximum residue levels (category B) permitted in food stuffs. The follow-up of non-compliant samples is performed by the Livestock Department within NVWA, according to Commission Delegated Regulation (EU) 2019/2090.

The FSIS auditors verified through interviews and record reviews that NVWA inspection personnel collect routine residue samples and NVWA 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 WSFR.

As indicated previously, in order to ensure compliance with MRLs recognized by FSIS, NVWA currently does not permit meat from carcasses tested under the NRCP to be exported to the United States. RE-31 includes additional requirements for veal slaughter establishments to detail the management of the differences in residue sampling plans between the European and the

United States regulations. These slaughter establishments certified to export to the United States must be aware of the differences between the European and United States regulations concerning residue levels. They should be able to demonstrate to NVWA that FSIS requirements concerning the residues are also known in the primary phase, at the farm. The establishments should have written procedures detailing how and with what frequency the establishment checks the compliance in the primary phase and should describe how inadequate results are handled. NVWA supervises and audits establishments' residue quality checks as part of its annual audit on the additional requirements of the United States. In these audits, NVWA verifies that establishments are following their own instructions related to the MRL requirements. The FSIS auditors reviewed NVWA verification records of residue quality checks generated by a major veal slaughter group in the Netherlands and identified no concerns.

The results of the remote 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 veal and pork products destined for human consumption.

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 products prepared for export to the United States are safe and wholesome.

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 Regulation (EC) No. 2073/2005-Annex I, Chapter 2, Sections 2.1.1 (cattle) and 2.1.2 (swine). NVWA also has requirements specific for swine slaughter establishments that are certified to export to the United States, described in RE-31, which indicates that swine slaughterhouses must implement indicator organism testing using two-point sampling (at pre-evisceration and at post-chill) to monitor the effectiveness of the process control for enteric pathogens. The sampling procedure, either for two-point sampling or for an approved alternative, must be approved by NVWA. 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 slaughterhouses certified as eligible to export products to the United States. NVWA also implements a verification testing program for *Salmonella* on carcasses in veal and pork slaughterhouses which includes performance standards that are consistent with Regulation (EC) No. 2073/2005, as outlined in RE-29 and RE-30.

The above referenced documents describe the sampling procedures and instructions for inspection personnel regarding sampling frequency, collection sites on veal and pork 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 inspection personnel and analyzed at the official

laboratory. The FSIS auditors reviewed government sampling results from two slaughter establishments and concluded that NVWA is verifying that establishment indicator organism and official *Salmonella* carcass testing programs are implemented as documented.

Within its RE-33, the NVWA outlines its verification testing program for STEC at veal slaughterhouses and processing facilities eligible to export raw veal 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 inspectors 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 sampled raw veal products until results are reported as negative for STEC.

The FSIS auditors interviewed personnel at WSFR 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 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 following finding was identified:

- 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, WFSR, 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 found that the Netherlands' veal and pork 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 on November 12, 2021, 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 HAZARD ANALYSIS AND CRITICAL CONTROL POINT 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.

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, WFSR, 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.

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.

Appendix: 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

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue, SW.
Washington, D.C., 20250
United States of America

Directorate-General Agro
Animal Supply Chain and Animal Welfare Department

Visit address
Bezuidenhoutseweg 73
2594 AC Den Haag
The Netherlands

Postal address
P.O. Box 20401
2500 EK Den Haag
The Netherlands

Organisation Code
00000001858272854000

T +31 (0)70 379 8911
F +31 (0)70 378 6100
www.rijksoverheid.nl/lnv

Dealt with by
drs. H.A. Lim

T +31 (0)6 151 787 62
H.A.Pogalin@minlnv.nl

Our ref.
DGA-DAD / 22138009

Your ref.

Encl.
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Date 5-Apr-2022
Re Official response to draft audit report on veal and pork products

Dear Dr. Catlin,

With this letter I would like to response to the draft audit report and corresponding letter which we have received on February 11, 2022. The Food Safety and Inspection Service (FSIS) conducted a remote verification audit of the Netherlands' veal and pork products inspection system from September 28 to November 12, 2021.

FSIS identified two findings within the six system equivalence components. As acknowledged in the audit exit meeting, the Netherlands Food and Consumer Product Safety Authority (NVWA) has taken corrective actions for both findings in order to bring the related items into compliance with FSIS requirements.

Enclosed with this letter you will find the more detailed response displayed in an overview table.

I look forward to continuing our good cooperation in the future.

Sincerely yours,

H.I.J. Roest, DVM, PhD
Deputy Chief Veterinary Officer

Enclosures:
- Official response FSIS draft audit report
- N60 analysis results example

COMPONENT	DEFICIENCY	REACTION THE NETHERLANDS CORRECTIVE ACTIONS
COMPONENT ONE: GOVERNMENT OVERSIGHT	No deficiency	
COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY, FOOD SAFETY, AND OTHER CONSUMER PROTECTION REGULATIONS	No deficiency	
COMPONENT THREE: GOVERNMENT SANITATION	No deficiency	

COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (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.	The requirement to have the documented verification of validation studies at the establishments is now laid down in NVWA's working manuals. Working manual RE-31 requires that establishments have the validation as part of their HACCP documents; establishments have to provide to NVWA, the most recent version of process-validation documents. RE-36, Supervision on FSIS requirements, lays down NVWA's responsibility to verify the validations. Part of the verification is the adequate documentation. The translation of the updated working manuals will be uploaded in PHIS as part of SRT 2022.
COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS	No deficiency	
COMPONENT SIX: 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, WFSR, 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 N60-procedure is amended. The N60 pieces are no longer trimmed and the whole sample is tested; nothing is discarded. The laboratory (WFSR) still divides the N60 sample into three subsamples, this is owed to the capacity of the recipients. The weight of each subsample is laid down in the analysis results. See annex, N60 analysis results example.